September 2, 2014

Administrator Marilyn Tavenner
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1612–P
P.O. Box 8013
Baltimore, MD 21244–8013
Submitted electronically via http://www.regulations.gov

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and other revisions to Part B for CY 2015

Dear Administrator Tavenner:

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. CSRO and the undersigned members of the coalition appreciate the opportunity to provide comments on proposals in the 2015 Medicare Physician Fee Schedule Proposed Rule.

Using OPPS and ASC Rates in Developing PE RVUs

CSRO remains unconvinced that CMS' plan to use hospital cost reports to revise the Medicare physician fee schedule (MPFS) practice expense (PE) methodology is appropriate. We disagree that hospital cost report data are more reliable than data provided by non-facility providers, particularly when a service is typically performed in a physician office setting. While CMS is not making any proposal to implement such a policy for CY 2015, we urge CMS against implementing any such measure that would use hospital-level data as the basis for physician office PE RVUs.

In addition, CMS' noted desire to better understand the impact of the shift in services from the physician office to the hospital outpatient department, the growing trend in hospital employment of physicians, as well as the acquisition of physician offices by hospitals, and subsequent redesignation of those offices as hospital outpatient departments (HOPDs), is warranted, given the significantly higher program spending and beneficiary cost sharing (without a notable change in patient care or quality) for the migrating services.

To understand the aforementinoed trend, CMS is proposing to establish a new HCPCS modifier to be reported with every code for physician and hospital services furnished in off-campus facilities of a hospital. We disagree that a new HCPCS modifier is the most effective way to collect the needed data, and urge CMS to abandon this proposal. The administrative burden to practices associated with the proposal, and the likelihood that the modifier would be inappropriately and/or inadequately applied to claims, is significant. It is our assertion that CMS' claims database already includes the information the agency needs; it is only a matter of working with CMS' software analytics team and programmers in the writing of a query that would identify and match HOPD and MPFS claims for the same patient, on the same date of service, for a select set of procedure codes of interest to CMS.

To further address CMS' concerns about redesignations, CMS could consider revising its regulations that allow hospitals to redesignate physician practices as HOPDs. Specifically, CMS could create a process that requires CMS approval for such redesignations based on a modified set of criteria. This would provide CMS an opportunity to determine whether a redesignation is appropriate and meets CMS' modified requirements for such a change. CMS could also place a moratorium on all redesignations until data can be collected and analyzed to inform future policy decisions. CMS should consider further revising its redesingation criteria based on data collected through the aforementioned processes. In addition, and as proposed last year in the 2014 MPFS, CMS could establish a new place of service (POS) code for off-campus provider-based clinics.

Potentially Misvalued Codes

CSRO disagrees with CMS that chemotherapy administration codes (CPT 96401 and CPT 96409) and therapeutic drug codes (CPT 96372 and 96375) are potentially misvalued given increased utilization of these services.

Advances in medical technology have enabled the use of monoclonal antibodies and biologic response modifiers in the treatment of cancer and other non-cancer conditions. Oncologists and other medical specialty physicians, such as rheumatologists, report the administration of monoclonal antibodies and biologic response modifiers using CPT codes 96401 and 96409, which is appropriate given the American Medical Associations (AMA) Current Procedural Terminology (CPT) coding guidelines that define chemotherapy administration as follows:

> *Chemotherapy administration is defined as the parenteral administration of non-radionuclide anti-neoplastic drugs for cancer diagnoses, anti-neoplastic agents provided for the treatment of non-cancer diagnoses or to substances such as* ***monoclonal antibody agents****, and other biologic response modifiers. These services can be provided by any physician and typically are highly complex services requiring direct supervision. Special consideration and training is often involved due to preparation, dosage or disposal of the substances. These services entail significant patient risk and frequent monitoring*.

Regarding CPT 96372 and 96375, these codes are commonly reported together when multiple medications are administered sequentially in patients with cancer and other non-cancer diagnoses where providers are managing multiple disease-related conditions.

Confusion on how to distinguish and report CPT 96401 and 96372 when administering monoclonal antibodies and other biologic response modifiers has been addressed by CSRO and other organizations representing rheumatologists and practice administrators, and we are confident that practices are reporting these services appropriately and consistent with AMA CPT guidelines.

As the art and science of pharmaceutical invention continue to improve for a variety of health conditions, CMS should expect that these services would be reported with greater frequency. As a result, **we believe these codes are appropriately valued and should not be considered as potentially misvalued by CMS**.

Valuing New, Revised and Potentially Misvalued Codes

CMS' proposal to increase transparency in the establishment of relative value units (RVUs) through a

revised process that would provide for improved notice and comment is welcomed, yet we are concerned with the specifics of the proposal. Medical specialty societies and Congressional leaders have urged CMS to take any and all steps necessary to ensure that the rulemaking process for changes in the MPFS under the initiative is transparent and allows for sufficient input by stakeholders well before the new values are implemented. Regrettably, CMS' proposal is overly complex, potentially burdensome, and goes well beyond the principal request of the medical specialty societies and Congress; that is, for CMS to publish reimbursement changes for misvalued codes in the proposed rule, as opposed to waiting until the final rule.

While we recognize that CMS needs time to employ its ratesetting methodologies that are part of the physician fee schedule, it is our understanding that CMS has enough time to incorporate revised values for misvalued codes into the proposed rule, given the ratesetting methodologies are mostly automated calculations. We note that CMS receives RVU recommendations for misvalued codes from the American Medical Association's Relative Value System Update Committee (AMA RUC) just days after the Spring meeting (typically in April), which is at least two months in advance of the release of the annual MPFS proposed rule.

Rather than simply addressing the predominant concern, CMS proposes to disrupt the entire process for establishing RVUs by proposing significant and potentially burdensome modifications that would also affect RVUs for new codes and technologies. Physicians and other providers that are reimbursed under the MPFS have an expectation of what their payments will be for most established services, whereas with new codes and technologies, there was little (if any) expectation, as reimbursement may or may not have been made previously.

We urge CMS to abandon its proposal, and simply begin publishing revised RVU for misvalued services in the proposed rule.

Chronic Care Management

We continue to support the agency's efforts to ensure payment for non-face-to-face work associated with coordinating care for chronically ill beneficiaries. CMS has made a concerted effort to emphasis the value of this important work by finding mechanisms to fund non-face-to-face services. We commend the agency for eliminating certain restrictions on billing the new chronic care management (CCM) services, for choosing not to adopt broad practice standards for providing CCM services, and for allowing CCM services to be performed "incident to".

Nonetheless, CSRO is concerned that CMS' proposed reimbursement would not be adequate to support the patient population for whom the service is intended. Patients that require CCM services are atypically complex; they have multiple chronic healthcare conditions managed by medications with a high risk of interaction and adverse events, and are more likely to have an emergency room visit or hospitalization. The proposed payment amount is more appropriate for "chronic disease management"; that is, care coordination geared toward a patient population that can be managed using standard practice guidelines, which typically call for office visits and lab/diagnostic testing at prespecified intervals. Patients with chronic rheumatologic conditions, such as Rheumatoid Arthritis (RA), along with other chronic, comorbid health conditions, would greatly benefit from CDM services. Patients with severe RA do significantly better when a rheumatologist actively manages their care; a new CDM code would help to facilitate this.

In addition, emphasizing the use of EHRs when meaningful interoperability is not a component the

certification requirements for EHR technology seems inappropriate. CMS is already aware of the current challenges associated with the availability of 2014 Edition certified EHR technology (CEHRT), which has created multiple other challenges for practices. The use of EHRs is not an essential component to providing care coordination services, therefore, we do not believe CMS should require practices to be meaningful users of EHRs in order to be reimbursed for care coordination services, at least not initially.

CSRO supports improved access to care coordination for ***all*** Medicare beneficiaries, therefore, **we urge CMS to adopt and implement codes for both CCM and chronic disease management (CDM) services, and provide a fair and appropriate payment amount for the work involved coordinating care for both**. We also request that you **eliminate the EHR requirements until meaningful interoperability among EHRs has been achieved**.

Physician Compare

We applaud CMS for making significant and substantive improvements of its Physician Compare website that will help beneficiaries navigate and better understand the data and information presented. Despite these improvements, we continue to be concerned with accuracy of the data and the resultant value to beneficiaries and their caregivers. CMS must be extremely cautious when moving from reporting physician participation data to performance and quality scores. Any misrepresentations, even by sheer accident, could put beneficiaries and physicians at significant risk and create a sense of distrust between both parties and further denigrate our already fragile healthcare system.

Physician Value-Based Payment Modifier

CSRO has raised concerns about the value-based modifier (VM) since the release of the first physician feedback reports with which CMS intended to improve physician understanding of their performance based on quality and cost metrics in advance of implementing any VBM payment adjustment. From the program's inception, CMS has recognized and admitted to the challenges related to implementation and administration of the VM, as well as the challenges to physicians-- particularly those in smaller, specialty practices-- that lack adequate clinical quality and cost measures or a fair and appropriate means for risk-adjustment. We understand that CMS has limited flexibility in certain aspects of the VM, including the timelines by which the program is implemented; however, CMS does have authority in other critical aspects of the VM. Given the challenges both CMS and physicians face with this new program, we are perplexed by CMS' proposal that would double the VM penalty to four percent in 2017, especially given that is the first year of adjustments for the very physicians that face the greatest challenges.

Even more frustrating is that CMS makes significant proposals to modify the Physician Quality Reporting System (PQRS) to include eliminating a host of important clinical quality measures and increasing the reporting burden, when the PQRS is the basis on which CMS calculates quality scores for the VM.

Increasing the penalty for the VM at a time when physicians are already facing multiple other penalties associated with CMS' remaining quality programs, such as the PQRS and Electronic Health Record (EHR) Incentive Program, not to mention the ongoing challenges with the Sustainable Growth Rate (SGR) and Part B drug reimbursement, could put many rheumatologists out of practice or lead to their early retirement, leaving vulnerable beneficiaries with limited or no access to care. For beneficiaries with chronic, complex rheumatologic conditions, this is a serious concern as breaks in their treatment regime can be devastating to their health status and ability to remain independent.

In addition, as physician shortages and workforce issues continue to be problematic, particularly in specialties like rheumatology, we worry that pushing them out of medicine with steep penalties – rather

than boosting their ability to providing high-quality, high value care – will leave beneficiaries, especially, those with significant disease burden, without care.

CMS is conscious of the fact that many physicians remain unaware of the VM despite our collective best efforts to create awareness and disseminate education. CSRO has repeatedly discussed the program as part of its almost monthly lectures on changes in the Medicare program, and we continue to see hands when we ask if audience members are aware of the VM.

We strongly oppose CMS' proposal to increase the VM penalty in 2017. Instead, CMS should use its authority to make the program as flexible as possible to enhance quality, encourage improved resource use, and strength physician practices. We also urge the agency to step-up its education efforts to improve awareness about the program among physicians. To accomplish this, **we urge CMS to consider alternative vehicles for educating providers that may include notices about the VM and links to educational information as part of Medicare Remittance Advice (RA) notices that accompany physician payments.**

Finally, CSRO has major concerns with CMS' reliance on crude, often irrelevant, and insufficiently adjusted cost measures to calculate the value modifier. While we support efforts to better coordinate care among healthcare providers and across settings, we oppose measures that hold physicians accountable for factors outside of their direct control. The Total per Capita Cost measures, which were previously finalized for use under the VBM program, hold physicians accountable for *total annual* costs related to the care of a patient. The newly proposed Medicare Spending Per Beneficiary (MSPB) measure holds physicians accountable for costs associated with the *totality of services furnished to a patient surrounding an inpatient hospitalization*, including 3 days prior to an admission through 30 days post-discharge. Both measures include Medicare Part A and Part B payments and incorrectly assume that physicians have control over the care plan and treatment decisions of other care providers who also treated the patient.

Both measures also specifically *exclude* Part D costs. CSRO has serious concerns that this exclusion could put physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order drugs covered under Part D since the former would appear to have higher Medicare expenditures than the latter. Many of the conditions treated by rheumatologists, including Rheumatoid Arthritis, can be treated with drugs that are self-administered by the patient and covered under Medicare Part D (e.g., self-injectibles) or administered by the physician in the office and covered under Part B (e.g., infusions). Since the decision usually comes down to patient choice, one rheumatologist may treat a patient with a Part B drug while another rheumatologist treating a patient with the same indications and risk factors could just as easily choose a Part D drug. Under the proposed VBM methodology, the patient who opted for the Part B drug would appear more costly than the patient who opted for the Part D drug, which would translate into higher resource use and potential financial penalties for the treating physician. This could unnecessarily and inappropriately pit rheumatologists against each other and potentially influence treatment decisions as physicians are perversely incentivized to prescribe Part D drugs when Part B drugs may be more appropriate for the patient.

Although the mechanism that CMS proposes to use to risk adjust the VBM cost measures, known as the Hierarchical Condition Categories (HCC) model, may account for some conditions that require Part B drugs and are therefore more costly, it does not distinguish between the appropriateness of Part D drugs versus Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for their patient. Many of the more complex diseases that rheumatologists treat

depend on Part B therapies. For example, Granulomatosis with Polyangiitis, a serious, potentially life threatening autoimmune disease, is treated with an infusible part B drug (Rituximab) that would be included in the value modifier's global cost determination. Systemic Lupus is also often treated with an IV Part B drug. Even after application of the HCC risk adjustment, rheumatologists who care for sicker patients with these complex diseases would be at greater risk for penalties.

CSRO urges CMS to implement a mechanism to better account for drug costs when evaluating physician resource use. Whether the solution is to remove Part B drug costs from resource use calculations or to incorporate Part D drug costs into these calculations, the most important thing is that cost-of-care measures not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient. CSRO would be more than happy to further discuss potential models with CMS and to partner with the agency to test various strategies to accomplish these goals.

Reports of Payments or Other Transfers of Value to Covered Recipients

CSRO appreciates the need for public transparency of industry-physician financial relationships and supports the intent of the Open Payments (Sunshine Act) program. However, we are concerned about CMS' proposal that would eliminate the "bright line" exception for accredited Continuing Medical Education (CME) activities that is currently afforded to physicians through CMS' existing regulations. One of the most challenging aspects of compliance with the Sunshine Act is accounting for "indirect payments" made through third parties, which is with what CMS proposes as a replacement for the current CME exception.

CME is an effective and necessary tool to aid CSRO members in the acquisition and retention of knowledge, attitudes, skills, behaviors and clinical outcomes necessary to provide high-quality, patient-centered rheumatology care. Eliminating the CME exception could have significant, negative ramifications, hindering physicians' ability and willingness to participate in accredited CME events out of concern that a speaking honorarium, travel fees, or any other payment or transfer of value received by physicians for participating in accredited CME events would become subject to public reporting.

As you know, with the promulgation of the Sunshine Act, the acceptance of funds from industry by physicians has come under extreme scrutiny. Consequently, many healthcare organizations, including employers, medical specialty societies, and publishers of medical and scientific literature, have initiated their own rules and requirements related to the acceptance of payments of transfers of value by physicians from manufacturers. For example, some teaching hospitals do not allow their physician employees to accept any funds or transfers of value as a condition of their employment. Many medical professional societies have also revised their by-laws to ban its Board, committee and task force members, and other society leadership from accepting any funds or transfers of value from manufacturers. Also, organizations that publish medical and scientific journals have also implemented rules for their physician medical editors and journal article reviewers that ban them from accepting any funds or transfers of value from manufacturers.

Physicians take their employment and other volunteer commitments very seriously, as these positions are considered a great honor within their professional communities. In fact, many physicians have been elevated into these distinguished roles as a result of their clinical research and participation in accredited CME events, among other things. CMS' proposal, if finalized, would have a negative and detrimental impact on physicians' ability to serve as faculty at many teaching hospitals; serve as volunteers in their professional associations; serve as medical editors and journal article reviewers; and,

ultimately, share their knowledge, skills and expertise with their colleagues to improve the quality and cost of healthcare. By eliminating the CME exception, CMS is putting physicians in a position where they will be unsure of which activities will be reportable, and which will not, thus limiting their ability and willingness to participate in accredited CME events.

Again, we recognize that there is some redundancy with the CME exception with other provisions, given the exclusion for certain indirect payments where the manufacturer is "unaware" of (that is, "does not know") the identity of the covered recipient. Nonetheless, it is our sense that the CME exception provides the level of clarity physicians truly appreciate when it comes to CMS' Open Payments program and its impact on their participation and engagement in accredited CME activities. As noted before, accounting for "indirect payments" is already challenging and the knowingly standard are likely to be more even more problematic for industry if accredited CME events are no longer excluded.

Similarly, CMS' proposal does not provide manufacturers with any assurances that if they decided not to report indirect payments or transfers of value that they become aware of after an accredited CME event, which the manufacturer would not be subject to penalties. Manufacturers with overzealous transparency compliance officers are more likely to report all instances to avoid financial penalties.

In addition, while we understand that CMS would prefer to distance itself from serving as the arbitrator for determining which entities are CME accreditors, and which are not, we note that CMS regularly engages in such activities through its other "deeming" activities. We do not see that maintaining a list of those groups that meet CMS' standards for accrediting CME events as being patently different in that regard. If CMS has concerns about its level of expertise in making decisions about the standards that it should hold CME accreditors, it should use the rulemaking process to gather input from experts and other stakeholders who could assist with this activity. CMS frequently engages in the development of similar standards, and this activity would be no different.

We have carefully considered CMS' proposal and multiple alternatives as part of a thorough review and discussion with CSRO staff, leadership, and relevant committees. **To that end, we have concluded that we do not support the elimination of the CME exception. Instead, we urge CMS to maintain the CME exception and expand the list of CME accreditors.**

Further, this action reverses a decision that CMS had previously reached after reviewing hundreds of stakeholder comments in a comprehensive rulemaking process. This decision, if finalized, would significantly disrupt the practice of CME and the confidence of doctors, educators, and others. **We urge CMS to reconsider its proposal to eliminate this exception, and instead, appropriately expand the list of certified CME accrediting/issuing agencies beyond the five currently cited in regulation.**

Finally, as CMS continues to implement the Open Payments system, we urge the agency to review ongoing issues reported by physicians attempting to register and to expand the registration timeframe accordingly to ensure covered recipients have ample opportunity to register, review, and dispute data on the Open Payments System before publication. We also request that CMS provide clarifying guidance that manufacturers and group purchasing organizations (GPOs) are not authorized to unilaterally dismiss disputes by physicians or teaching hospitals. Given the inconsistent interpretations of the Sunshine Act evidenced by manufacturers to date, information collected in the Open Payments system should be flagged as disputed in the public database until resolution is reached between the parties.

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Thank you for considering our comments, and we look forward to working with you as you continue to improve the Medicare physician fee schedule and associated policies in years to come. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P, at 703-975-6395 or egraham@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Arkansas State Rheumatology Association
Arizona United Rheumatology Alliance
California Rheumatology Alliance
Florida Society of Rheumatology
Kentuckiana Rheumatology Alliance
Maryland Society for Rheumatic Diseases
Massachusetts, Maine, & New Hampshire Rheumatology Association
Michigan Rheumatism Society
MidWest Rheumatology Society
Mississippi Arthritis and Rheumatism Society
New York State Rheumatology Society
Ohio Association of Rheumatology
Oregon Rheumatology Alliance
Rheumatology Alliance of Louisiana
South Carolina Rheumatism Society
Washington Rheumatology Alliance
West Virginia State Society
Wisconsin Rheumatology Association