September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013
Submitted electronically via Regulations.gov

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

Dear Ms. 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.

On behalf of CSRO and the undersigned state rheumatology societies, we are pleased to provide feedback on the 2018 Medicare Physician Fee Schedule (MPFS) proposed rule. Through the Alliance of Specialty Medicine and Cognitive Care Alliance, CSRO provides feedback on other proposals and comment solicitations that broadly impact specialists and those providing cognitive care, including rheumatologists. In this comment letter, however, CSRO and the undersigned state rheumatology societies, focus on specific issues that uniquely impact practicing rheumatologists and the beneficiaries they serve.

Transition from Traditional X-Ray Imaging to Digital Radiography

To implement provisions in the Consolidated Appropriations Act of 2016 that call for a reduction in payment amounts under the PFS for the technical component (including the technical component of a global service) of imaging services that are X-rays taken using film by 20 percent effective for services furnished beginning January 1, 2017, CMS established Modifier FX for use on claims for X-rays that are taken using film.

The statute also reduced payment amounts for imaging services under the MPFS that are X-rays using computed radiography technology (including the X-ray component of a packaged service) by 7 percent in CYs 2018, 2019, 2020, 2021, or 2022, and by 10 percent in CY 2023 or a subsequent year. In this rule, CMS proposes to establish a new modifier to be used on claims beginning January 1, 2018 for the technical component of X-rays (including the X-ray component of a packaged service) taken using computed radiography technology. This will allow CMS to implement the statutory 7 percent reduction.

When Modifier FX was proposed and finalized in the 2017 MPFS, we expressed concern about the potential for problems with CMS' implementation strategy. Unfortunately, our concerns were not heeded and very little education has been done by the agency and Medicare Administrative Contractors (MACs) to ensure practices have been informed about this new modifier and how it should be applied.

Now, CMS is proposing yet another modifier that will not be well understood by most physician practices. While we anticipate subregulatory guidance will be developed, similar to last year, it has been released too close to the date by which providers are required to modify their practice management/billing systems to accommodate the new modifier or other mechanisms by which they will be able to identify which services were preformed using "antiquated" radiography technology.

We are deeply concerned about the potential for future audits and extrapolation of Medicare reimbursements simply because practices were not well-educated or made aware of the rules and requirements associated with the digital radiography "incentive" program. There are simply too many regulatory changes happening all at once, and physician offices, particularly small rheumatology practices, cannot manage these massive modifications to the reimbursement system.

We recognize CMS is required to implement that law, however, it is incumbent upon the agency to ease the regulatory burden as much as possible. Toward that end, ***CMS should hold physician practices harmless from financial and criminal repercussions if they omit or incorrectly apply the new modifiers when billing for imaging services using outmoded equipment, at least for the first three-years of the program (i.e., 2017 - 2019).*** The grace period should be used by CMS, the Medicare Administrative Contractors (MACs) and specialty societies to educate practices on the requirement to use the new modifiers. Similarly, ***CMS must not approve audits by Recovery Audit Contractors (RACs) related to the implementation of the transition from traditional x-ray imaging to digital radiography using the aforementioned modifiers***, given the aforementioned concerns.

Proposed Valuation of Specific Codes

Ultrasound of Extremity (CPT codes 76881 and 76882)

CSRO opposes the proposed change to the direct practice expense (PE) inputs for CPT code 76881 as submitted by the American Medical Association Relative Value System Update Committee (AMA RUC) and urges CMS to maintain the existing practice expense values until accurate PE inputs can be established and used in an appropriate valuation.

CMS proposes to accept the AMA RUC recommendations that would essentially shift the majority of the practice expense relative value units (PE RVUs) from CPT code 76881, *Ultrasound, extremity, nonvascular, real-time with image documentation; complete* to CPT code 76882, *Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific*. We understand that the AMA RUC determined that code 76882 is now typically performed by radiologists, and therefore assigned PE inputs for a PACS workstation and an ultrasound room to the code. Further, the AMA RUC determined that code 76881 is now typically performed by podiatry, resulting in removal of PE inputs for the PACS workstation and an ultrasound room. The inputs for code 76881 were replaced with a portable ultrasound unit which the AMA RUC believes is more typically used by the performing specialties**.**

Contrary to the findings of the AMA RUC, ***rheumatologists provide a significant and growing proportion of ultrasounds using CPT code 76881.*** Moreover, rheumatologists maintain and use a dedicated ultrasound room, a *non-portable* ultrasound unit, and a PACS system (such as the overreadservices.com website, a virtual PACS system that transmits, stores, and displays images), as well as employ a dedicated sonographer. The AMA RUC recommendations for direct PE inputs for CPT code 76881 are *atypical* for rheumatologists and fail to reflect the practice expense costs associated with how our members perform this service.

If finalized, CMS' reductions in PE for this ultrasound service will have a significant and dampening impact on clinical care provided by rheumatologists and the beneficiaries they serve. Many

rheumatologists utilize ultrasound for diagnostic purposes. Rheumatoid arthritis (RA) is the most common inflammatory arthritis with a prevalence of 2%. Diagnosis of RA can at times be challenging as up to 15% of patients with RA may have normal markers of inflammation (ESR, CRP) and be serologically negative (i.e., lack rheumatoid factor and antibodies to CCP). Diagnostic erosions and joint space narrowing are often not present early in the disease when imaging with plain radiographs. Ultrasound can be a valuable tool in this setting for identifying early changes of RA and assessing risk of more aggressive disease thus leading to more timely and appropriate therapy. With a drastic decline in reimbursement for a complete ultrasound, most rheumatology practices will be forced to limit or close their ultrasound programs and refer Medicare beneficiaries for more expensive and hospital-based diagnostic services, including magnetic resonance imaging (MRI). This would hinder efforts within the specialty to train residents and fellows in the use of this emerging diagnostic modality based on evidence showing that substitution of ultrasound for MRI of musculoskeletal (MSK) disorders in the Medicare population results in measureable cost-savings. In fact, a recent survey of rheumatology fellowship programs found that MSK ultrasound is currently being taught in 94% of programs, with 41% having a formal MSK US curriculum.[1] Moreover, a 2008 study found that, *"The substitution of MSK [ultrasound] for MSK MRI, when appropriate, would lead to savings of more than $6.9 billion in the period from 2006 to 2020."*[2]

CMS has expressed a strong commitment to *payment accuracy* as an active purchaser of health care services for beneficiaries. The proposed change is *inaccurate* with respect to how rheumatology practices deliver ultrasound of the extremities and thus inconsistent with CMS' objective. ***Rheumatologists must be engaged in the process to establish <u>accurate</u> practice expense inputs before any change is made to the current values.***

While issues of relative value within a family are generally reserved when discussing work RVUs, we must point out that the "parent code" for a complete ultrasound study (CPT code 76881) will have a total RVU significantly less than the limited ultrasound study (CPT code 76882). ***Within rheumatology, the PE inputs do not vary across these diagnostic ultrasound studies.***

Not only will CMS' proposed change significantly increase Medicare program spending, it will greatly burden beneficiaries by raising their cost-sharing amount. Many beneficiaries are on fixed incomes and may not be able to absorb these additional costs. As a result, they may delay or defer important, medically necessary treatment, which may limit their short- and long-term health outcomes and impair their quality of life.

At a time when CMS is moving the Medicare program toward rewarding value-over-volume and incenting providers for improving quality and the appropriate use of resources, we are disappointed that CMS would propose a substantial reduction in the use of a cost-effective diagnostic imaging service in lieu of the more expensive alternative.

Again, we oppose the proposed changes to the direct PE inputs for CPT code 76881 and urge CMS to maintain the existing values until rheumatologists can engage in a process to establish accurate PE

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[1] Torralba, K D, et al. "Musculoskeletal Ultrasound Instruction in Adult Rheumatology Fellowship Programs." www.ncbi.nlm.nih.gov/pubmed/28777891.

[2] Parker, L., L. N. Nazarian, J. A. Carrino, W. B. Morrison, G. Grimaldi, A. J. Frangos, D. C. Levin, and V. M. Rao. "Musculoskeletal Imaging: Medicare Use, Costs, and Potential for Cost Substitution." (n.d.): n. pag. *Journal of the American College of Radiology : JACR*. U.S. National Library of Medicine, Mar. 2008. Web.

inputs. CSRO welcomes the opportunity to work with CMS to identify a long-term solution that would ensure ongoing access to ultrasound services for Medicare beneficiaries.

Payment for Biosimilar Biological Products

The Biologics Price Competition and Innovation Act (BPCIA) created a mechanism for the Food and Drug Administration (FDA) to approve "biosimilars," which are copies of biologics. Because each of these products is distinct, the paradigm for small-molecule generics is not appropriate in the context of biosimilars. The BPCIA contemplates two levels of similarity: biosimilarity and the higher threshold of interchangeability. Such a distinction does not exist for traditional generics.

While the FDA has approved several biosimilars, the agency has not yet held that any biosimilar meets the higher threshold of interchangeability. As such, none of the approved biosimilars have met the statutory requirements that would allow them to be substituted for the reference product without concern for safety or efficacy. Because of minor but important clinical differences between a biosimilar and its reference product and various biosimilars for the same reference product, we believe that each biosimilar should have its own, distinct J-code.

While this approach differs from the payment policy applicable to traditional generics, as noted above, biosimilars are sufficiently different from traditional generics that Congress found it appropriate to create a unique and distinct regulatory approval pathway. As such, a different payment policy is warranted. Applying a single J-code policy does not recognize this distinction; indeed, it implies that all biosimilars for a single reference product can be used interchangeably, which is not the case. Given the current climate of payers aggressively pushing use of the lowest-cost therapy regardless of clinical appropriateness, we are concerned that, with one blended payment rate for all biosimilars in a group, a payer may mandate use of the lowest-cost biosimilar without regard for any other factor.

Applying a single, averaged payment rate to all biosimilars for one reference product departs from Congress' intent when it established a distinct approval pathway for biosimilars – one that contemplates varying levels of similarity. ***We urge CMS to provide each biosimilar its own, distinct J-code.***

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Thank you for considering our comments, and we look forward to working with you on Medicare physician payment policy for 2018 and future years. 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 Rheumatology Association
Alabama Society for the Rheumatic Diseases
California Rheumatology Alliance
South Carolina Rheumatism Society
Florida Society of Rheumatology
Kentuckiana Rheumatology Alliance
Michigan Rheumatism Society
Midwest Rheumatology Association
Mississippi Arthritis and Rheumatism Society

New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Oregon Rheumatology Alliance
Pennsylvania Rheumatology Society
Rheumatology Association of Nevada
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Virginia Rheumatology Society
Wisconsin Rheumatology Association
West Virginia Rheumatology State Society