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Coalition of State Rheumatology Organizations

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August 25, 2022

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Through the Alliance of Specialty Medicine, CSRO provides feedback on several proposed policies in the aforementioned rule that broadly impact specialists and subspecialists. Below, however, CSRO highlights additional issues that uniquely impact our members and the beneficiaries they serve.

Valuation of Services: Neuromuscular Ultrasound

We are deeply concerned with CMS' proposed valuation of neuromuscular ultrasound, which will further reduce reimbursement and potentially limit beneficiary access for this important imaging service.

As demonstrated by Medicare claims data, rheumatology is the primary specialty furnishing complete joint ultrasound (CPT 76881) at 25.7 percent[i]. This not surprising as a growing body of evidence shows the value of neuromuscular ultrasound (aka, musculoskeletal ultrasound (MSUS)) in the early diagnosis and ongoing management of rheumatoid arthritis.[ii,iii] It has also been shown to improve resource use by reducing rheumatologists' reliance on other imaging modalities, such as magnetic resonance imaging (MRI), and lowering health care costs, including for the Medicare program and the Department of Defense.[iv,v, vi]

Work. CSRO disagrees with CMS' reduction in the work value because the service is frequently reported with an Evaluation and Management (E/M) service. The physician work associated with an E/M is separate and distinct from the physician work associated with

this imaging service; the E/M and ultrasound require different cognitive and technical skills by the rendering physician. When these services are delivered during the same encounter, the physician work is not overlapping nor duplicative and should be separately valued and reimbursed.

In addition, we refute the argument that rank order anomalies (in the neuromuscular ultrasound family) created by CMS' proposed work values are negated because measures of intraservice work per unit of time (IWPUT) prove relativity will be maintained. On face alone, it is illogical that the work associated with a complete joint ultrasound would be *less* than a limited joint ultrasound, considering all that is involved in furnishing the former vs. the latter. Equally important, CMS is well aware of the multiple challenges associated with IWPUT, so it is frustrating that the agency would drive down work values based on this formula. It is the work values themselves should be used to determine relativity.

Finally, as we highlighted in comments through our coalition partner, the Alliance of Specialty Medicine, CMS has used an alternative methodology, "reverse building block," to arrive at a predetermined work value that better suits the agency. This is a significant frustration of the specialty medical community.

Practice Expense. CSRO also disagrees with the direct practice expense inputs for this code. As we shared in prior comments, many rheumatologists maintain and use a dedicated ultrasound room, a *non-portable* ultrasound unit, and a PACS system, as well as employ a dedicated sonographer. Even those practices that have a portable unit will still utilize a dedicated ultrasound room and a PACS system, and employ, or contract the services of, a sonographer or other appropriately-credentialed and certified clinical staff.

A review of the January 2022 meeting minutes of the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) only states that the specialty societies who conducted the most recent survey "*convened a panel that included a number of experts familiar with these services to evaluate the direct practice expense inputs for neuromuscular ultrasound*."[i] The direct PE inputs reflected in the RUC minutes and in CMS PE files are not "typical" for rheumatology practices where this imaging modality is employed. Rheumatology practices are telling us that their equipment and clinical labor costs associated with furnishing this service are significantly higher. We also understand that our sister organization, the National Organization of Rheumatology Management (NORM), collaborated with other relevant stakeholder organizations to better understand practice costs for providing diagnostic ultrasounds, and that these findings will be submitted to CMS as part of this notice-and-comment rulemaking.

We urge CMS to adopt the work relative values as recommended by the AMA RUC (see below) and to update the direct PE inputs to reflect the equipment and clinical labor costs of delivering this service in a rheumatology practice. CSRO would be happy to work with CMS to provide supplemental information to further inform the direct PE inputs for CPT 76881.

COMPARISON OF CMS PROPOSED AND AMA RUC RECOMMENDED WORK RVUs

Code	Long Descriptor	CMS Proposed Work RVU	RUC Recommended Work RVU
76881	Ultrasound, complete joint (i.e., joint space and peri-articular soft-tissue structures), real-time with image documentation	0.54	0.90
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (e.g., joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation	0.59	0.69
76XX0	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	0.99	1.21

Advancing Rheumatology Patient Care MVP

Last year, CMS finalized its proposal to move forward with MIPS Value Pathways (MVPs), starting in 2023, with an introductory set of optional MVPs, including Advancing Rheumatology Patient Care. CSRO and other stakeholders expressed concerns with this MVP, including the following:

- **Cost measurement:** The MVP includes the Total Per Capita Costs (TPCC) measure, which does not account for ***all*** pharmaceutical costs when evaluating physician resource use. This is problematic for many rheumatologic conditions, such as rheumatoid arthritis (RA), where Part B and Part D drugs are available. Recognizing the challenges including Part D costs in these measures, the lack of their inclusion puts physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order/prescribe drugs covered under Part D, since the former would appear to have higher Medicare expenditures than the latter.
- **Improvement Activities:** The MVP does not include either *IA_BE_ 24: Financial Navigation Program* or *IA_BE_25: Drug Cost Transparency*, despite the fact that most of rheumatology patients require this type of assistance given the associated costs with the medications used to manage their rheumatologic disease.
- **APM "Glidepath":** CMS touts the MVP as a "glidepath" for clinicians to participate in APMs; however, there are no rheumatology-specific APMs, and most rheumatologists have not had meaningful engagement in Medicare's Accountable Care Organizations (ACOs) since, according to the ACOs, the cost of the medications used to treat rheumatic diseases negatively impacts ACO benchmarks.

In last year's rulemaking, CMS did not respond to or even acknowledge our concerns about the TPCC cost measure, nor lack of a rheumatology-focused APM, including the difficultly of participating in ACOs. CMS did, however, agree that it should consider the inclusion of the aforementioned IAs, and said it would consider doing so in future rulemaking. In this proposed rule, CMS continues to ignore our concerns and does not propose the addition of the aforementioned IA's. ***We again urge CMS to adopt the aforementioned IAs as part of this MVP.***

We note that CSRO's nominee was selected to serve on the newly convened MACRA Wave 5 Clinician Expert Workgroup that is tasked with developing an episode-based cost measure for Rheumatoid Arthritis (RA). We are hopeful that the issue of pharmaceutical costs will be meaningfully addressed, and that there will be a more appropriate cost measure for this MVP in the future. In addition, CSRO was invited to share feedback with CMS' Innovation Center on issues affecting rheumatologic patient care, and presumably with the goal of creating a specialty-specific APM. CSRO has long advocated for a rheumatology-focused model that would prioritize improved patient outcomes and reduce or eliminate barriers to care.

Considering the challenges with this MVP and the agency's related efforts that would have a significant impact, ***we urge CMS to postpone the implementation of the Advancing Rheumatology Patient Care MVP.***

Discarded Drug Rebates

To assist the agency with implementation of Section 90004 of the *Infrastructure Investment and Jobs Act*, which requires manufacturers to provide a refund to CMS for discarded amounts from certain single-dose container or single-use package drugs, CMS will require providers to report a *new* JZ modifier on their Part B drug claims when there are no discarded drug amounts. This reporting requirement is in addition to the existing requirement that providers report the JW modifier to indicate when there are discarded drug amounts. This information is necessary for CMS to calculate the amount owed by the drug manufacturer.

CMS explains that many claims are submitted without the JW modifier, which could be due to the fact there are no discarded drug amounts. But, it could also mean that providers are simply not reporting this information because they are unaware of the requirements. To improve reporting, ***CSRO would like to extend an invitation to partner with CMS on developing and disseminating educational materials on reporting these modifiers.***

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Thank you for considering our comments, and we look forward to working with you as you finalize policies outlined in this proposed rule. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

Madelaine A. Feldman, MD, FACR
President, Coalition of State Rheumatology Organizations

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[i] https://www.ama-assn.org/system/files/jan-2022-ruc-meeting-minutes.pdf
[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7305070/
[iii] https://advancesinrheumatology.biomedcentral.com/articles/10.1186/s42358-018-0023-y
[iv] https://pubmed.ncbi.nlm.nih.gov/18312965/
[v] https://pubmed.ncbi.nlm.nih.gov/23982974/
[vi] https://pubmed.ncbi.nlm.nih.gov/33123731/