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Coalition of State Rheumatology Organizations

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September 13, 2021

Chiquita Brooks-LaSure, JD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016
Submitted online via regulations.gov

RE: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

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.

Today, we write to share feedback on the impact of proposals outlined in the aforementioned rule on rheumatologists and their patients. These comments are in addition to those provided through the Alliance of Specialty Medicine and Cognitive Care Alliance, where we provide broader feedback on key issues facing specialists.

Clinical Labor Pricing Updates

CMS' proposed updates to clinical labor wage rates, while necessary and important to maintaining accuracy in the physician fee schedule (PFS), will result in significant reductions to key services, including drug administration, delivered by rheumatology practices.

When factoring in the -3.75 percent cut to the conversion factor, certain drug administration services will be reduced between an estimated -10 and -18 percent. Those estimates will drop even further if CMS is required to implement the Medicare and PAYGO sequesters, which are set to reduce Medicare payments by an additional 2 and 4 percent, respectively. ***Reductions of this magnitude, particularly for practices whose service mix includes a***

high volume of drug administration services, are untenable and will prompt disruptions in beneficiary access.

Moreover, the anticipated cuts are in contrast to the aim of the policy, which is to pay accurately for PFS services. Clearly, CMS recognizes that costs borne by physician practices in delivering PFS services is growing, exemplified by the increase in clinical labor rates; however, the payment for certain PFS services will be drastically reduced under this policy.

Finally, if CMS were to revise its reimbursement policies for COVID-19 monoclonal antibodies (MABs) to mirror those when MABs are used in other diseases (e.g., rheumatoid arthritis (RA)), most physician offices with infusion suites will not be able to deliver COVID-19 MAB treatments simply because they won't be able to afford to.

Given the above, ***we urge CMS to delay, for one-year, the implementation of the updated clinical labor inputs***, which would give the agency additional time to work with Congress on a longer-term solution to challenges facing the Medicare physician payment system – namely, budget-neutrality – and for organizations like CSRO to determine whether more appropriate data sources are available for their clinical labor costs. In addition, ***we urge CMS to phase-in the use of updated clinical labor inputs over a four-year transition***, similar to the phase-in used for the other direct practice expense inputs (i.e., supply and equipment prices), which will help lessen the negative impact should a more permanent fix.

Monoclonal Antibodies Used to Treat COVID-19

As noted above, many rheumatology practices are equipped to deliver COVID-19 MABs, which are the same MABs rheumatologists administer for conditions, such as RA. The key challenges will be isolating COVID-19 patients from autoimmune patients to prevent disease transmission; establishing and training clinical staff on new workflows, including the evolving guidance associated with COVID-19 MAB treatments; and, equipping administrative and clinical staff with enhanced personal protective equipment (PPE).

If CMS revises its reimbursement policies for COVID-19 MABs to mirror those when MABs are used in other autoimmune diseases, the additional work and practice expense costs must be factored into the payment. As a first step toward accomplishing this, CMS must address the steep reductions in drug administration services due to the clinical labor pricing update proposal. Secondly, CMS must make an enhanced payment to cover the additional work and practice costs. A way to accomplish this would be to follow the approach used to enhance payment to acute care hospitals for COVID-19 cases and treatments through the end of the PHE. Specifically, CMS should 1) apply a payment enhancement to drug infusion services when a COVID-19 MAB is administered and a COVID-19 diagnosis is present on the claim, and 2) apply a payment enhancement to the COVID-19 MAB when a COVID-19 diagnosis is present on the claim.

Regarding home administration of MABs – COVID-19 or otherwise – this is not recommended given the substantial risk and safety profile for these drugs, which is well articulated in the American College of Rheumatology (ACR) Position Statement on Patient Safety and Site of Service for Biologics.

Telehealth and Virtual Care Services

As we've shared previously in our individual and coalition comments, CSRO greatly appreciates the flexibilities provided through CMS' COVID-19 blanket waivers and interim final rules with comment

(IFCs), which have significantly improved access to care for beneficiaries during the ongoing PHE. Many rheumatology practices have invested heavily in the technology needed to deliver telehealth and virtual care services, which has allowed them to continue managing their patients with chronic and complex diseases.

For the majority of CMS' telehealth policy proposals, we refer you to the Alliance of Specialty Medicine comments. With regard to "virtual presence," we generally support allowing physicians to provide direct supervision through the use of real-time audio/visual technology beyond the PHE; however, as noted in the section above on COVID-19 MABs, we have concerns about this policy being used to facilitate the provision of complex drug therapies in the home. Complex drug therapies, such as MABs and other biologics, have serious safety warnings or the potential for adverse reactions, which would be difficult to appropriately manage in the home by the physician's clinical staff or their contractor and puts patients at risk. We urge CMS to closely monitor how this policy is being used in practice to ensure patients are not exposed to increased risk of harm.

Rheumatology MVP

We are deeply concerned with CMS' proposed Rheumatology MIPS Value Pathway (MVP) and strongly urge CMS to delay implementation until the end of the PHE, which will give the agency time to address our chief concerns.

First and foremost, the Rheumatology MVP does not address the challenges practicing rheumatologists face in the current MIPS construct – namely the lack of an appropriate cost measure. In the proposed Rheumatology MVP, CMS proposes to adopt the Total Per Capita Cost (TPCC) measures, which does not account for *all pharmaceutical costs* when evaluating physician resource use. As we've shared before, this is for many rheumatologic conditions, such as RA where Part B and Part D drugs are available. And, while we understand 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. We know that CMS understands these challenges because it has discussed them in the context of certain Bundled Payments for Care Improvement (BPCI) models (e.g., Inflammatory Bowel Disease, or IBD) and in direct conversations with CSRO's leadership on potential alternative payment models (APM) pathways for the specialty.

In addition, we are deeply dismayed that CMS did not include IA_BE_ 24 Financial Navigation Program or IA_BE_25 Drug Cost Transparency as Improvement Activities in the Rheumatology MVP, despite the fact that most of our patients require this type of assistance given the associated costs with the medications used to manage their rheumatologic disease. Frankly, it is unclear why CMS is limiting practices to a narrow set of IA's when these measures are scored only on performance – not improvement.

Finally, 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.

Again, we urge CMS to delay implementation of the Rheumatology MVP until the aforementioned issues are addressed, and after the COVID-19 PHE has ended.

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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, should you require additional information.

Sincerely,

Madelaine A. Feldman, MD
President
CSRO