CSRO
Coalition of State Rheumatology Organizations

POLICY UPDATE
Summer 2022

IN THIS ISSUE

RHEUM FOR ACTION

Medicare Agency "Ping-Pong", Who's in Charge?

CSRO President Dr. Madelaine Feldman explains the advocacy work being done to address local Medicare policies that are threatening access and practice stability in the below reproduction of the July edition of *Rheum for Action*, CSRO's advocacy column produced in partnership with Rheumatology News.

Rheumatologists who administer medications in their office for Medicare patients, specifically those that are infused, have in recent years encountered problems providing certain medication formulations as well as coding and billing for their administration. In attempting to resolve these issues, rheumatologists and their professional organizations have found themselves caught in a morass of Medicare agency "ping-pong," where it is unclear who the decision makers are.

The private health care insurers that process medical claims for Medicare beneficiaries, called A/B Medicare Administrative Contractors or more commonly known as MACs, are the operational intermediary between the Centers for Medicare & Medicaid Services' fee-for-service program and the physicians enrolled in it. The country is divided into 12 sections, each with a MAC that has jurisdiction over that area. Among other things, the MACs establish local coverage and payment policies based on their understanding of CMS' rules, regulations, and the Medicare statute, and therein lies the problem: When a physician has a question on a policy or decision that was made by a MAC, it is very difficult to determine the origins of the issue and who can address the problem. It's a lot of "running in circles" between the MACs and CMS headquarters, hoping that someone will take the time to listen to your concern, but more importantly, work toward resolving the problem.

Who can address problems?
Meaningful, solutions-driven engagement with the MACs and CMS has become frustrating for physicians and advocacy organizations attempting to address a host of problems. The two issues alluded to above include the Self-Administered Drug Exclusion List (SAD List), which excludes certain Part B medication formulations from coverage under certain conditions and the "down coding" of certain infusion administration codes when specific drugs are delivered. These problems are compounded by the curtailment of physician stakeholder input via Contractor Advisory Committees (CACs). Each state has its own CAC, but the CAC meetings have been restructured as a result of the 21st Century Cures Act, and ultimately eradicated the involvement of these physician advisers in policy development at the local level.

This has left many of rheumatology representatives to the CACs demoralized and generally unhappy about certain decisions being made without their input. There is also inconsistency in terms of coverage and payment policies throughout the country. *(continued inside)*

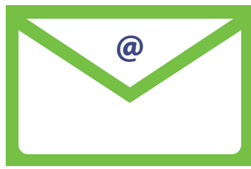
For example, in one MAC jurisdiction, a certain medication may be on the SAD List and excluded from Part B coverage, meaning beneficiary access is only available through Part D (and assuming they can afford it), while in an adjacent MAC jurisdiction, both formulations are covered.

The Coalition of State Rheumatology Organizations (CSRO), along with the American College of Rheumatology (ACR) and other specialty groups, is attempting to address these issues from many different angles. There is not enough space to explain the nuances of local coverage policy development, but the timeline below highlights the long and winding road that we have traveled to resolve these issues:

- **February 2021** – CSRO meets with CMS' Coverage and Analysis Group (CAG) to raise concerns about ustekinumab (Stelara) and its inclusion on the SAD List.
- **April 2021** – CSRO follows up with CMS' CAG on SAD List concerns in a letter.
- **May 2021:** Most MACs issue or revise local coverage articles, or "billing and coding" articles, that down code the administration of certain biologic medications, with some expanding the list of biologic medications subject to the policy, prompting a strong response from CSRO.
- **September 2021:** CSRO meets with multijurisdictional MAC Contract Medical Director (CMD) work group to discuss down coding, SAD List, and physician/CAC engagement.
- **October 2021:** At the suggestion of the CMDs, CSRO re-engages with CMS' CAG to raise concerns about down-coding policies and physician/CAC engagement, and continue the SAD List discussion.
- **November 2021:** CSRO is connected with CMS' "payment ombudsman" on down coding and the SAD List.
- **January 2022:** CSRO signs on to multispecialty coalition effort aimed at improving local coverage and payment policy and restoring the importance of the CAC.
- **February 2022:** CSRO participates in CMS CAG meeting with multispecialty coalition, raising concerns about the down-coding and SAD List policies.
- **March/April 2022:** Through its coalition partner, the Alliance of Specialty Medicine, CSRO meets with the principal deputy CMS administrator and raises awareness to these issues.
- **May 2022:** CSRO participates in follow-up discussion with CMS' CAG as part of multispecialty coalition, reiterating concerns about the down coding and SAD List policies. With the assistance of the CMS' Office of the Administrator, CSRO meets with CMS' Center for Program Integrity to seek a "pause" in down-coding policies for certain biologic medications.
- **June 2022:** CMS notifies CSRO of a "temporary pause" in medical review while the agency reviews various manuals and policies to determine the appropriate steps forward. To assist the agency, CSRO works with practices to develop a resource that CMS can use to establish criteria for determining when a medication warrants use of complex drug administration codes. CSRO re-engages with multijurisdictional MAC CMD workgroup to continue discussions on SAD List.
- **July 2022:** CSRO meets with new multijurisdictional MAC CMD workgroup focused on improving the process for developing local coverage and payment policy.

Our dialogue with CMS leadership and staff continues. In the most recent communication, staff in the CMS administrator's office informed us that the issue is complicated and crosses several different parts of the agency, and they are still determining next steps.

The rheumatology community's journey toward solving the challenges facing practices and patients is emblematic of the communication problem between provider groups and the CMS-MAC establishment. While we understand this is how bureaucracy works, it is not to the benefit of Medicare beneficiaries to have a system that is so difficult to navigate, even by the best of the regulatory gurus. This is not an indictment of any specific group but a call to action on the part of the government and their contractors to create a clear, transparent path to getting answers when we have a problem.



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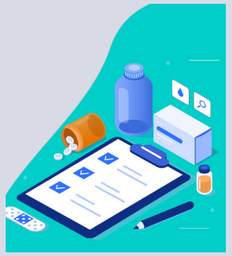
Join our email list at csro.info.

Rheumatology Highlights: CMS Release of 2023 MPFS Proposed Rule



On July 7, 2022, the Centers for Medicare and Medicaid Services (CMS) released its CY 2023 Medicare Physician Fee Schedule (PFS) proposed rule, which includes key changes to the physician fee schedule (PFS) and other Medicare Part B payment policies, as well as proposed updates to the Quality Payment Program (QPP) and Medicare Shared Savings Program (MSSP). Of note, CMS estimates the CY 2023 PFS CF to be $33.0775, which reflects the 0.00% update specified in law, a budget neutrality adjustment and the expiration of the 3% increase for services furnished in CY 2022.

A few highlights specific to rheumatology:

- **Rebasing and Revising the MEI** – CMS proposes to rebase and revise the Medicare Economic Index (MEI) cost share weights from a 2006-base year to a 2017-base year, but delay implementation for both PFS ratesetting and the proposed CY 2023 GPCIs. CMS notes that there would be significant shifts in specialty level payments if it were to use the proposed rebased and revised MEI cost share weights (i.e., specialties with relatively high practice expense (PE) costs would realize positive impacts, whereas specialties with higher physician work costs would realize negative impacts). CMS also believes it is critical for the public to have an opportunity to comment on the proposed rebased and revised MEI before it is incorporated into PFS ratesetting and the PE GPCIs.
- **Updating PE Data Collection and Methodology** – Stakeholders have raised concerns about CMS' PE data collection and methodology. As an example, in CY 2022, CMS proposed and finalized the use of updated data for clinical labor wages. Of course, after not updating these data for 20 years, and operating in a budget neutral system, this wreaked havoc on several specialties and the services they provide, including drug administration. CMS agrees that it is necessary to establish a roadmap toward more routine PE updates and signals its intent to move to a standardized and routine approach to valuation of indirect PE, which will be included in future rulemaking. As part of this effort, CMS has contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates. Considering the impact delayed updates to clinical labor pricing continues to have on drug administration services, it is important for CMS to make routine updates.
- **Discarded Drug Rebates** – CMS proposes 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. With regard to Medicare providers who administer Part B drugs, since 2017, providers have been required to report the JW modifier on their Part B drug claims to indicate discarded amounts. However, many claims are still submitted without that modifier and CMS now needs that information to calculate the amount owed by the drug company. Thus, CMS will continue requiring the JW modifier for any discarded amount but, starting on January 1, 2023, CMS will also require a new JZ modifier if there were no discarded amounts.
- **QPP** – The updated 2023 category weights, per statute, are as follows: 30% quality; 30% cost; 15% improvement activities; 25% promoting interoperability. CMS will modify the MVP development process to allow for a 30-day comment period for new candidate MVPs determined by CMS as "ready for feedback" prior to rulemaking; CMS will also host a public webinar for certain revisions to established MVPs. Additionally, CMS is modifying the Advancing Rheumatology Patient Care MVP, noting that CSRO has asked CMS to update the improvement activities in the MVP, and while CMS agreed with our suggested improvements in the CY 2022 PFS Final Rule, they did not incorporate those in this rulemaking. CMS proposes to maintain the MIPS performance threshold at 75 points for the 2023 performance year (as a reminder, there's no exceptional performance bonus starting in 2023), and they also propose to increase the data completeness threshold from 70% to 75% for the 2024 and 2025 performance periods, as well as changes to Rheumatology Specialty Set.

CSRO will submit comments to CMS on the proposed rule by the September 6 deadline, *with the final rule expected on or about November 1, 2022.*

State Advocacy: Impact on Legislation

We've reached the halfway point of 2022 and many state legislatures across the country have adjourned for the year or are nearing the completion of this session. While others will continue through the end of the year, current progress provides a solid foundation for where issues stand across the country.

The immense number of successes CSRO has seen in the past few years has left fewer, and more difficult, targets for this and subsequent years. We have also seen new policy options enter the fray, and they take time to gain the same momentum as more mature policy issues.

What is CSRO Doing to Impact Legislation?

CSRO works to advance its priority issues in the states through a variety of means. First and foremost, CSRO hopes to empower state societies and their members to be active participants in advocating for their practices and patients. To that end, CSRO works to alert rheumatologists across the country when there is legislation of import in their state so that they can communicate with their elected officials. To facilitate this communication, CSRO offers its convenient action center, which streamlines this activity for rheumatologists. In addition, CSRO helps coordinate testimony opportunities for rheumatologists when they present themselves.

Beyond generating grassroots support from the rheumatology community, CSRO also works actively to support legislation from an organizational level. CSRO communicates with legislators via policy memos and social media. In addition, CSRO staff or its board members are often on the ground in state capitols helping to advance priority issues. In some cases, when CSRO targets a specific state, it may hire local lobbying support to supplement its efforts.

CSRO staff also regularly interfaces with likeminded partners to coordinate support on legislation of import to the broader community of patients and providers. In states that CSRO has prioritized it is able to leverage these connections to build support for legislation.

Finally, CSRO helps influence the development of model policy and subsequent legislative negotiations. This helps ensure the perspective of the rheumatology community is considered in state legislative efforts.

Accumulator Adjustment Programs

This year two states, Maine and Washington, have seen accumulator legislation signed into law, bringing the total number of states with legislation on the books to thirteen and Puerto Rico. Several states such as Massachusetts, Minnesota, New York, Ohio, Pennsylvania will continue to work on the issue for the remainder of the year. Due to a conflict with IRS rules regarding health savings account eligible high deductible health plans some states with existing laws have moved to exempt such plans from their laws or legislation.

In Pennsylvania specifically, CSRO staff participated in negotiations with opposition to help ensure the bill remained beneficial for the patients rheumatologists treat. Staff also worked directly with the local lobbying team of the Pennsylvania Rheumatology Association to help coordinate grassroots support and strategy.

Non-medical Switching

Non-medical switching continues to be a politically difficult issue across the states. High drug costs being a leading component of increasing health care expenditures continues to be a pervasive narrative in state policy circles, and serves as a headwind legislation on this issue. Colorado did see some success this year, with non-medical switching protections being signed into law as part of a broader patient access package. This follows the signature of a law in New York at the end of 2021.

CSRO's continued support of non-medical switching legislation in Iowa demonstrates the manner in which CSRO helps empower rheumatologists and state societies to participate in advocacy. Over the years, CSRO helped the rheumatology association craft letters of support, connected rheumatologists to media opportunities designed to support the legislation, and numerous rheumatologists took advantage of CSRO's action center to communicate with their representatives in Des Moines.

Prior Authorization

The new Texas "Gold Card" law is an exciting development representing willingness to try new approaches towards reducing prior authorization burden. A number of states across the country pursued legislation in 2022 following Texas's lead. The gold carding policy is new and unproven.

There remain numerous questions regarding the concept will be operationalized for prescription drugs, which is of chief concern to rheumatologists. Helping to ensure that state policy reflects the needs of the rheumatology community is one of CSRO's main goals. To that end, CSRO took the time to comment on the Texas Department of Insurance's proposed rules regarding the new law. CSRO's full comments can be accessed CSRO's website at **csro.info/advocacy/correspondence**. CSRO intends to monitor implementation of the Texas law to inform its advocacy efforts across the states.

Rebate Pass Through & PBMs

In 2021, West Virginia passed a first-of-its-kind law requiring payers to reduce patient cost sharing amounts for prescription drugs commensurate with rebates received in conjunction with that patient's purchase. Although no states have followed West Virginia's lead so far this year, 15 states saw legislation introduced. CSRO has joined with the Patient Pocket Protector Coalition to coordinate on rebate pass through legislation across the country.

Stay Connected!

Join the conversation on Facebook and Twitter to get real time updates on rheumatology news and events.

Follow us at @CSROAdvocacy

Be informed!

All of our priority issues, what they mean, and what CSRO is doing about them are outlined on our website.

Learn more at csro.info/advocacy/our-issues

State Advocacy *(continued)*

Step Therapy

Step therapy remains an issue area generating a great degree of success. To date, signature of laws in Colorado, Kentucky, and Tennessee have brought the total number of states with some form of law on the books to 35. States such as California, Pennsylvania, and New Jersey continue to work on legislation.

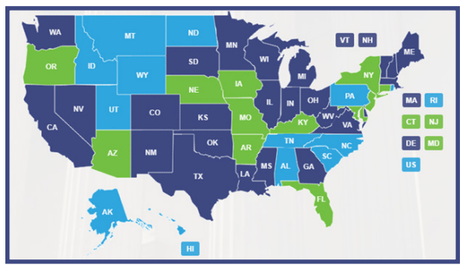
In addition to CSRO's leadership in Kentucky, CSRO also serves as chair of the State Access to Innovative Medicines Coalition (SAIM). The coalition is the central coordinating vehicle for step therapy legislation across the country, which allows CSRO to influence policy, strategy, and legislation across the country. This helped CSRO staff work behind the scenes to formulate language in Colorado that was consistent with the model language supported by CSRO.

White Bagging

White bagging has emerged as an important issue to the rheumatology community. as a result, it has become a hot issue for state legislatures. Louisiana remains the only state with a prohibition on mandatory white bagging on the books, although practices lacking an internal dispensing pharmacy are excluded from the law's protections. CSRO has worked proactively across the states to ensure that this exclusion is not replicated across states that have introduced legislation on this issue. In states such as Kentucky and Nebraska, CSRO staff met with stakeholders in order to secure amendments that would ensure all rheumatology practices would be protected by the proposed legislation. To date, thirteen states have seen legislation introduced on this issue.

How You Can Impact Legislation

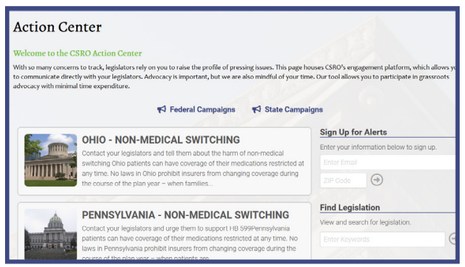
Legislative Map Tool
csro.info/map



CSRO's website has an interactive legislative map tool that showcases current and proposed policy in your state!

Updated regularly, you simply visit **csro.info/map**, click on your state, and get information about legislation that can or is impacting the rheumatology community in your area.

Action Center
csro.info/advocacy-campaigns

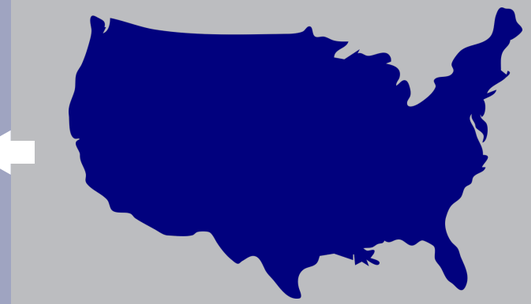


CSRO's Action Center allows you to communicate directly with your state legislators about proposed policy.

Visit **csro.info/advocacy-campaigns** to see if your state has any pressing issues. From there, you can read more about the issue and voice your support by sending a template message to lawmakers and make an impact on your state legislation!

Want to know the laws in your state?

Visit the CSRO legislative map tool at csro.info/map to find out, and email info@csro.info with any questions.



Leader in Drug Pricing Reform: Pharmacy Benefit Managers (PBMs)

Currently, prescription drug formularies are designed to maximize revenues for pharmacy benefit managers (PBMs), which is why medications with high list prices – and thus high rebate potential for the PBM – are sometimes preferred over lower-cost alternatives with lower rebate potential. In a particularly egregious example, a recent article described a $10,000 brand being preferred on formulary while its $450 generic was not covered or covered on a lower tier. Since patient cost-sharing is often based on list prices, these types of formulary design decisions are financially prohibitive for patients. Additionally, insurers and their PBMs often put in place onerous utilization management requirements that create additional access barriers for patients.

For these reasons, CSRO was one of the first groups to advocate reform of PBM industry. Over the years, we have engaged federal and state policymakers and regulators to seek meaningful reform based on the foundational principle that formularies should be designed based on efficacy, safety, and lowest cost for the patient. In addition to our own efforts, we have partnered with coalitions and the independent pharmacy community to amplify our voice on this issue.

In recent years, several pieces of legislation have been introduced to create transparency within the PBM industry, including bills to mandate studies by the Federal Trade Commission (FTC) and the Government Accountability Office. On the regulatory side, the Office of the Inspector General finalized an elimination of the safe harbor from antikickback law for the payments from drug manufacturers to PBMs in exchange for formulary placement, although Congress continues to delay the effective date of that rule. For its part, the Centers for Medicare and Medicaid Services (CMS) recently finalized a regulation requiring PBMs to reflect all pharmacy price concessions in the negotiated price, including any retroactively assessed fees and payments. CSRO had supported the independent pharmacy community in a litigation asking for exactly that, and we are hopeful that a similar policy will eventually be extended to manufacturer price concessions as well. In that same regulation, CMS also established for the first time a program-wide definition of "price concession" in Part D, which is broad and intended to include all forms of discounts, subsidies, or rebates.

Most recently, on June 7, the FTC announced it will conduct a study involving six major PBMs. The announcement follows the FTC's solicitation of public comments on the business practices of the PBM industry, to which CSRO submitted detailed comments. As part of its study, the FTC will examine issues related to formulary design and utilization management, which often create severe access barriers for rheumatology patients. The PBMs will have 90 days from receipt to respond to the FTC's information requests, but it may take the Commission some time to review that information, so the study will likely not be completed before the end of this year.

Overall, CSRO is encouraged by the increased action by lawmakers and regulators with regard to this largely opaque and unregulated area of the pharmaceutical market. Our goal will always be to increase access and lower costs for our patients, and we will continue to work towards PBM reform until meaningful change is accomplished.

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[1] "When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system" by Zachary Brennan, Endpoints News (Feb. 18, 2022)

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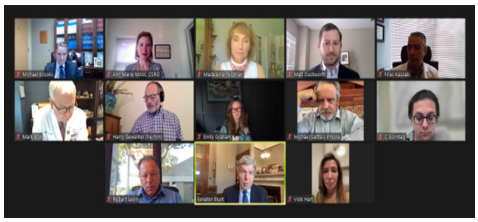
Virtual Advocacy: CSRO Annual Hill Day



In June, CSRO leadership virtually visited Capitol Hill, connecting with bipartisan Members of the U.S. House of Representatives and U.S. Senate to voice their policy concerns, focusing on the topics of Medicare payment policy and patient access to prescription drugs.

Throughout the day, CSRO was joined by State Society members interested in connecting with their congressional leaders and plan to make this type of formal "Hill Day" an annual event. If you are interested in attending future events in person or at the Capitol, email **info@csro.info**.

State Society Member Benefits

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

CSRO's benefits exclusive to members include:

- ***Travel stipend for two representatives to attend the CSRO State Society Advocacy Conference***
  - Held annually, this conference focuses on the most relevant rheumatology policy issues, state advocacy strategies, and ways to support CSRO's state society members
    - Contact your state society president or executive director for more information, or email **achristensen@csro.info** and we will help connect you with your state society
- ***Grants to support state advocacy activities***
  - CSRO is proud to support the advocacy efforts of our members with exclusive grants to underwrite the costs of a day at the capital, educational webinars, and more
    - Visit **csro.info/membership/member-benefits/advocacy-grant** for more information
- ***Session on advocacy and legislation at state society annual meeting***
  - To help ensure members are connected and informed, CSRO will cover all associated costs for a CSRO Board member to attend and speak at the annual meetings of our members
    - Email **info@csro.info** to schedule a session at your society's annual meeting

Membership Questions?

Email Communications & Membership Manager Anna Christensen at **achristensen@csro.info** or visit **csro.info/membership**.