CSRO
CELEBRATING 20 YEARS

POLICY UPDATE

Summer 2023

IN THIS ISSUE

RHEUM FOR ACTION: In-office infusions at risk with new Medicare Part B reimbursement recommendation

CSRO's Immediate Past President and Vice President of Advocacy & Government Affairs, Dr. Madelaine Feldman, highlights the potential negative impacts of MedPAC's recent recommendations in the below reproduction of the July edition of Rheum for Action, CSRO's advocacy column produced in partnership with Rheumatology News.

The Medicare Payment Advisory Commission (MedPAC) is an independent agency to advise Congress on Medicare (MC) policy, much of which pertains to payment issues. The 17 commissioners meet publicly and issue two reports a year with their recommendations to Congress, who then decides whether to enact these recommendations or not.

One MedPAC recommendation in 2023 was quickly introduced in the House of Representatives in May and passed the Energy and Commerce Committee 49-0. That recommendation relates to "site neutrality" payments to MC providers. If passed by Congress, it would result in some "site-neutral" cuts to hospitals. That MedPAC recommendation was acted upon very quickly by Congress. Consequently, it is important to discuss the potential negative ramifications of other MedPAC recommendations released in June regarding reimbursement of Medicare Part B drugs and proactively educate Congress accordingly on those ramifications.

Medicare Part B drugs

Medicare Part B drugs are those administered by providers, unlike the Part D medications which are generally obtained through pharmacies. Presently, MC reimburses providers for the administered Part B medication based on the average sales price (ASP) plus 6%. However, with sequestration, that add-on amount is reduced to ASP plus 4.3%. It has long been touted by MedPAC and other policy makers that physicians choose to infuse higherpriced drugs in order to increase reimbursements. That has not been borne out when it comes to rheumatologists, and, in fact, a retired MedPAC commissioner even stated that premise did not hold true for rheumatologists.

Regardless, it continues to be suggested that MC should reduce its costs for Part B medications by reducing reimbursement to physicians. It should be noted that often the margins on the drugs are already quite thin, and at times the reimbursement amount, compared with the acquisition cost of the drug *(continued inside)*

even leaves the physician "underwater."

A few years ago, there was a proposed Part B demonstration project that essentially removed the +6% add-on and replaced it with a very low fixed amount that would have left most physicians "underwater" in their Part B drug acquisitions.

This was vigorously opposed by physicians around the country, who let Congress know exactly how they felt. We have been told that the Coalition of State Rheumatology Organizations was one of the most vociferous organizations that helped in fighting back this proposal and resulting in its withdrawal.

MedPAC recommendations

That brings us back to MedPAC. In June, MedPAC released recommendations to Congress in an attempt to address the "high price of drugs" covered under MC Part B. Unfortunately, the recommendations do nothing to address the root cause of high drug prices, but once again attempt to balance MC expenditures on the backs of physicians. In this case, it is physicians who infuse Part B drugs in their office to chronically ill patients. In-office infusions have been shown to be the most cost-effective site of care, as well as being safer when compared with home infusion for a number of rheumatologic medications.

One of the MedPAC recommendations gives the Secretary of Health & Human Services the authority to establish a single ASP for drugs with "similar health effects." The ambiguity of the phrase "similar health effects" should put us all on alert as to the significant unintended consequences that may result. For example, HHS could assign one ASP to all drugs that treat rheumatoid arthritis based on the lowest ASP of the group. This certainly would lead to a number of drugs being out of reach for MC beneficiaries if the artificial ASP of the medication is much lower than the actual acquisition cost of the drug, leaving physicians unable to acquire it. Yet, MedPAC states this recommendation would not affect access to care for MC beneficiaries.

Another recommendation would require HHS to reduce or eliminate the add-on percentage to the ASP for higher-priced drugs and/or put in an added fixed amount. This recommendation is clearly reminiscent of the old ill-conceived Part B demonstration project.

A fixed "add-on amount" might work if it is sufficient to cover the overhead of maintaining a provider's infusion suite. But if practices are left underwater in their purchases of certain Part B drugs, there may be no choice but to stop offering those infusions to MC beneficiaries or – worst-case scenario – shut the door completely. Yet again, MedPAC stated that this recommendation would not result in a loss of access to these treatments for MC beneficiaries.

Loss of access?

Rheumatologists have gone to great lengths to continue offering care to MC patients in spite of the yearly cuts and threats of more cuts in the future to physician reimbursements. In addition, physicians have no annual inflationary update to their reimbursements. I am not sure how MedPAC concludes that continued cuts to physician fee schedules, along with a decrease in reimbursement for administered drugs, will not affect access to care for MC beneficiaries.

Finally, the timing on these recommendations is confusing, considering that implementation of the Inflation Reduction Act (IRA) has just begun. Next quarter, a number of Part B drugs will be subject to inflationary penalties; there will also be additional Part B biosimilars coming to market, resulting in lower ASPs. And don't forget, the IRA just instituted an ASP plus 8% reimbursement for biosimilars in an attempt to get physicians to do something that the Centers for Medicare & Medicaid Services has asked them not to do. That is, choose a drug based on its reimbursement, not necessarily the one which is right for the patient.

Overall, with so many variables up in the air, now is not the time to create even more uncertainty for physicians and the Medicare patients that they take care of.

Rheum for Action, CSRO's advocacy column produced in partnership with *Rheumatology News*, shares updates on current advocacy issues. Visit our website to review the latest editions.

Dealing with the Middle Men: CSRO's Work to Reform the Pharmacy Benefit Manager Industry Bears Fruit

Years ago, when CSRO first began discussing the harms of pharmacy benefit manager (PBM) industry practices, the reception was simple, if a touch frustrating: few people even knew what a PBM was. We've come a long way since then, with Congress actively considering several bipartisan PBM reform bills and the Federal Trade Commission scrutinizing the practices of six major PBMs and their affiliated entities. As one of the first physician groups to sound the alarm bell on the pharmaceutical middlemen and a founding member of a major coalition focused on PBM reform, CSRO is now recognized as a trusted expert to provide the clinician perspective on PBMs.

For example, when the House Oversight and Investigations Committee then-minority staff held a forum entitled *Reviewing the Role of PBMs in Pharmaceutical Markets*, they invited Dr. Madelaine Feldman to testify on behalf of CSRO. Dr. Feldman described the harm to patients that occurs when formularies are constructed for the sole purpose of maximizing income to the PBM. A short time later, the Committee issued a report with its initial findings, followed by an official announcement in March 2023 that the Committee was launching an investigation into the role of PBMs in rising drug costs.

Similarly, in May of last year, CSRO responded to a request for information from the Federal Trade Commission (FTC), highlighting the formulary construction and utilization management issues faced by our patients and urging the FTC to move forward with a thorough investigation of the PBM industry. The FTC received a staggering 24,000 responses, the vast majority of which echoed our concerns. In June, the FTC announced it would build on that public record and launch an inquiry into six major PBMs, which was later expanded to include some of the PBMs' "aggregator" entities.

For its part, the U.S. Congress is considering several bipartisan bills to reform the industry to varying degrees. One bold idea that has gotten legislative traction is the concept of "delinking," or severing the connection between a drug's list price and a PBM's compensation. Right now, the higher the list price of a medication, the greater the price concession potential for the PBM. Research shows that for every $1 increase in rebates, there is an associated $1.17 increase in list price. Two separate bipartisan bills – one in the House and one in the Senate – would sever that connection by requiring PBMs in Part D to accept flat fee payment for their services and prohibiting compensation that is tied to the price of the product.

All of CSRO's policy positions flow from the core principle that the patient should be centered and prioritized in our drug pricing and access system. From that principle, the need for various policy reforms becomes clear:

- price concessions should be fully passed through to the patient,
- formularies should be constructed based on clinical information, and
- utilization management should be limited, reasonable, and data-driven.

Although we have a long way to go, the momentum behind meaningful reform is higher than it's ever been, and we're excited to keep driving it forward.

Understanding the Problem with PBMs

Pharmacy benefit managers (PBMs) directly impact drug prices and have unchecked control over the amount patients pay for their prescriptions, as well as what drugs are accessible to the public.

Learn more in this piece from *Investigate TV* featuring CSRO Vice President of Advocacy & Government Affairs Dr. Madelaine Feldman explaining the issue.

STATE ADVOCACY: CSRO's Legislative Impact

2023 is a milestone year for CSRO as we are *celebrating two decades of serving as a voice for the rheumatology community*. We remain dedicated in our efforts to improve access to care, and as we build on our past successes, CSRO is optimistic with the status of our advocacy efforts so far this year.

Our Priority Issues: Where We Stand in the States

Accumulator Adjustment Programs

Colorado, the District of Columbia, and New Mexico signed new accumulator bans into law this year, while California, Massachusetts, Michigan, Ohio, Pennsylvania, and Wisconsin continue to work on the issue for the remainder of the year.

New variations of these types of programs continue to emerge, like Copay Maximizer and Alternative Funding Programs, and CSRO remains dedicated to addressing these issues.

Biomarker Testing Coverage

Requiring biomarker testing coverage is a new priority issue for CSRO, as it better enables rheumatologists to diagnose conditions. So far this year, Arkansas, Georgia, Kentucky, Maryland, Minnesota, New Mexico, Oklahoma, and Texas have signed bills supported by CSRO into law.

Insurance companies are actively trying to limit this legislation to only apply to cancer diagnoses and the voices of our physicians and their practice partners will be crucial to ensuring these new technologies are accessible to our patients.

Non-medical Switching

Non-medical switching continues to be a difficult issue in state legislatures, as lawmakers remain hesitant to constrain health plan flexibility when it comes to containing prescription drug costs. Nonetheless, CSRO, along with many patient and provider advocacy groups, is continuing to advocate for this important issue and has seen some success with Nevada enhancing its existing law this year.

Prior Authorization

Carrying momentum over from 2022, "gold carding" continues to be a significant issue for state legislatures across the country. Arkansas joined Texas as the second state to implement this new legislation – *learn more about gold carding on page 5 of this Policy Update.*

Rebate Pass Through & PBMs

Both Arkansas and Indiana signed bills into law this year, and new legislation was introduced in New York that expands the state's existing transparency requirements to encompass PBM-affiliated businesses such as rebate aggregators. CSRO applauds this introduction and hopes to see other states follow suit.

Step Therapy/Fail First

Reforming the use of step therapy has been a priority of CSRO for many years and are pleased to have Nevada join the ranks of states with legislation on the books. Additionally, Maryland updated their existing law to include more scenarios under which a provider can override the step therapy protocol, and Colorado expanded parts of their law to cover those in the Medicaid program.

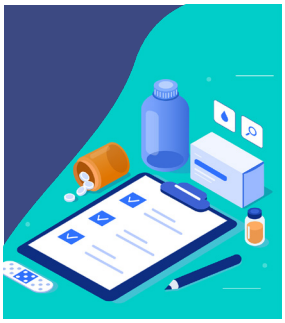
One new development we've seen beginning to circulate in state legislatures is the potential to allow for non-medical switching. This legislation would enable a health plan to require trial and failure of biosimilar products regardless of whether any of the law's exceptions criteria are met. CSRO is working to ensure that the decision to switch a stable patient remains between the patient and their physician.

White Bagging

CSRO is continuing to support legislation across the country to prevent plans from implementing specialty pharmacy mandates. Both North Dakota and Texas have signed legislation into law this year, and *a breakdown of the policies states are pursuing can be found on page 5 of this Policy Update.*

To learn more about CSRO's priority issues and the work we are doing at the state and federal level to address them, visit www.csro.info/advocacy.

Gold Carding: Better on Paper?



Prior authorization reform to alleviate administrative burden and ensure timely delivery of care has been a long-standing issue in the rheumatology community. Previous reforms have focused on the use of standardized forms and the allowance of electronic submission of prior authorization requests. While overall positive reforms, the impact on time saved has been minimal and frustration continues.

On the back of this frustration in 2021, Texas passed first-of-its-kind legislation to exempt physicians from prior authorization requirements for a specific service or product if they garnered a 90% approval rate on authorization requests for that product or service over a six-month lookback period. Also known as a "gold card," this law was an exciting development for physicians nationwide, as policymakers were finally taking action to reduce the burden of prior authorizations.

During the regulatory process, CSRO did raise questions about how this law would operate. Because of the diversity of treatment options used by rheumatologists and a number of payers, tracking this type of information could, in itself, present a significant administrative burden. In addition, the law requires a minimum number of prior authorization requests over a six-month period in order for a gold card to be re-issued. Based on treatment intervals and patient volume, there may be difficulty qualifying for exemptions for certain drugs. It is also unclear how an exemption granted under the law interacts with other utilization management tools, such as step therapy, that apply to prescription drugs.

With the law going into effect late last year, CSRO surveyed the Texas rheumatology community to gauge the true effectiveness of this approach. Overwhelmingly, most respondents struggled to qualify or were not awarded an exemption, and for those that did qualify, it was unclear whether they were exempt from other utilization management restrictions. Responses did show some success, with reports that when a gold card exemption was received for MRIs, administrative burdens faced by offices did decrease.

With these experiences in mind, it is clear more work needs to be done to truly address the issue. However, CSRO is encouraged that state legislators across the country are considering policy to help reduce the administrative burden issues created by prior authorization – for the first time ever, states are seriously considering reducing the number of prior authorization requirements with legislative action and that is a tremendous step forward in this ongoing policy debate.

White Bagging: Progress in 2023

When pharmacy benefit managers (PBMs) and insurers began implementing broad requirements to white bag specialty drugs, Louisiana was quick to respond by prohibiting insurers and PBMs from making the drug acquisition method mandatory with its passing of a new law in 2021. CSRO was hopeful for similar legislation throughout the states, but 2022 saw no success.

This year has brought new momentum to the issue with both North Dakota and Texas enacting laws protecting against mandatory white bagging. The legislation follows the general framework established by Louisiana; protecting patients from increased out of pocket costs or lack of coverage if their provider buys and bills, and protecting providers from refusal to authorize treatment or reductions in reimbursement because they buy and bill.

The Texas law is somewhat unique as it does not apply to a hospital-based setting where drugs are administered by providers, helping to mollify stakeholder concerns regarding the cost of provider-administered drugs in these instances. This law also requires the consent of both the patient and provider if the insurer wishes to white bag a prescription drug.

While both new pieces of legislation are quite strong, the policy environment remains nuanced. Many states are considering policies that primarily focus on obtaining patient consent and protecting patients from increased out of pocket costs. Some states are focused on anti-steering provisions that may fail to substantially benefit rheumatology practices that do not "dispense" drugs. Other states are considering policies, which CSRO remains hesitant of, that require certain safety and logistic standards to be met by PBMs and insurers that white bag drugs.

CSRO is focused on ensuring that patients and practices benefit from these protections, and are hopeful this momentum will carry forward into 2024.

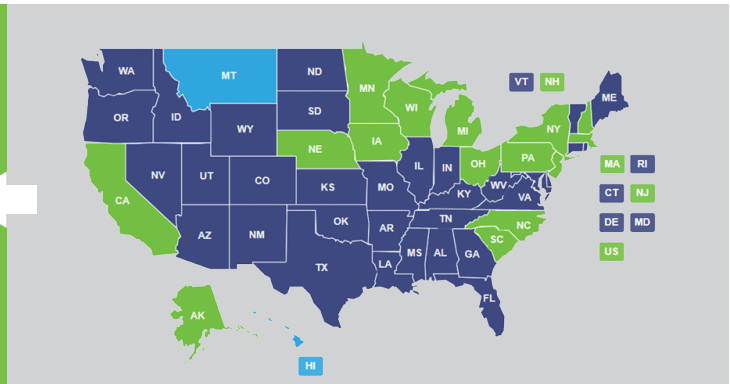
Award Winning Resource: CSRO Legislative Map Tool

In recognition for its positive impact, CSRO's **Legislative Map Tool** has been awarded a **Profiles of Excellence Award** from the American Association of Medical Society Executives (AAMSE) and the **Power of Associations Silver Award** from the American Society of Association Executives (ASAE).

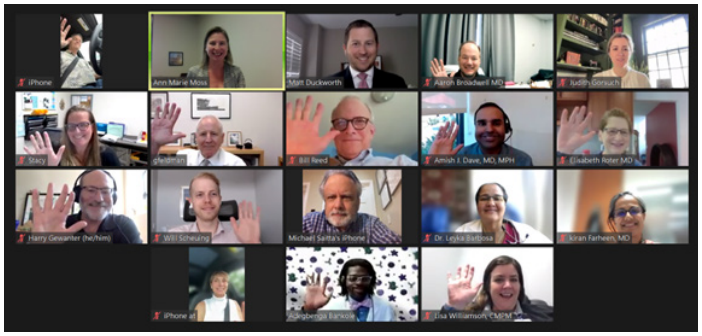
Launched in 2020, CSRO's Map Tool showcases current and proposed policy in all 50 states and is unmatched in its ability to provide information and supplemental details on the legislation impacting practices and patient access to care. CSRO is honored to have our resource recognized by the broader community.

Want to know about the laws in your state?

Check out our map tool!



CSRO Advocacy in Action: Annual Virtual Advocacy Day



In July, rheumatologists and their practice partners from across the country gathered for CSRO's Virtual Advocacy Day to connect with nine Members of Congress and discuss legislation that would help patients and practices. Issue topics included meaningful reform of the pharmacy benefit manager (PBM) industry, changes to utilization management practices, and protection of patients' ability to use the full value of copay assistance.

Throughout the day, the group heard from bipartisan, bicameral Members of Congress, including champions of some of the legislation CSRO has been advocating in support of. For example, Rep. Buddy Carter (R-GA) spoke about his PBM reform proposals, which are informed by his thirty years of experience as an independent pharmacist before coming to Congress. He also discussed the HELP Copays Act, bipartisan legislation supported by CSRO that would enable patients to access the full value of copay assistance.

Rep. Kim Schrier (D-WA) spoke about the need for utilization management reform, a subject she has personal experience with not only as a pediatrician, but also as a patient living with Type 1 diabetes. With several Committee markups and floor votes happening this same day, it was an incredibly hectic time even by Capitol Hill standards, and CSRO appreciates having the opportunity to share our experiences directly and highlight the issues that are impacting the rheumatology community.

Status Update: CSRO Makes Progress on Drug Administration Service Challenges

In 2022, CSRO advocacy led to the Centers for Medicare and Medicaid Services (CMS) to issue a Technical Direction Letter (TDL) (dated August 12, 2022) to its Medicare Administrative Contractors (MACs) that effectively "paused" the "down coding" of complex drug administration services. Shortly after the TDL was issued to the MACs, CSRO led a multispecialty group of physicians and infusion providers in a discussion on this issue, highlighting concerns and offering solutions.

Since that time, CMS senior staff have told us they continue to actively work on the down coding issues, as well as other challenges related to the Self-Administered Drug (SAD) List Exclusion criteria. Because of the nature of the issues at hand, CMS said that it may need to use rulemaking to begin addressing these issues, and the rulemaking vehicle would be the Medicare physician fee schedule (PFS).

On July 13, 2023, CMS made good on that commitment; the CY 2024 PFS included a request for information (RFI) titled, Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding. Here, CMS describes the challenges that CSRO has repeatedly raised and provides an opportunity for the public to provide feedback on these topics.

We shared previously that CSRO has pushed for robust criteria that would account for AMA CPT requirements, Medicare valuation, and other clinical factors, including complexity of the patient population, all of which demonstrate that the administration of rheumatologic and other complex medications warrant use of the chemotherapeutic administration codes. CSRO has also advocated for changes to the criteria used by CMS and its Medicare Administrative Contractors (MACs) to include medications on the Self-Administered Drug (SAD) Exclusion List.

On down coding, CMS has told us the TDL remains in effect, and CSRO is working to have the substance of that document shared publicly to address compliance concerns that have, understandably, been raised. CSRO is also in the process of scheduling a meeting with CMS senior staff and leadership for the multispecialty group to continue the dialogue on these topics.

CSRO will continue to share updates with the rheumatology community as appropriate. To review CSRO's past statements about the CMS "pause" on downcoding or to join our email list to receive the latest news straight to your inbox, visit **www.csro.info/news**.

Legislative Map Tool	Step Therapy Cover Sheets	Payer Issue Reporting Form
Find your state on our *award-winning* interactive map tool to learn about current or proposed policy and ways you can take action to make an impact.	Review CSRO's state-specific step therapy materials that help guide practices in gaining an exemption from step therapy protocols.	Request assistance from CSRO's Payer Issue Response Team with any payer relation issues that may be impacting your patients or office.

Find these tools and more at **www.csro.info/resources** – all offered as *free resources to the rheumatology community.*

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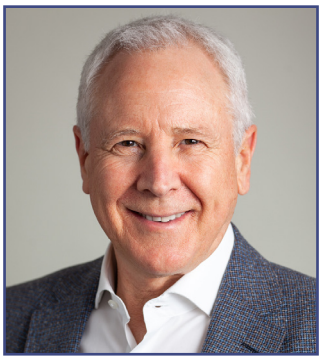
A Message from the President



Gary R. Feldman, MD, FACR
CSRO President

Advocacy has been the cornerstone of CSRO's mission since our inception two decades ago, and as CSRO's President during this milestone year, I'd like to take a moment to reflect on our history.

The initial concept for this organization began in 2002 with a small meeting of practicing rheumatologists and state society presidents from different states. This group was experiencing firsthand how their patients and practices were being severely impacted by federal legislation and regulation without feeling like they had a voice to impact the formation of these laws and regulations.

After successfully advocating at the federal level for rheumatologists to receive parity with oncologists for Rituximab infusion reimbursement, the Coalition of State Rheumatology Organizations was officially formed in 2003 to ensure practicing rheumatologists continued to have a voice to lawmakers, first at the federal level and now at both the federal and state level.

Today, CSRO is comprised of nearly every active state rheumatology society in the nation and is at the forefront of advocacy efforts to grant access, affordability, and relief for the rheumatology community. We remain steadfast in our mission to improve access to care for the management of rheumatologic and musculoskeletal diseases.

Whether you discovered us this year or have been with us for the past 20, we appreciate your involvement in this critical advocacy work.

Gary R. Feldman, MD, FACR
President of the Board of Directors

Upcoming Events

Rheumatic Disease Awareness Month: September
Help create awareness about how rheumatology patients suffer because they are not protected from utilization management practices.

Business of Rheumatology: October 4 & December 6
CSRO's virtual seminar series to help support rheumatology practices.

Fellows Conference: March 1-3, 2024
Annual CSRO event curated by rheumatologists for rheumatology fellows to help them as they prepare for their future roles as physicians.

Visit our website to learn more & register to join us!