POLICY UPDATE

Winter 2024

2023-2024 CSRO Board of Directors

IN THIS ISSUE

The President's Message

2023 was a milestone year. It was not only the 20th anniversary of CSRO serving as a voice for the rheumatology community, working to ensure patients have access to the highest quality of care, but also marked my first full year of serving as CSRO's President of the Board of Directors.

Together, we achieved many successes in 2023: a "pause" in down coding of complex drug administration services by MACs through a technical direction letter and subsequent transmittal from CMS, with plans for a long-term "fix" in future rulemaking; progress with CMS regarding the SAD list; and our long-time advocacy for PBM reform has resulted in incredible bipartisan momentum, with over 50 bills being introduced in Congress.

CSRO remains at the forefront of state, federal, and payer policies working to grant access, affordability, and relief for the rheumatology community. This year, CSRO is taking a leading role in addressing the PDAB legislation being introduced around the states, launching an employer education program to help shine a light on PBMs, and actively monitoring and responding to emerging issues like alternative funding programs – learn more about these and other updates inside this newsletter.

Advocacy is the cornerstone of CSRO's mission and we appreciate your involvement in this critical work.

Thank you,

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

Status Update: CSRO Continues to Lead Efforts to Address Drug Administration Challenges

For several years, CSRO has actively engaged with regulators to address key challenges facing rheumatology practices and their patients, specifically "down coding" of complex drug administrative services and inclusion of rheumatologic drugs on the Self-Administered Drug (SAD) Exclusion List, most of which have been implemented by Medicare Administrative Contractors (MACs) using broad discretion provided by the policies set by the Centers for Medicare and Medicaid Services (CMS).

Down Coding

In 2022, CSRO advocacy led CMS to issue a Technical Direction Letter (TDL) (dated August 12, 2022) to its MACs that effectively "paused" the "down coding" of complex drug administration services.

CSRO has repeatedly appealed to CMS to have the substance of that document shared publicly to address compliance concerns that have, understandably, been raised. Finally, in December 2023, CMS published program transmittal #R12397OTN that makes public the substance of the August 12, 2022, TDL language to the MACs.

View CMS Program Transmittal

SAD List

In 2022, shortly after the TDL was issued, CSRO led a multispecialty group of physicians and infusion providers in a discussion on this issue and to raise concerns about the SAD Exclusion List, which they contend is discriminatory and hinders access to therapies for beneficiaries that are unable to administer themselves due to their condition.

When a medication is "usually" (i.e., 50% of the time) administered "by the patient," CMS' current policy manual directs MACs to place the drug on the SAD Exclusion List. When this happens, the provider-administered formulation is excluded from Part B coverage and a beneficiary that may require this formulation would be subject to the full cost medication.

CSRO was a leader in addressing this issue with CMS, noting concerns with CMS' definitions and criteria, which discriminate against Medicare beneficiaries who are unable to self-inject a medication. CMS senior staff recognized these challenges and said it would need to use rulemaking to begin addressing these issues, namely the Medicare Physician Fee Schedule (PFS).

In July 2023, CMS took its first step by including a request for information (RFI) in the CY 2024 PFS, noting the challenges CSRO has repeatedly raised and providing an opportunity for the public to provide feedback on these topics.

CSRO was one of the first to provide comments on the matter. After hearing more from a broad coalition of physicians providing detailed feedback, CMS noted its intent to address both the SAD list and down coding issues through future rulemaking.

This fight is a marathon, not a sprint, and CSRO remains dedicated to leading the charge in finding a solution. Our engagement with key Agency staff continues and we will keep the rheumatology community informed of any proposals for a longer-term "fix."

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**.

Aligned Priorities: Hilighting CSRO's Partnerships

The successes shared by CSRO are only achieved through collaboration across a broad network of coalitions, alliances, and other partnerships. Most notably, CSRO meets bi-monthly with an informal coalition of national rheumatology groups to be sure there is active collaboration on issues affecting the rheumatology community, called the Voice of Rheumatology. Other members include: **Aimed Alliance**, **AWIR**, **ACR**, **Arthritis Foundation**, **LADA**, **NICA**, **NORM**, **RNS**, and **Spondylitis Association of America**.

Also of note are CSRO's activities as part of active state and national coalitions and alliances, working together to address issues of priority to rheumatology:

- **Alliance of Specialty Medicine:** through weekly meetings and annual Fly-In events to Capital Hill, Alliance members collaborate on utilization management reform, drug pricing, reimbursement, and other issues impacting access to specialty medicine. *Details available at www.specialtydocs.org.*
- **All Copays Count Coalition:** working at both the state and federal level, members from across specialties advocate for policy and legislation that limits or eliminates accumulator adjustments, maximizers, and alternative funding programs. *Learn more at www.allcopayscount.org.*
- **Alliance for Transparent and Affordable Prescriptions (ATAP):** advocating for pharmacy benefit manager (PBM) reform by requiring pass-through of price concessions to patients and delinking drug prices from PBM revenue, ATAP was started by CSRO and officially founded in 2018 to bring attention to PBMs. *More information available at www.atapadvocates.com.*
- **Aimed Alliance:** as a not-for-profit collaborator, CSRO partners with other collaborators of the Alliance to further our shared mission to improve patient access to treatment. *Visit www.aimedalliance.org to learn more.*

Specific to CSRO's state advocacy, we work through several established coalitions to advocate for utilization management reform:

- **State Access to Innovative Medicines Coalition (SAIM):** with the Coalition's support, CSRO has introduced and passed step therapy legislation in various states and now works to increase awareness of the protections offered by the laws. SAIM also works to limit out of pocket costs for patients due to accumulators and maximizers. *More information available at www.saimcoalition.org.*
- **Value of Care Coalition:** a new coalition working to ensure prescription drug affordability boards (PDABs) are aware of unintended consequences regarding access to treatment through community-based clinics when upper price limits are set for medication. *Details at www.valueofcarecoalition.org.*
- **Patient Pocket Protector Coalition:** a group working to unify advocates to drive policy change in the states for rebate pass through, as part of PBM reform. *Learn more at www.patientpocketprotector.org.*

CSRO is also active in many state-specific coalitions and groups that work to establish legislation that targets step therapy, prior authorization, and other priority issues. When appropriate, CSRO will convene ad hoc alliances to address immediate issues. Currently, CSRO is leading a multi-specialty drug administration services coalition in meetings with CMS about complex coding administration and the Self Administered Drug (SAD) List.

These collaborations, and many others not listed here, elevate our collective work and help us make the greatest impact for you, the rheumatology community. We thank all of our partners across the country and look forward to making progress in 2024.

Pharmacy Benefit Manager Reform: 2023 Strides

Last year, CSRO shared the exciting developments around reform of the pharmacy benefit manager (PBM) industry. CSRO continues to be on the front-lines of this debate, both in its own right and as a founding member of the Alliance for Transparent and Affordable Prescriptions (ATAP).

In particular, CSRO's Vice President of Advocacy & Government Affairs, Dr. Madelaine Feldman, has become a nationally recognized expert on PBM reform, including as a witness and resource for the U.S. Congress. As an organization, *CSRO is recognized as a trusted expert to provide the clinician's perspective on PBMs and their impact on patient care*.

Congress Addressing PBM Reform

Even in this time of heightened partisanship, there is widespread bipartisan agreement in Washington that it is past time to meaningfully reform the PBM industry. Last year, several committees of jurisdiction took up legislation to do just that, with the most prominent example being the Senate Finance Committee.

The Finance Committee reported out comprehensive PBM reform policies that included CSRO's twin pillars of reform: *delinking drug pricing from PBM income* and *requiring PBMs to pass through price concessions*. The Committee accomplished this across different working sessions throughout the year.

July 26:
The Finance Committee voted to advance a comprehensive PBM reform bill, which included a provision to delink drug prices from PBM compensation in Medicare Part D.

In the days leading up to the markup, *CSRO provided Committee staff with support for that provision, which was noted in the Committee's press materials.* CSRO also asked the Committee to include a provision requiring pass-through of price concessions to patients in the form of lower out-of-pocket costs because, at that time, the bill did not yet include such a provision. Chairman Wyden (D-OR) and Ranking Member Crapo (R-ID) committed to working towards including a pass-through provision in the fall. The legislation was voted out of Committee with overwhelming support.

November 8:
Committee leadership made good on its promise when it considered legislation entitled the *Better Mental Health Care, Lower-Cost Drugs, and Extenders Act*.

The legislation was wide-ranging in scope, but included significant PBM reforms that the Committee had worked on throughout the summer and fall. Notably, the legislation included a limited mandatory pass-through of discounts for certain frequently used drug categories in Part D.

CSRO, other provider and patient groups, and many Senators, would have preferred an unlimited pass-through for all medications covered by the program, but the provision's scope was narrowed down in response to an unfavorable score from the Congressional Budget Office (CBO).

The CBO assumes that a pass-through would increase premiums, which would in turn increase federal government spending. Hence, pass-through provisions always generate a "score" in terms of increased spending. Even in its narrowed form, the Finance Committee's pass-through provision will still provide immediate relief for beneficiaries who rely on several categories of commonly prescribed medications.

From a strategic perspective, creation of a new provision in federal law is the biggest hurdle, whereas expansion of an existing provision tends to be easier. Thus, ensuring that a pass-through is codified into federal law, even if it is narrower than the ideal, provides that opportunity for expansion in the future. In the end, the Committee voted to advance the bill in a unanimous 26-0 vote.

PBM Reform *continued*

At the time of this writing, PBM reform policies are on the short list for inclusion in a package of bipartisan health policies to be attached to a government funding deal in early March. CSRO is in touch with Finance Committee staff and will continue to provide feedback to ensure these remain frontrunners for inclusion.

Federal Trade Commission Investigation

Meanwhile, the Federal Trade Commission (FTC) continues its study of the business practices of six major PBMs and their affiliated entities. As a reminder, that work is the result of a request for information by the FTC on, among other things, the role of PBMs in formulary construction and utilization management. CSRO joined over 24,000 other respondents, the vast majority of which expressed concerns similar to ours. As a result, the FTC announced in 2022 that it would build on that public record and launch an inquiry into six major PBMs.

Fast forward a year and a half, and the Congress is becoming impatient to see the results of the FTC's investigative work. Recently, a group of fourteen Senators led by Senator Grassley (R-IA) and Senator Cantwell (D-WA) wrote to the FTC, highlighting the extensive work of congressional committees on PBM reform and requesting a status update from the Commission.

CSRO is equally eager to see the FTC's findings, and appreciates the FTC taking the time it needs to thoroughly examine what is a very complex and opaque industry. We are also encouraged by the Commission's expansion of the study scope to include the PBM's aggregator entities, which were not named in its original document.

All of *CSRO's policy positions on this topic flow from the core principle that the patient should be centered and prioritized in our drug pricing and access system*. CSRO will carefully analyze any public-facing results the FTC releases and share updates as appropriate.

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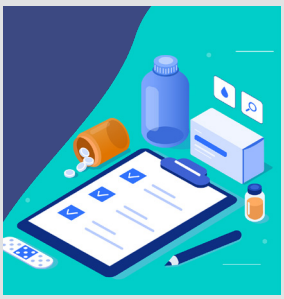
Priority Issue: PDABs



Prescription drug costs continue to be an issue throughout the healthcare system and is an issue top of mind for legislators who are hearing about burdensome costs from their constituents. In response, states have begun to use Prescription Drug Affordability Boards (PDAB) to control the cost of drugs. A PDAB is a board comprised of appointed members that represent stakeholders such as clinicians, pharmacists, insurers, etc., who are empowered to conduct affordability reviews of prescription drugs and set a purchase and reimbursement limit known as an upper payment limit (UPL).

Where Does CSRO Stand

In fulfilling our goal of improving the practice environment for rheumatologists across the country, CSRO believes that provider administered drugs should be excluded from PDAB legislation in order to ensure access to critical rheumatological care remains, uninterrupted. CSRO is also committed to protecting reimbursement for providers where provider administered drugs are included in PDAB legislation and potentially subject to UPLs.

Colorado, Maryland, Minnesota, Oregon, and Washington all have or will have PDABs that allow for the implementation of a UPL. Some states are recognizing the need to protect reimbursement by clarifying that providers may still bill for administration services even if a drug has a UPL applied, but issues related to any drug add-on payments are not being addressed.

CSRO is focused on educating legislators and other stakeholders about the supply chain for provider administered drugs and the access issues that could arise from the implementation of an upper payment limit. Illinois, Michigan, and Virginia are currently considering PDAB legislation, with many more states likely to take up the issue this year, and CSRO is working to ensure that rheumatologists' concerns are being heard throughout the policymaking process.

Visit **www.csro.info/advocacy/our-issues** to learn more about drug affordability boards and CSRO's other priority issues.

Insights for Employers

CSRO's employer education program provides employers with insights into benefit administrator practices and the systems driving the behaviors.

CSRO has a new webpage for organizations and companies to request a presentation to learn more about these hidden realities – check it out.

Alternative Funding Programs: A New Challenge for the New Year

For a long while, insurers and pharmacy benefit managers have waged a war against copay assistance. These efforts manifested in the form of accumulator adjustment and copay maximizer programs. These programs allowed insurers to undermine the purpose of copay assistance while also threatening their sustainability. Recently, there has been a new entrant into this battle – alternative funding programs.

The Problem

These new programs shift their focus from copay assistance designed for insured patients to patient assistance programs and charitable foundations designed for the un-insured or patients in financial need. They also carveout the administration of a plan's specialty drug benefits to a third-party vendor which will subsequently exclude coverage for some or all of the specialty drugs that are supposed to be covered by the plan.

The third-party administering the program will then apply to charitable organizations and patient assistance programs on behalf of the patient acting as though the patient is uninsured. If the patient's application is granted then the manufacturer bears the entire cost of the prescription drug, and the third-party vendor takes a cut of the plan's savings.

These programs very clearly violate the intent of patient assistance programs, and threaten their existence because of an influx of applicants who would not otherwise be eligible for the programs; an undesirable outcome for the patients who truly need the assistance of charitable foundations and patient assistance programs.

However, even the patients who find themselves artificially uninsured in order for their health plan to take advantage of patient assistance programs may end up on the losing end of this deal.

Many pharmaceutical companies have improved screening of applicants so that charitable funds are not taken advantage of in direct response to the proliferation of these programs. As a result, the patient may be left without recourses because of their plan's decision to exclude coverage for their prescription. Some programs even try to force a non-medical switch on the patient if they are not eligible for the patient assistance program for the drug they are presently taking.

CSRO's Response

Following the lead of Tennessee, CSRO plans to introduce legislation in both Louisiana and North Carolina, seeking to push back against the use of these programs. In both of these states, CSRO will maintain a presence in the capitol and work with stakeholders to find members of the legislature who are well-versed in issues related to patient assistance programs, willing to work on the issue, and well-positioned to lead with their colleagues.

These efforts will help ensure that CSRO's legislation is able to hit the ground running once the legislatures begin to take up new business. We will continue to keep the rheumatology community updated as more progress is made.

State Advocacy: 2023 Recap & Look Ahead

Total Legislation Across the United States

STEP THERAPY	PRIOR AUTHORIZATION	ACCUMULATOR PROGRAMS	BIOMARKER TESTING	NON-MEDICAL SWITCHING	WHITE BAGGING	REBATE PASS THROUGH
38	43	19	13	10	4	4

For over 20 years, CSRO has remained dedicated to ensuring access to the highest quality care for the management of rheumatologic diseases by actively advocating at both the state and federal level to aid rheumatologists in protecting their patients and their livelihood.

Our work throughout 2023 helped to *move the needle in the fight to improve access to care*, with 25 states passing priority issue legislation. Notably:

- Ensuring all copays count for patients with the passing of accumulator legislation in four states
- Successfully advocating for the requirement of biomarker testing coverage in a record 13 states
- Cordinating passage of white bagging legislation in two states, North Dakota and Texas – the first states to do so since 2021
  - More than 15 states debated legislation around this issue last year, which helps spur momentum and has already resulted in Colorado and Oregon introducing white bagging bills this year

In looking to the year ahead, CSRO expects significant developments in the areas of drug pricing. The expansion of interest in prescription drug affordability boards will be a significant issue facing providers in 2024 – find more information about this on page XX.

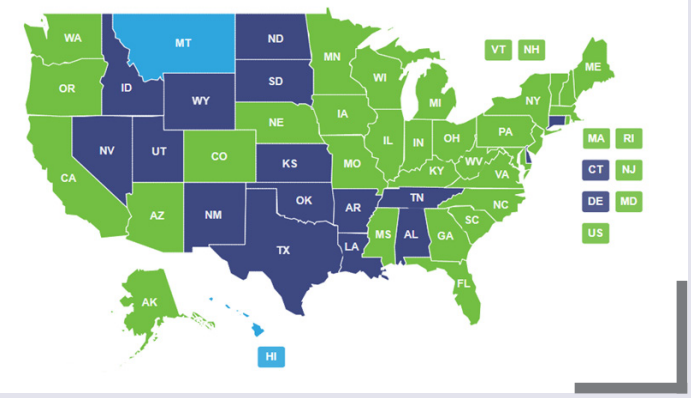
The other major area where CSRO expects to see significant developments is prior authorization. In 2022, Texas passed a first-of-its-kind law to exempt physicians from prior authorization if they met a certain approval rate over the course of a six-month period. While well received, physicians have struggled to garner exemptions under this new legislation.

To help make the concept more effective, and reduce the overall burden of prior authorization more generally, innovative approaches are starting to develop such as: exploring plan-wide reductions in prior authorization requirements rather than individual exemptions, requiring peer to peer consults prior to a denial being issued, prohibitions on retroactive clawback payments for authorized services, and extended minimum duration for an authorization.

Overall, CSRO is optimistic as we look to our advocacy efforts for the year ahead and will work to support our priority issues by continuing to advocate for legislation and regulatory reform.

Want to know about the laws in your state?

Check out CSRO's award-winning map tool!



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That's a Wrap: 20th Anniversary

Cheers to a wonderful 2023! Officially founded in 2003, last year marked two decades of CSRO serving as a voice for the rheumatology community, working to ensure patients have access to the highest quality of care.

Rheumatologists and their practice partners joined us in celebrating the impact we've had on rheumatology and improving access to care at our various events and activities throughout the year, all of which culminated during our Advocacy Conference in Austin, Texas, which featured a special 20th Anniversary Celebration.



Pictured left to right: Cheers to 20 Years CSRO Past Presidents toast; CSRO Board of Directors and Executive Director; CSRO Board Members and special guests.

Thank you to everyone who gathered with us to celebrate CSRO's 20 years of service to the rheumatology community! Advocacy remains the cornerstone of CSRO's mission. Whether you discovered us this last year or have been with us for the past 20, we appreciate your involvement in this critical work.

Upcoming Events

Business of Rheumatology: Returning Spring 2024
Back by popular demand, CSRO's virtual seminar series to help support rheumatology practices is returning for another year.

Virtual Advocacy Day: Summer 2024
Advocate alongside CSRO as we host live conversations with health care leaders from the U.S. Senate and U.S. House of Representatives.

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

Advocacy Conference: September 20-22, 2024
Mark your calendars to join CSRO this fall for our flagship event at a new location in Nashville, Tennessee.

Fellows Conference: February 21-23, 2025
Annual CSRO event curated by rheumatologists for rheumatology fellows to help them transition to their career.

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