



A Message from the President



Gary R. Feldman, MD, FACR
CSRO President

Happy 20th anniversary to CSRO! Officially founded in 2003, this year marks two decades of CSRO serving as a voice for the rheumatology community, working to ensure patients have access to the highest quality of care.

As CSRO's new President, I'm looking forward to the year ahead and invite you to join us in celebrating the impact we've had on rheumatology and improving access to care. Mark your calendars for CSRO's Advocacy Conference and special in-person celebration of our

20th Anniversary in Austin this August 25-27.

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We will also be hosting Regional Town Halls this spring to gather virtually with our rheumatology community and discuss issues affecting you at the local level, plus we are launching a new online seminar series: the Business of Rheumatology – more information on all of CSRO's 2023 events are included on page 8 of this Policy Update.

Advocacy has been the cornerstone of CSRO's mission since our inception, and as we kick off this milestone year, it is important to take a moment to reflect on our successes from 2022: five states signed step-therapy legislation into law and 13 states started discussing the issue of white bagging, just to name a few. Read more in the excerpt on the following page from the latest edition of *Rheum for Action*, CSRO's advocacy column with Rheumatology News.

The environment of health care is changing, and as a specialty, rheumatology must respond to ensure that our patients have access to the highest quality of care possible. Your participation in your state society and CSRO is needed for us to continue this crucial work. Our successes are only possible when we all act together. Whether you discovered us this past year or have been with us for the past 20, we value your involvement.

Thank you for your continued partnership to improve access to care for the management of rheumatologic and musculoskeletal diseases,

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

RHEUM FOR ACTION: Use 2022's advocacy successes and frustrations as a catalyst for the new year

CSRO's Immediate Past President and Vice President of Advocacy & Government Affairs, Dr. Madelaine Feldman, reflects on the successes CSRO saw last year in the following excerpt of the November edition of *Rheum for Action*, CSRO's advocacy column produced in partnership with *Rheumatology News*. To read the full article or view past editions, visit www.csro.info/news.

...Substantive progress continues to be made on access issues in the states. A total of 5 states signed step-therapy legislation into law, 3 states have new copay accumulator program bans, 13 states began to debate the issue of white bagging, and 16 states began to consider the next stage of pharmacy benefit manager (PBM) reform with rebate-pass-through legislation.

At the federal level, the Inflation Reduction Act (IRA; H.R. 5376) was enacted in August and, like all major pieces of legislation, there are pros and cons. On the positive side, the legislation reforms Medicare Part D cost-sharing, including – for the first time – the creation of an annual cap on cost-sharing by beneficiaries. That will especially help patients with high, ongoing prescription drug needs. On the negative side, despite its extensive drug-pricing provisions, the IRA did not include any reform of PBM practices. In fact, Congress has delayed implementation of the so-called “rebate rule” for 10 years. That rule would have essentially ended payments from drug companies to PBMs in exchange for formulary placement by removing safe harbor protection from antikickback law for these payments, allowing patients to benefit from these payments.

Finally, the IRA included extensive provisions applicable to drug manufacturers, including a mechanism for Medicare to set prices directly for medications that have been on the market for a certain number of years but are still without a biosimilar or generic. This will apply fully to selected Part B drugs as of 2028. The key for rheumatologists and our patients in the next few years will be to engage with the Centers for Medicare & Medicaid Services as it implements this provision to ensure that rheumatologists are not underwater financially on the acquisition of medications subject to the new pricing mechanism.

With regard to utilization management reform at the federal level, the Ensuring Seniors' Timely Access to Care Act (H.R. 3173) would reform prior authorization in Medicare Advantage, but after passing in the House on Sept. 14, the bill has slowed down in the Senate. In some part, that may be because of a surprising score from the Congressional Budget Office, which projected that the bill would cost \$16 billion. However, this is not insurmountable: The legislation enjoys broad bipartisan support in the Senate, and its sponsors remain committed to enactment before the end of the year. Additionally, the Safe Step Act (S. 464) would reform step therapy practices in employer-based coverage, but that legislation has not passed either chamber of Congress despite bipartisan support and is unlikely to be enacted before the end of this congressional session.

...PBMs escaped meaningful scrutiny or reform in the IRA, but the Federal Trade Commission took a different approach when it announced earlier in 2022 that it would conduct an investigation into the business practices of several major PBMs. That study is ongoing and, when finished, will likely result in some additional ideas for meaningful legislative reform.

Finally, there's the frustration of the egregious Medicare Physician Fee Schedule that has decreased physicians' reimbursement in a time of accelerated inflation in the cost of running a practice. At the same time, Medicare Advantage plans and everyone else in the government-reimbursed health system are getting at least an inflationary raise. This has created an ire among all physicians that we have not seen in quite a while and which we are leveraging into grassroots outreach.

...The good news is that there is widespread recognition in Congress that a system built on temporary legislative “patches” to avoid deep payment reductions is unsustainable and must be fixed. The Supporting Medicare Providers Act of 2022 (H.R. 8800) that's currently pending in the House to offset the looming 2023 Fee Schedule cuts also includes a Sense of the Congress, or nonbinding resolution, establishing the need for administrative and legislative actions for long-term, meaningful reform of Medicare physician payment, along three principles: ensuring financial stability and predictability, promoting and rewarding value-based care innovation, and safeguarding timely access to high-quality care by advancing health equity and reducing disparities...

Let's celebrate the wins of 2022 and not let the frustrations with the system diminish our passion – that's the hard part! Onward to 2023 as “Rheums for Action!”

CSRO ADVOCACY AT WORK: Reversal of Flawed Medicare Policy on Neuromuscular Ultrasounds

In a win for rheumatologic care, CMS responded favorably to CSRO's and other stakeholders' request to reinstate the professional and technical component (TC and PC, respectively) for neuromuscular ultrasound (i.e., CPT 76881). The change was reflected in newly released Medicare payment files, and a follow-up communication from CMS staff that it was "persuaded to address [the issue] given the implications."

For background, CSRO leadership met with staff at the Centers for Medicare and Medicaid Services (CMS) Center for Medicare (CM) on December 19, 2022, to discuss concerns about CMS removal of the technical (TC) and professional (PC) components for CPT 76881, forcing practices to bill the "global" service. During the meeting, CSRO noted that eliminating the TC and PC would mean that many rheumatology practices would no longer be able to provide this medically necessary service to Medicare beneficiaries because many practices outsource the interpretation and report in order to reduce appointment wait times and expand access to rheumatologic care. Long wait times have been a challenge in rheumatology given workforce and other challenges created by declining reimbursements.

CSRO Takes the Lead: Discussion with CMS on Drug Administration Service Challenges



On December 19, 2022, CSRO led a multispecialty group of physicians and infusion providers in a discussion with CMS' Center for Medicare (CM) and Center for Clinical Standards and Quality (CCSQ) on long-standing challenges with drug administration service payment and policy. Most of the conversation centered on "down coding" of complex drug administration, which the Medicare Administrative Contractors (MACs) had implemented through "local coverage articles" without input from clinicians. As a result of CSRO advocacy, CMS issued Technical Direction Letters (TDLs) which "paused" the down coding temporarily while CMS works toward a long-term solution. The TDLs will not expire until CMS has promulgated rulemaking or program instruction (e.g., updates to its policy manuals) that permanently addresses the issue. 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 these medications warrant use of the chemotherapeutic administration codes.

The multispecialty group also raised concerns about the Self-Administered Drug (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. As rheumatologists

know, medications often have two formulations; one that is administered in a physician's office and reimbursed under Part B, and one that is self-administered by the patient and paid under Part D. However, 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 List, meaning Medicare will no longer pay for the provider-administered formulation under Part B. CSRO described issues with CMS' definitions and criteria, which discriminate against Medicare beneficiaries who are unable to self-inject a medication. For example, CSRO raised concern that CMS uses a weighted average across all indications to determine Part D use, disregarding the fact that certain disease states make it more difficult for the patient to self-inject. CSRO also noted that many patients who utilize a self-injected Part D medication, are not self-administering; instead, they have a relative, friend, or clinical staff in the physician's office, administer the drug. In fact, a survey conducted by Global Healthy Living Foundation (GHLF) revealed that 40% of Medicare patients fall into this category. Given all of these concerns, the groups urged CMS to revise SAD List criteria, as outlined in the Medicare Benefit Policy Manual, and offered ideas to help ensure more beneficiaries are able to access in-office medications.

CMS recognized the challenges with both of these issues and asked to meet with CSRO again in early 2023.

STATE ADVOCACY: CSRO's Impact on Legislation & Overview of 2023

Priority Issues

For 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 2022 has helped to *move the needle in the fight to improve access to care*:

- Delaware, Maine, New York, and Washington successfully advocated for all copays to count for patients with the passing of legislation prohibiting the use of accumulator adjustment programs
 - *A record 16 states now have active accumulator laws*
- Colorado, Kentucky, Massachusetts, Pennsylvania, and Tennessee have helped ensure patients get the right medicine at the right time by reforming the use of step therapy programs
 - *More than 30 states have active step therapy laws*
- Colorado further protected patients by prohibiting non-medical switching
- 16 states started debating the issue of rebate pass through, while 13 states have begun to recognize the need to ban specialty pharmacy mandates

Building on these successes, CSRO is optimistic as we look to our advocacy efforts for the year ahead and will work to support each of the below priority issues by continuing to advocate for legislation and regulatory reform.

Accumulator Adjustment & Maximiser Programs

Maximiser programs alter a patient's regular cost sharing obligations under their insurance plan in an attempt to extract the full value of copay assistance the manufacturers have made available. The use of these programs continue to increase and existing accumulator program state laws do not fully address the implementation of maximiser programs, and CSRO hopes that states considering legislation will address both programs.

Also newly emerging are "alternative funding" schemes which removes a patient's specialty drugs from coverage under their health plan. The third parties administering these programs then attempt to pay for a patient's drugs by applying for patient and other assistance programs on their behalf. CSRO plans to raise awareness about both programs and pursue policies that could potentially restrict their use.

Biomarker Testing Coverage

Biomarker testing is a subject of increasing interest in the rheumatology community and various states have begun to consider legislation requiring its coverage. CSRO has identified requiring biomarker testing coverage as a new priority for 2023, as it better enables rheumatologists to diagnose conditions, and we will work towards making these new technologies accessible to more patients and practices.

Non-medical Switching

CSRO plans to continue to support legislation to protect stable patients from the practice of non-medical switching and anticipates new legislation will focus on "grandfathering" coverage of a stable patient's prescription drugs. A bill would do this by requiring plans to continue covering a patient's drug regardless of whether the plan has removed the drug from their formulary between plan years or at another time.

While no state has yet to pass legislation like this, a number have recognized the impact non-medical switching has on patients and enacted laws to prohibit switching during the course of a plan year.

Prior Authorization

In 2022, Texas passed a first-of-its-kind law to provide exemptions from prior authorization if a certain approval threshold is met. This “Gold Carding” law was a novel approach to tackling the administrative burden issue and CSRO anticipates this type of legislation will be popular among state legislatures during the 2023 session – *read more about Gold Carding on page 6 of this Policy Update.*

Specialty Pharmacy Mandates/White Bagging

The increasing prevalence of insurance mandates to white bag drugs instead of buy and bill sparked three main types of legislation across the states in 2022. First, legislation to prohibit mandates to white bag and to prohibit insurers from using practice reimbursement or a patient’s out of pocket expenses to effectuate a mandate. Second, legislation to prohibit requirements for patients to use a specialty pharmacy or insurers penalizing patients for not using a specialty pharmacy. Third, legislation that established safety standards when white bagging is used. CSRO anticipates this legislation will continue to evolve and grow in the year ahead.

Step Therapy/Fail First

Reforming the use of step therapy has been a priority of CSRO for many years. CSRO has helped lead efforts across the states, and will continue to do so through its membership in the State Access to Innovative Medicines Coalition (SAIM). This year, there will be a focus on improving existing laws to increase effectiveness and addressing reporting requirements for insurers to help compliance monitoring.

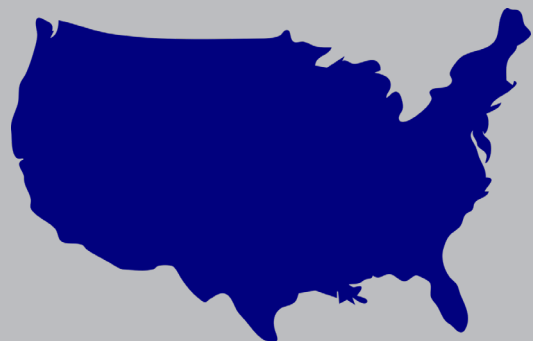
Rebate Pass Through & Pharmacy Benefit Managers (PBMs)

Last year, CSRO turned its attention to a new type of pharmacy benefit manager legislation: rebate pass through. The goal of rebate pass through legislation is to require PBMs to share their rebates directly with patients at the point of sale in an effort to reduce a patient’s out-of-pocket costs. Policies like this could go a long way in reducing the financial burden that many of our patients face.

**Want to know the laws
in your state?**

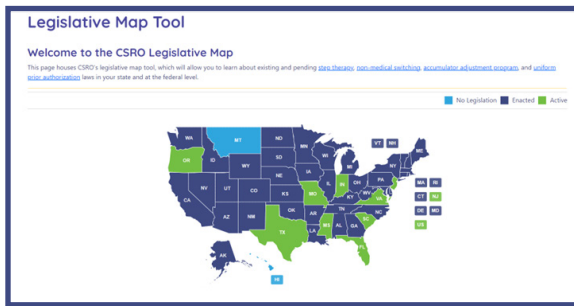
Visit the CSRO legislative map tool
at www.csro.info/map to find out.

Questions? Email info@csro.info.



How You Can Help Impact Legislation

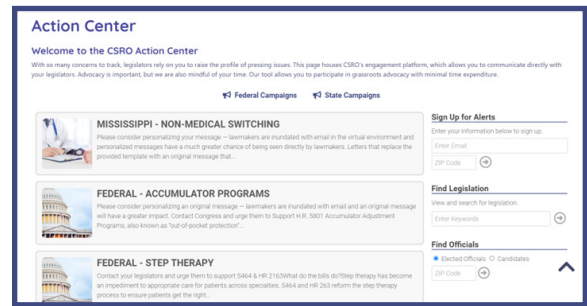
Legislative Map Tool www.csro.info/map



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

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

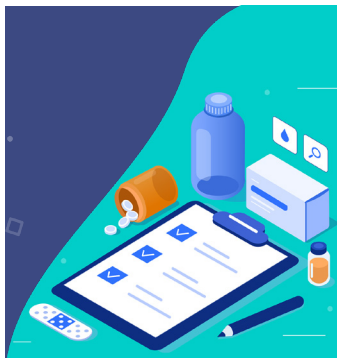
Action Center www.csro.info/advocacy/action-center



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

Visit www.csro.info/advocacy/action-center 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!

Gold Carding: A Path Forward on Prior Authorization?



In 2022, Texas passed new legislation which provided a novel approach to addressing administrative burden issues related to prior authorization. Under this law, if a physician had a certain percentage of prior authorizations approved for a service, they would be exempted from prior authorization requirements for that service moving forward.

This "gold card" approach to negating administrative burden is the first state law that promised to actually reduce the amount of paperwork generated by the prior authorization process. CSRO is intrigued by this new policy and what it could mean for the development of additional methods to reducing administrative burden.

The novelty of this law means there are significant unknowns about how well the gold card approach will work in practice. Specifically, if this law will achieve significant gains in the area of prescription drugs.

This law states that an exemption will be issued on a drug-by-drug and payer-by-payer basis. 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, it may be the case that rheumatologists will have great difficulty qualifying for exemptions for certain drugs.

Finally, CSRO is unclear on how an exemption granted under the law interacts with other utilization management tools, such as step therapy, that apply to prescription drugs. It may be the case that a rheumatologist qualifies for an exemption from prior authorization for a certain drug under this new law, but that does not necessarily mean they are exempt from the plan's requirement for the patient to try prescription drugs in a certain sequence.

These unknowns may prove to reduce the effectiveness of this gold card approach, however, CSRO remains excited that innovation is occurring in this policy space and is hopeful that it will make room for additional ideas as we move forward.

Finally, Reforms to Utilization Management: And More to Come

For years, CSRO has sounded the alarm bell on insurers' increasingly aggressive use of utilization management (UM), such as prior authorization and step therapy. Patients with ongoing high-cost drug needs – such as rheumatoid arthritis (RA) patients – suffer most from these protocols, but UM has become pervasive and disruptive in other specialties as well. In 2022, we began to reap the fruits of our labor in the form of significant movement on prior authorization reform, and we expect more action on this topic in 2023.

In the last Congress, legislation to reform prior authorization in Medicare Advantage (MA) passed the House of Representatives in September, but stalled in the Senate after receiving an unfavorable \$16 billion “score” from the Congressional Budget Office (CBO). However, since then, the Centers for Medicare and Medicaid Services (CMS) has proposed reforms to prior authorization that may significantly reduce that \$16B CBO score, which puts the bill in a great position to make it across the finish line in the new Congress. The overwhelming bipartisan support – over half of all U.S. Senators cosponsored the legislation – is a good indicator that Members of Congress are eager to work across the aisle to legislate on this topic.

As for the aforementioned reforms proposed by CMS, these were contained in several rules and consisted of both procedural improvements and substantive changes to UM protocols. For example, via the annual MA-PD rulemaking cycle, CMS has proposed reforms to minimize care disruptions, including a requirement for MA plans to provide transition periods for new enrollees' ongoing courses of treatment, during which no new or additional prior authorizations can be required. Additionally, CMS proposed a requirement that will minimize plans' ability to demand multiple authorizations for the same treatment during the course of that treatment. Although insurers will likely oppose these proposals, CMS is certain to receive a large volume of supportive comments as well, which will hopefully result in the finalization of these policies.

It is worth noting that the last Congress considered other bills on the topic of utilization management as well. Some of these addressed different kinds of UM protocols, such as step therapy: the Safe Step Act would require employer-sponsored plans to establish a clear, convenient, and readily available process to request step therapy exceptions. The legislation would also codify exceptions to step therapy in five specific circumstances, including for stable patients and in situations where the treatment required by the step therapy protocol is contraindicated or expected to be ineffective for the patient. That legislation did not advance as far as the *Improving Seniors' Timely Access to Care Act* described above, but it also enjoyed significant bipartisan support in both chambers and is likely to be reintroduced this year.

Other bills also tackled prior authorization, but in unusual and creative ways: for example, Senators Hassan (D-NH) and Marshall (R-KS) introduced the Medicare & You Handbook Improvement Act of 2022, which would require notification to beneficiaries of the kinds of utilization management used by MA plans, including information on how a beneficiary can find out whether and how such protocols apply under a MA or standalone prescription drug plan they're considering enrolling in. The bill would also require clearer communication to beneficiaries who are considering enrolling in MA that, if they want to switch back to fee-for-service Medicare in the future, they may not be able to purchase a Medigap plan, which is an issue that often confronts rheumatology patients. A similar bill was introduced in the House as well.

CSRO will continue to engage with our champions on this topic to seek reform to utilization management practices, through pushing for substantive reforms in legislation, engaging with the agency for regulatory changes, and exploring targeted, creative improvements. In all of our engagement on this topic, our overarching goal is to bring relief to rheumatology patients and ensure that rheumatologists can provide excellent clinical care without undue interference from insurers.

UPDATE: CMS Posts CY 2023 Medicare PFS Conversion Factor



CMS recently posted updated Medicare payment files associated with the CY 2023 Medicare PFS, which includes the revised conversion factor of \$33.8872 reflecting the statutory adjustment outlined in the recently enacted Omnibus legislation. As a reminder, the CY 2022 conversion factor was \$34.6062, thus physicians will continue to see a reduction of approximately 2 percent. Adding additional pressure is CMS' phase-in of the clinical labor pricing update, currently in year two, which has negatively impacted the Medicare payments for drug administration services.



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Introducing: Business of Rheumatology Seminars



New this year, CSRO is launching a Business of Rheumatology series to help support you and your practice. The first virtual seminar will launch this spring and focus on the realities of in-office dispensing, and future topics to include expanding your infusion suite and partnering with advance practice professionals to address the workforce shortage.

Be the first to know when details are released by joining our email list at www.csro.info.

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Cheers to 2023! A Milestone Year for CSRO

Happy 20th anniversary to CSRO! Officially founded in 2003, this year marks two decades of CSRO serving as a voice for the rheumatology community, working to ensure patients have access to the highest quality of care.

Throughout the year, we invite you to join us in celebrating the impact we've had on rheumatology and improving access to care at our various events.

Fellows Conference: March 10-11

An annual CSRO event that is curated by rheumatologists specifically for rheumatology fellows to help them as they prepare for their future roles as physicians.

Regional Town Halls: Monday evenings in April & May

Join other members of the rheumatology community from your area in hearing policy and advocacy updates from CSRO specific to your state and network directly about issues impacting you and your practice.

Advocacy Conference: August 25-27

Mark your calendar to be with us, in-person, in Austin, Texas for CSRO's flagship Advocacy Conference and special anniversary event!

Additional details and registration for all of CSRO's upcoming events can be found on our website at www.csro.info/conferences/upcoming-events.

Other ways to celebrate with CSRO:

- **Visit us at your state society meeting:** CSRO attends various state rheumatology society meetings to network, share information, and present on advocacy – check out a list of upcoming meetings on our website at www.csro.info/conferences/state-conferences.
- **Share your stories with us:** If you have memories of CSRO's founding, we'd love to hear from you – email info@csro.info to share your stories or photos.
- **Support CSRO's ongoing advocacy work:** CSRO is a 501c3 nonprofit organization dedicated to ensuring access to the highest quality care for the management of rheumatologic diseases. Help make a difference by making a tax-deductible donation in honor of our 20 years of advocacy today at www.csro.info/donate.

Celebrating 20 years of serving as a voice for rheumatology.