

POLICY UPDATE

Winter 2022



IN THIS ISSUE

President's Messagepage 1
A Look Back on 2021page 2
Rheum for Actionpage 3
Looking Ahead to 2022page 4
MACs New Coverage Consideration page 6
Medicare Payment Cutspage 6
Annual Hill Daypage 6
CSRO Resourcespage 7
Drug Pricing Reformpage 7
Advocacy Grantpage 7
Upcoming Eventspage 8

A Message from the President



Madelaine Feldman, MD CSRO President

Through strong partnerships and vocal advocacy, CSRO actively works toward our mission to advocate for excellence in the field of rheumatology, ensuring our patients have access to the highest quality of care.

2021 saw many successes for the rheumatology community: seven states signed accumulator program bans into law; five states reformed the use of step therapy protocols; Texas passed an innovative "gold carding" law to reduce the burden of prior authorization; and West Virginia passed a rebate

pass-through law to directly assist patients with high out-of-pocket costs – the first-of-its-kind in the nation.

It is our collective efforts that makes these wins possible, and we are committed to building relationships to facilitate more wins for our community. In fact, at CSRO's strategic planning retreat in January, our focus on partnerships joined advocacy and communications as our three main pillars in the coming years.

As we move forward in 2022, we have new opportunities to improve access to care for rheumatology patients. CSRO is working to address white bagging, step therapy requirements, PBM transparency, rebate passthrough, accumulator programs, and more at the state and federal level, in both the legislative and regulatory spheres. We continue to meet with CMS about "down-coding" and SAD list issues and are actively working to ensure physician input is received prior to CMS decisions, returning to the original intention of CAC meetings.

To join us, sign up for our Action Alerts by visiting our website. You'll receive state-specific notifications of pending and enacted legislation that affects rheumatology practices. For more in-depth discussions on policy and advocacy, be sure to mark your calendars for the State Society Advocacy Conference on September 9 and 10 in Chicago, IL.

For our state members, apply for an advocacy grant to hold your own Advocacy Day with your state legislature, and save the date for our Federal Advocacy Day on June 23. Read more about both inside!

However you connect with CSRO this year, know that your voice makes a difference to improve the lives of all our patients.

Madelaine A Feldman

Madelaine A. Feldman, MD, FACR President, CSRO

2021 - A Look Back at Progress Made in the States



With the many ways we continually work to ensure access and affordability of treatments for our patients, or to improve the practice environment for rheumatologists, it leaves little time to reflect on where we have been and the progress we have made to date. 2021 saw many wins for the rheumatology community, accomplishments on which we are building as we move into the 2022 state legislative sessions.

CSRO has worked to support each of the below areas by advocating for legislation and regulatory reform through a variety of means, including di-

rectly meeting with lawmakers, providing on-the-ground resources and testifying in state capitols, supporting negotiations on legislation, sending letters of support, and helping to generate grassroots support from the rheumatology community.

We are proud to work alongside likeminded stakeholders and rheumatologists across the country willing to lend their support on these issues. Rheumatologists sent 364 messages to their elected representatives on state legislative issues over the course of the past year using CSRO's digital engagement tools, plus supported our efforts with individual meetings, testimony, and other forms of advocacy – **thank you** for the many ways you have taken action this year.

Accumulator Adjustment Programs

Accumulator adjustment programs threaten certain patients' ability to afford their medications, and the patient and provider advocacy community responded quickly to their development with efforts to curtail their use. Entering 2021, five states had enacted legislation to hamper plans' ability to use these programs. By the end of 2021, Arkansas, Connecticut, Kentucky, Louisiana, North Carolina, Oklahoma, and Tennessee had joined their ranks, bringing the total number of states with legislation on the books to twelve. In all, over 20 states pursued legislation in 2021, many of which will continue to pursue reforms on the issue in 2022.

Non-Medical Switching

Non-medical switching continues to be a tough issue for advocates to tackle at the state level within the current drug pricing environment, but an encouraging number of legislatures continued to examine it. Bills were filed in a total of 11 states this year, and legislation was eventually signed into law in New York. Signature of the law in New York caps an effort that spanned a number of years, which suggests that continued efforts on the part of patient and provider advocacy groups can eventually overcome some of the barriers and other obstacles currently being experienced in state legislatures. The issue remains an important one with increasing use of formulary exclusions as a utilization management tactic by payers.

Pharmacy Benefit Managers

States have come a long way in taking action to regulate the activities of pharmacy benefit managers since CSRO began raising awareness about their practices. To date, much of that legislation has focused on creating infrastructure to regulate PBMs and requiring reporting of rebate data. States continued to pursue legis-

lation in this vein during the 2021 sessions. However, based on what the rebate reporting data has revealed in some states, West Virginia took the next logical step of requiring that PBMs pass rebates through directly to the patients who generate them by reducing patients' cost sharing obligations. HB 2263 is first-of-its-kind legislation that serves to resolve the issue of patients paying coinsurance based on a percentage of the list price rather than off of the substantially discounted net-price. CSRO is encouraging other states to follow West Virginia's lead in 2022.

Prior Authorization

States continued to pursue reforms to the use of prior authorization, with a main focus on the use of standard forms, common response timeframes, and electronic submission. Of particular note, however, was the enactment of HB 3459 in Texas. The legislation implements innovative reforms to the use of prior authorization that CSRO is hopeful will put a meaningful dent in the out-of-control administrative burden that prior authorization has become. The new law takes the novel step of exempting providers from prior authorization requirements for services and prescription drugs if the provider has a 90% or greater approval threshold. CSRO is exploring other states that could follow Texas' example in implementing "gold carding" legislation.

Step Therapy Reform

In 2021, CSRO was proud to directly lead efforts to reform the use of step therapy protocols in both Arizona and Arkansas. CSRO developed large coalitions of patient and provider advocacy organizations in each state, and organized both in support of step therapy reform legislation. CSRO's efforts in these states were an example of our organization's expanded commitment during the past few years to directly lead state legislative efforts.

CSRO is pleased to report that the legislation it spearheaded in both of these states was ultimately signed into law. Indeed, the law in both of these states now represent some of the strongest laws in the country. California and Nebraska joined the aforementioned states with bills being signed into law in 2021. More than half the states across the country have implemented some form of step therapy law, and CSRO is optimistic that the strong momentum in 2021 will carry over into the future.

White Bagging

The past few years has seen the increasing use of mandates by payers for offices to replace the buy and bill acquisition model with a white bagging acquisition model. CSRO has fielded concerns from many of its members regarding the increasing use of this tactic by payers.

As CSRO was considering how to address the issue moving into the 2022 state legislative sessions, Louisiana passed a first-of-its-kind law to prohibit payers from requiring the use of white bagging in dispensing practices. Passage of the law has spurred activity to address white bagging in states across the country, and CSRO is working to ensure that non-dispensing practices are covered under these proposed laws.



Hear more about these and other issues in CSRO's advocacy column *Rheum for Action*, produced in partnership with Rheumatology News - read the latest editions at csro.info/news.

A Look Ahead for 2022 - CSRO's Priorities



Building on the great success for the rheumatology community's legislative and regulatory efforts in 2021, CSRO is optimistic as we look to the year ahead. Following the disruption of the state legislative sessions in 2020 due to the onset of the pandemic, the patient and provider advocacy community adapted successfully to the new operating environment in 2021, and much of the arrested progress of 2020 was unlocked. Even as we enter another pandemic-stricken year, CSRO anticipates that it will be another year where successes can be achieved.

Over the past few years CSRO has begun to contribute direct leadership to the introduction of legislation important to our patients and community, and CSRO will continue and expand this leadership on state advocacy initiatives. As such, CSRO's priorities will have a large degree of continuity with its priorities in past

years. The emergence of new issues and policy options in the states allow for some new areas of focus, as well

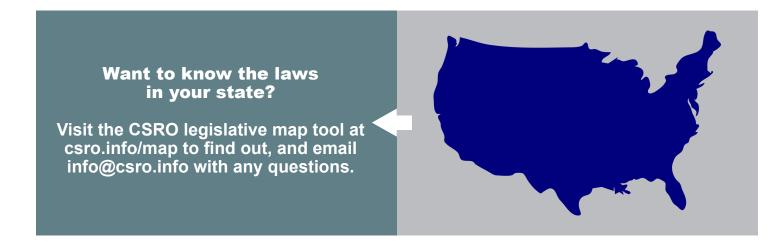
Utilization Management Reform

Reforming overly stringent utilization management tools that prevent our patients from getting the right medicine at the right time, introduce untenable administrative burden for physicians, and threaten our patients' ability to adhere to medications will continue to be a top priority for CSRO. These issues include:

- Accumulator adjustment programs
- Non-medical switching
- Prior authorization
- Step-therapy

In particular, CSRO will continue to proactively lead on step therapy legislation in the states as a member of the State Access to Innovative Medicines Coalition, and on accumulator legislation as a member of the All-Copays Count Coalition.

Most recently, CSRO contributed its resources and leadership to step therapy reform efforts in Arizona and Arkansas. While CSRO intends to continue to proactively lead on similar legislation in 2022, working on awareness and compliance with existing laws is an equally important issue on CSRO's 2022 agenda. CSRO will continue to develop educational materials to assist practices in states with laws already on the books.



White Bagging



CSRO President Madelaine Feldman, MD, FACR and Wisconsin practice manager Nilsa Cruz join fellow advocates in Wisconsin to support SB753 be covered by future laws.

The buy and bill acquisition model has come under threat from payer mandates to use the white bagging acquisition model. On the back of a first-of-its-kind law in Louisiana that sought to prohibit payers from mandating the use of white bagging, CSRO will proactively engage policymakers on this issue in the states during the 2022 legislative sessions.

Although the Louisiana law does not cover practices that do not dispense medications from an internal pharmacy, CSRO is hopeful that its engagement will ensure that private practitioners who operate such practices will be covered by future laws.

Legislation to curtail the use of white bagging has already been filed in Florida, Ohio, and Wisconsin. CSRO has been highly involved in supporting the legislation in Wisconsin, our home state, and helped to ensure that non-dispensing rheumatology practices were covered by the proposed protections. In addition, CSRO plans to directly lead legislation to prohibit payers from mandating use of white bagging in the state of Illinois consistent with its leadership on state legislation over the past few sessions. Additional states are sure to see legislation on this topic in 2022, as more practices across the United States encounter issues with white bagging.



CSRO President Madelaine Feldman, MD, FACR testifies alongside Nilsa Cruz in support of Wisconsin's SB753 white bagging legislation

Pharmacy Benefit Managers

Increasing awareness of the role that pharmacy benefit managers play in our drug supply chain, their effects on drug prices, and impact on ability to access therapies will continue to be a priority for CSRO in 2022. Many states have begun to collect data from PBMs regarding the rebates they receive, and CSRO will continue to support states' efforts to improve transparency around PBM practices.

Off the heels of a new law in West Virginia, CSRO will also be turning its attention to a new type of pharmacy benefit manager legislation: rebate pass through. The new policy in West Virginia requires PBMs to reduce patient cost-sharing amounts consistent with 100% of the rebate dollars they receive from a manufacturer. Such policies could go a long way towards reducing the financial burden that many of our patients face. CSRO expects that numerous states will follow West Virginia's example and take up the policy during the 2022 session, and CSRO also intends to personally pursue legislation in this issue in 2022.

Stay in the know!

Get updates about all the above priority issues directly to your inbox by joining our email list.

Sign up now at csro.info.

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

5

MACs Consider Coverage for Predictive Testing Tools

On December 7, 2021, a group of Medicare Administrative Contractors (MACs) convened a contractor advisory committee (CAC) meeting to "provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing [a local coverage determination] and promote communications between the MACs and the healthcare community" on a molecular diagnostics (MolDx) policy for "Predictive Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis."

During the meeting, rheumatologists tapped as subject matter experts were asked to consider relevant clinical literature and answer key questions to assist the MACs with developing its policy. The discussion was facilitated by Contractor Medical Directors (CMDs) for the MolDx program, which is run by Palmetto GBA. As follow up, CSRO was asked to share our perspective on these tools - view the comments at csro.info/advocacy/correspondence. Given the potential utility here, CSRO will keep states apprised of any new developments.

Virtual Advocacy: CSRO Annual Hill Day



Last year, CSRO leadership and our State Society members assembled virtually to voice their policy concerns with congressional leaders on Capitol Hill. While CSRO has met with federal lawmakers many times over the years, this event was the first time the meetings had been designated as a formal Hill Day.

We plan to host a **2022 Virtual Hill Day on June 23** with various Congressional representatives yet to be announced, and *we hope you'll save the date!* Our member societies will again be invited to join us throughout the day, should their state lawmakers be in attendance - stay tuned for more information.

Congress Mitigates Steep Cuts in Medicare Payments to Physicians



On Friday, December 10, 2021, President Biden signed into law the *Protecting Medicare and American Farmers from Sequester Cuts Act* (S. 610), which makes important changes to Medicare payments and other policies of interest to rheumatology practices, as outlined below:

- Provides a one-year increase of 3% to the Medicare Physician Fee Schedule conversion factor.
- Delays the 2% Medicare sequester for three months (January 1- March 31, 2022), followed by a reduction of the Medicare sequester to 1% for next three months (April 1-June 30, 2022).
- Delays the 4% "Pay-As-You-Go" (PAYGO) sequester until CY 2023.

Following enactment, the Centers for Medicare and Medicaid Services (CMS) posted the revised CY 2022 conversion factor of **\$34.6062**.

Absent Congressional action, rheumatologists would have faced a steep reduction in their Medicare payments, greater than 9% depending on their mix of services, at the start of the year. However, even with this reprieve, rheumatology practices took a hit of ~0.8% beginning January 1, 2022. And, as these provisions are temporary, CSRO will be working with lawmakers throughout the year on a long-term solution to the Medicare physician payment system, to include advocating for the inclusion of a inflation index to account for the rise in practice costs.

CSRO is a 501c3 nonprofit organization dedicated to ensuring access to the highest quality care for the management of rheumatologic diseases.

Donate today at csro.info/donate.

CSRO Resources

LEGISLATIVE MAP TOOL

Our interactive legislative map tool 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

The Action Center allows you to communicate directly with your state legislators about policy.

See if your state has any issues at csro.info/advocacy/action-center.
You can then read more about the issue and voice your support by sending a template message to lawmakers and make an impact on your state legislation!

POLICY CORRESPONDENCE ARCHIVE

Policy letters CSRO has submitted to payers, state, and federal governments are on our website for easy access by members and the broader community.

Find these, along with templates that can be used for contacting payers, at csro.info/advocacy/correspondence

Find all of these resources and more at csro.info.

Drug Pricing Reform Remains a Key Focus for Policymakers

On December 27, 2021, the Biden Administration completed its official withdrawal of the Most Favored Nation (MFN) Model, which would have tied Medicare Part B drug reimbursement to the lowest of prices in a group of comparable countries. The MFN Model had been proposed in the final weeks of the Trump Administration and suffered from serious procedural flaws, which led a court to issue an injunction against its implementation in a lawsuit joined by CSRO. That injunction provided the incoming Administration with time to fully reassess the Model, a process that ultimately led to its withdrawal over the holidays.

While the MFN Model is now officially withdrawn, the concept underlying it is not. There has been longstanding, bipartisan interest in Part B drug payment reform, including in tying Part B payments for medication to the prices paid in other countries. For example, the *Build Back Better* legislation (H.R.5376) as introduced included an international reference pricing mechanism for high expenditure drugs in Parts B and D. That evolved throughout the legislative process so that the version passed by the House on November 19, 2021 still included a government price-setting mechanism, but one that was narrower in its applicability and tied to a domestic reference point. At this point, the fate of the legislation — including the drug pricing provisions — in the Senate is unknown. If *Build Back Better* does not advance, Congress may consider the drug pricing provisions on their own or as part of a different vehicle.

Starting with the very first Part B drug model back in 2016 and through the latest iteration of *Build Back Better*, CSRO has focused its education and advocacy on the potential impacts of drastic Part B changes to buyand-bill providers and the patients we serve. Any policy that jeopardizes the stability of rheumatology practices would negatively impact patient access to medication administration in the physician's office, which is by far the most cost-effective setting. Additionally, CSRO has continued to call for reforms to the pharmacy benefit manager (PBM) industry, which is a key driver of the pricing distortions in today's pharmaceutical market.

A Member Focus: CSRO Advocacy Grant

CSRO offers an Advocacy Grant to our member societies to assist with advocacy efforts at the state level. Funding may be used for activities such as a sponsored advocacy day at the state capitol; advocacy training for member rheumatologists; or webinar development to educate on specific issues.

We are pleased to announce our most recent recipient is the **Michigan Rheumatism Society -** congratulations!

Interested in learning more or applying? Member societies may visit csro.info/resources/advocacy-grant or email us at info@csro.info.



555 E. Wells Street, Suite 1100 Milwaukee, WI 53202

> Phone: 414.918.9825 Email: info@csro.info

> > csro.info



BOARD OF DIRECTORS

President

Madelaine A. Feldman, MD, FACR

Vice President

Gary R. Feldman, MD

Secretary

EVENTS

JPCOMING

Michael S. Brooks, MD, FACP, FACR

Treasurer

Michael Saitta, MD, MBA

Directors

Leyka M. Barbosa, MD, FACR
Kostas Botsoglou, MD
Mark Box, MD
Aaron Broadwell, MD
Adrienne M. Burford Foggs, MD
Amish J. Dave, MD, MPH
Sarah Doaty, MD
Harry Gewanter, MD, FAAP, MACR
Adrienne R. Hollander, MD
Firas Kassab, MD, FACR
Robert W. Levin, MD
Amar Majjhoo, MD
Gregory W. Niemer, MD
Joshua Stolow, MD

Fellow-at-Large Mehrin Jawaid, DO

EXECUTIVE OFFICE

Executive DirectorAnn Marie Moss

Administrative & Meetings Manager Anna Christensen

FELLOWS CONFERENCE: March 19

A unique professional development opportunity designed specifically for rheumatology fellows to provide insight on practical, real-world issues not taught in academic training, sharing skills to help them transition successfully into their future roles as practicing rheumatologists, academic researchers, or industry partners.

Exclusive to Rheumatology Fellows: CSRO offers a stipend to cover coach airfare, travel, and lodging for this event.

Learn more and register at csro.info/fellows/fellows-conference.

STATE SOCIETY ADVOCACY CONFERENCE: September 9-10

Annually, CSRO hosts our State Society Advocacy Conference to bring like-minded rheumatologists and advocates together to strategize about state advocacy and learn from nationally-recognized experts.

Check out csro.info/conferences/upcoming-conferences/ssac for more details.

Don't forget! CSRO provides our state society members with a stipend to pay for transportation and lodging expenses for two representatives to attend this event. Contact your state society directly if you are interested in being considered as a recipient.

SAVE THE DATE! 2023 FELLOWS CONFERENCE: March 11

Return to San Francisco for our 17th Annual Fellows Conference!

You can find all of CSRO's event dates by visiting our Upcoming Events page at csro.info/conferences/upcoming-events.

Tell us about your meetings!

CSRO has a listing of state society meetings on our website, csro.info/conferences/state-conferences.

Email your known meeting dates to info@csro.info – we will add them to our listing and this helps us plan for future CSRO events.