

CSRO Update

CSRO

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

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The background of the slide features several concentric, curved lines in shades of gray, some solid and some dashed, creating a sense of motion and depth. These lines are primarily located in the upper and lower portions of the slide, framing the central content.

CSRO

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Presentation Overview

- CSRO Overview
- Resources for You
- Federal Activity
- State Activity
- Michigan Laws & Legislation of Interest
- Questions?

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COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Who We Are

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of over 30 state and regional professional rheumatology societies, representing 36 states. CSRO was formed by physicians to ensure excellence and access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease.



Our Issues

Utilization Management Reform

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

PBM Reform

- Transparency
- Rebate pass through
- Federal drug pricing initiatives

White Bagging, Brown Bagging, Home Infusion

- Prohibit payer mandates

Federal Issues

- Reimbursement
- Performance metrics
- Part B and Part D reforms

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COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Membership in Other Coalitions

- **All Copays Count Coalition**
 - State & Federal working groups
- **Alliance for Specialty Medicine**
 - Steering Committee Member
- **Alliance for Transparent and Affordable Prescriptions**
 - Executive Committee Member
- **Coalition for PBM Reform**
- **Cognitive Care Alliance**
- **Get the Medications Right Institute**
- **Keep My Rx**
- **Let My Doctor Decide**
 - Campaign Steering Committee
- **State Access to Innovative Medicines Coalition (SAIM)**
 - Chair

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Resources for You

Legislative Map Tool

Welcome to the CSRO Legislative Map

This page houses CSRO's legislative map tool, which will allow you to learn about existing and pending [step therapy](#), [non-medical switching](#), [accumulator adjustment program](#), and [uniform prior authorization](#) laws in your state and at the federal level.

Using the Map

1. SELECT YOUR STATE

For Federal issues click the "DC" icon.

2. SELECT YOUR ISSUE

See what utilization management reform laws are on the books in your state, what their provisions are, how they apply, and what issues are pending in the state legislature.

3. NO LEGISLATION?

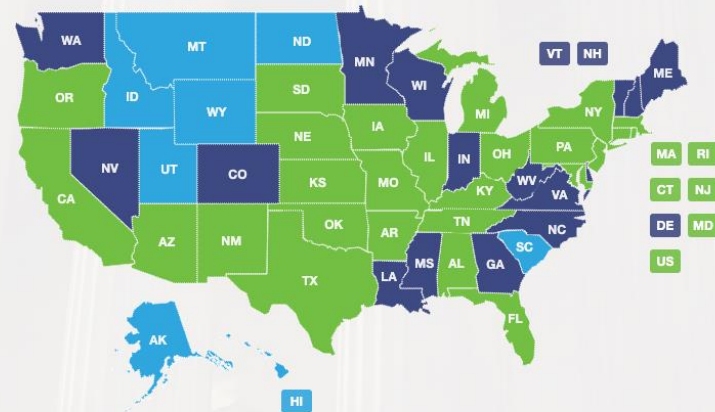
[Find out how you can get involved](#), and what resources CSRO offers to help you change that.

4. COMMUNICATE WITH US!

We want to hear from you. [Let us know](#) what can be improved, what questions you have, and what issues you would like to see detailed on the map.

How to Stay
Up to Date

■ No Legislation ■ Enacted ■ Active



State Society Advocacy Conference

SSAC

Most Recent Meeting: Saturday, September
11, 2021.

Session Topics:

- Federal Issues Update
- Hide and Seek With Rebates – What Next for Rutledge?
- Cross-specialty Collaboration: Oncology and Rheumatology Working Together for Patient Access to Care
- Advocacy at the State Level – A Panel Discussion
- KEYNOTE: Looking Ahead – A Forecast for Rheumatologists

Recordings available in the near future via the CSRO website. Subscribe to the CSRO mailing list for updates on our future meetings!

Other Resources

- **Fellows Conference**
- **Bi-weekly advocacy update**
- **Member organization advocacy grant**
- **Newly formed insurance committee**

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Federal Activity

Drug Pricing and Utilization Management



Federal Drug Pricing

What's next?

Procedure is just
as important as
substance!

- **House: Democrats' H.R. 3 may be included in the budget reconciliation bill**
 - Last Congress, H.R.3 passed the House, but Democrats' vote margin is narrower now
- **Senate: Finance Committee chairman Wyden (D-OR) is assembling his own drug pricing reform options for inclusion -- unclear whether H.R.3 would garner all 50 Dem votes**
- **Ultimately, the procedural limitations of budget reconciliation may determine what can be enacted:**
 - Provision must be budgetary, first and foremost, rather than policy-driven with an incidental budgetary impact

H.R. 3: The Basics

- Health and Human Services Secretary would identify 250 high-spend drugs every year
- Of these 250, HHS selects 25 for negotiation in 2025 and at least 50 in subsequent years
- “Negotiations” between HHS and the drug company would be subject to a ceiling (“maximum fair price”), set at 120% of the average price paid in six other countries
- Also establishes inflationary rebates in Medicare Parts B and D
- Establishes annual OOP cap of \$2,000 for Part D beneficiaries, payment of which can be spread out across the year
- Main concern is: will providers always have access to maximum fair price? Bill tries to guarantee this, but unclear logistics.

H.R.19

- No federal price-setting mechanism
- Collection of bipartisan policies, including provisions affecting ASP:
 - Creates varying ASP add-on percentage based on allowed charges for drug, starting with a 4% add-on for drugs in the 85th percentile up to 8% for drugs in the 50th and below percentile
 - Establishment of maximum ASP add-on payment of \$1,000 (autologous cellular immunotherapy add-on cap is \$2,000)
- Of interest: requires manufacturers of Part B single-dose container or single-use-package drugs to provide refunds to Medicare for discarded amounts
- Lots of other provisions: transparency, pay-for-delay, cost-sharing reform, etc.

Do the bills have anything in common?

- **H.R.3 and H.R.19 share a key policy: reform of Part D out-of-pocket cost-sharing**
- Both bills create a cap on annual OOP costs for beneficiaries in Part D
 - H.R.3: \$2,000 annual cap
 - H.R.19: \$3,100 annual cap
- Both bills would also allow beneficiaries to spread out these costs in equal installments over the year (versus requiring full amount at once)
- Currently, even in the catastrophic coverage phase, beneficiaries must pay 5% coinsurance, so this is a much-needed reform

Part B drug spending will continue to draw attention from policymakers

There is longstanding bipartisan interest in reforming Part B drug payment (2016 demo under Pres. Obama; IPI and MFN under Pres. Trump).

The previous three proposals were never implemented, in large part due to significant stakeholder concern.

Remains to be seen whether the Innovation Center, under new leadership, will propose any Part B payment model.



Status of CMS' Drug Pricing Models

Part B Drug Payment Model (2016)

- Proposed Rule
- Mandatory
- Reduced payments to providers, value-based arrangements
- Withdrawn

International Pricing Index (2018)

- Advance Notice of Proposed Rulemaking
- “Conceptual”
- Tied Medicare Part B drug payments to intl' prices
- No further action

Most Favored Nation (2020)

- Interim Final Rule
- Tied Medicare Part B drug payments to intl' prices, tested flat rate to providers
- Multiple court orders
- **CMS has proposed to withdraw the rule.**

Biden Administration on Part B Drug Reform

- Officially proposed withdrawal of the MFN Model
- New head of CMMI has commented that the Administration is waiting to see what Congress does with regard to drug pricing before it proposes another Part B drug payment model
- HHS released “Comprehensive Plan for Addressing High Drug Prices” on Sept. 9
 - Mostly relies on legislative action
 - However, the Plan references Part B drug payment reform models under potential administrative actions

MAC Issues

- **MAC policies creating challenges for rheumatology practices**
 - LCA: Complex drug administration
 - SAD List
 - Provider engagement
- **Ongoing CSRO engagement with CMS, MACs**
 - Meeting with CMS Coverage and Analysis Group (CAG)
 - Meetings with individual CMDs/CMD workgroup
- **Key Asks**
 - Remove rheumatology drugs from LCA
 - Remove Stelara from SAD list, collaborate with physicians to overhaul the SAD list
 - Improve dialogue with rheumatology community – federal/state societies, CAC representatives



Sequestration

Two Separate Sequestrations

Medicare Sequester (2%)

- CARES Act moratorium will end December 31, 2021
- Moratorium was viewed as a pandemic relief provision, so whether it expires may depend on the status of the pandemic at the end of December

“PAYGO” Sequester (4%)

- *American Rescue Plan*, i.e., latest COVID relief package, triggered “Pay-As-You-Go” sequester, which for Medicare means a 4% cut (*in addition to the previous 2%*)
- Set to take effect in the next fiscal year (2022): will coincide with expiration of the moratorium on the 2% collection, for a combined functional 6%
- Congress must act to avert this before the end of the year



Utilization Management

Federal Reform Proposals

Utilization Management: Legislative Reform

- **Prior Authorization**
 - Bipartisan *Improving Seniors' Timely Access to Care Act* was just reintroduced in the House
 - Streamlines PA in Medicare Advantage plans
 - CSRO engagement: letter of support to bill sponsors; shared recent data on the harmfulness of PA in rheumatoid arthritis treatment
- **Step Therapy**
 - Bipartisan *Safe Step Act* (H.R.2163/S.464) has been reintroduced to establish clear, transparent exceptions process for step therapy requirements
 - Statutorily creates five ST exceptions for which an appeal must be granted

First Annual CSRO Hill Day

July 27th – CSRO members assembled to meet virtually with Federal policymakers Topics discussed:

- **Safe Step Act (S. 464/H.R. 2163)**, which would establish a clear, transparent, and streamlined appeals process for step therapy protocols in employer sponsored plans.
- **Improving Seniors Timely Access to Care Act (H.R. 3173)**, which would make several improvements to prior authorization in Medicare Advantage, including for medical benefit drugs.
- **Medicare Payment Policy:** Urges members of Congress to extend financial relief to physicians facing the looming threat of sequestration and Medicare conversion factor reimbursement cuts.
- **Patient Access to Prescription Drugs:** Urges members of Congress to protect access to Part B medications by rejecting further cuts to provider reimbursement for administering these medications, and instead pursue proposals to maximize access to the most cost-effective setting for medical benefit drug administration: the physician's office.

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State Activity

**CSRO Initiatives, Michigan,
and Other Updates**

A green speech bubble graphic with a tail pointing downwards, containing the text 'CSRO-Led State Initiatives'.

CSRO-Led State Initiatives

■ **Arkansas Step Therapy Reform Legislation**

- SB 99 (Commercial Insurance & State Employees) & SB 446 (Medicaid Expansion).
- Both bills signed into law in February & April respectively.
- CSRO led coalition of 30 organizations.
- Arkansas now the strongest law in the country once in effect.

■ **Arizona Step Therapy Reform Legislation**

- SB 1270 (Commercial Insurance & State Employees)
- Signed into law in early July.
- CSRO led coalition of 47 organizations.
- Arizona law would be among stronger state laws (upper quartile).

Michigan – Accumulator Legislation

HB 4353

Passed the House 98-9-3, Held in Senate Health Policy and Human Services Committee

- Requires a health plan or PBM to apply amounts paid by or on behalf of a patient towards their deductible / cost-sharing obligations.
 - A health plan or PBM may exclude co-pay assistance from counting towards a patient's cost sharing obligations if the drug has an AB rated generic alternative...
 - Unless the patient obtained access to the drug through prior authorization, step therapy, or the exceptions process.

Michigan – Accumulator Legislation

HB 4353

Tie-barred to broader package of healthcare reforms

- HB 4347: Manufacturer price reporting
- HB 4348: PBM licensure, pharmacy practice, and reporting
 - Must report amount of rebates received and retained. Report published annually by the department.

Michigan – Accumulator Legislation

HB 4350

- Amends exception to health care false claims/kickback law.
 - Manufacturer to consumer discounts currently excepted
 - HB 4350 amends current law to provide the exception only when the discount is provided in conjunction with a drug that does not have a generic or biosimilar...
 - Unless the brand name drug is acquired through prior authorization, step therapy, or the exceptions process.

Michigan – Step Therapy Law ?

REFORM LEGISLATION GENERALLY:

- Allows prescribers to override the step therapy protocol under certain circumstances.
- Consistent determination timelines.
- Adds additional process clarity.

Other State Utilization Management Activity

Accumulator Adjustment Programs

- CSRO participates as a member of the All Copays Count Coalition
- 25 states filed legislation this year
 - Seven states (AR, CT, KY, LA, NC, OK, TN) signed bills into law so far this year.
 - Join AZ, GA, IL, VA, WV, Puerto Rico
 - 5 states still pending
 - Legislation prohibits use of accumulator programs in state regulated plans.
 - Some states have opted to include a carveout allowing use of an accumulator program if a generic equivalent is available.

Other State Utilization Management Activity

Non-medical Switching

- Nine states (CO, FL, IA, MN, OH, OK, PA, NY, TX) filed legislation this year.
 - OH & PA still pending.
 - Legislation prohibits mid-year formulary changes from affecting stable patients (CO, FL, MN, OH, OK, PA, NY), and also may allow drug coverage to be grandfathered year-over-year (IA, TX).

Other State Utilization Management Activity

Step Therapy

- CSRO serves as Chair of the State Access to Innovative Medicines (SAIM) Coalition Board
- 11 states (AR, AZ, CA, FL, MA, MO, NE, NJ, OR, PA, RI) filed legislation this year
 - AR, AZ, NE, OR signed into law.
 - CA, MA, NJ, PA still pending.
 - Legislation provides guardrails for use of step therapy by health plans
 - Requires that the protocol be based on clinical guidelines and provides for minimum conflict of interest standards.
 - Allows prescribers to override the protocol under certain circumstances.
 - Requires expedient responses to exception requests.

Other State Drug Pricing Activity

- Majority of state drug pricing legislation has been drug manufacturer and pharmacy focused.
 - Most PBM related bills were about the transparency, billing and access issues with community pharmacists.
 - CSRO currently following over 160 drug pricing bills.
- Wins in 2021
 - West Virginia – Bill requires that a covered individual's defined cost sharing for each prescription drug be calculated at the point-of-sale, based on a price that is reduced by an amount equal to at least 100% of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug.
 - Montana Passed PBM reporting and state registration bill.
 - Virginia Passed PBM reporting bill.

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Questions?

- Website: **www.csro.info**
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