



## President's Message



*Michael P. Stevens  
CSRO, President*

Advocacy on behalf of patients has been at the forefront of the CSRO efforts since 2003. Our influence across state lines has grown tremendously over the years and especially this past Legislative year. We've accomplished many of our goals through our partnerships with colleagues, advocacy groups, patient groups and direct interactions with legislators. Together, we've helped steer the passage of legislation involving Step-therapy, Biosimilar regulation and Prior authorizations. We've even educated legislators regarding the harm Non-medical switching causes their constituents and our patients!

With regard to Step-therapy policies promulgated by Insurance companies, the CSRO has most recently supported passage of legislation in Iowa and West Virginia directed against these policies that have delayed and limited patient access to medications through a Step-therapy design. In Texas, another bill limiting Step-therapy practices is awaiting the Governor's signature. We continue to pursue these arrant Insurance policies in dozens of other states as well.

The CSRO has proudly overseen the passage of legislation now in 31 states that will allow patient access to Biosimilars with the proviso these new formulations are adequately regulated and monitored. Through educational efforts, legislators in a number of these States are beginning to regard the safety of Biosimilars paramount along with the hope these drugs will lower healthcare costs. As I write this, legislation regarding Biosimilars in Maryland and Nebraska sits on the desk of each state's respective Governor. The CSRO joins physicians and advocacy partners like the Arthritis Foundation and Global Healthy Living in helping legislators create bills that allow for Biosimilar access for patients while providing prescribers early notification of any switching of their prescriptions to Biosimilars done independently by the pharmacist. We feel that knowing what medications our patients may have been switched to by a pharmacist is fundamental to safe medical practice.

The CSRO has long advocated for a more streamlined Prior authorization process starting with a single, universal form available online

to everyone. With the time commitment and indirect costs to obtain Prior authorizations ever increasing, developing a standard form and insisting on prompt responses from Insurers will provide timely patient access to care and ultimately benefit the entire Healthcare system. This has been done in some States like California but many more States still need to get on-board.

We have also joined with other advocacy groups and medical organizations to battle Non-medical switching. Educating legislators and generating discussions across the country have resulted in multiple State legislatures finally addressing this issue. We believe that decisions regarding patient treatments should remain the purview of the patient and their physician. It should not be decided by an Industry motivated by corporate profits for shareholders.

This year, the CSRO has developed a new initiative to recognize and build transparency surrounding the obscure practices of Pharmacy Benefit Managers (PBM). These PBMs have been growing exponentially for almost 50 years with yearly revenues topping \$100B in some cases. They control, manage and manipulate drug prices with the promise of lowering healthcare costs; yet, copays and Insurance premiums continue to rise. Their adjustments to formularies and discounted payments to Pharmaceutical Manufacturers have rarely provided cost savings to the patient. Why is that? We intend to address this question at our 2017 State Society Advocacy Conference (SSAC) in Chicago later this year. Check our website for details: [www.csro.info](http://www.csro.info).

As our plans for the 2018 Legislative season take shape, we look forward to the continued participation of physicians, advocacy groups and patients that have made our coalition so effective in these many endeavors.

Please check our website at [www.csro.info](http://www.csro.info) for information about our upcoming State Society Advocacy Conference in Chicago and other information pertaining to our events and advocacy efforts.

I look forward to seeing you next in Chicago.

Sincerely,



Dr. Michael P. Stevens, MD

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### The Coalition of State Rheumatology Organizations

Since it was founded in 2003, CSRO's mission has been to advocate for excellence in the field of rheumatology.

# States Stride Toward Addressing Patient Access Legislation

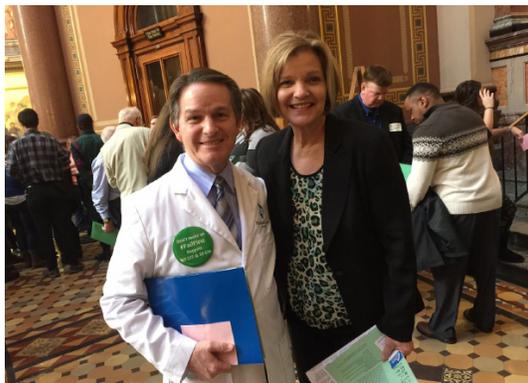
## Step Therapy and Biosimilars lead the way

The latest legislative season has brought many victories in legislatures across the country, and the CSRO has continued to track the priority issues vital to physicians and their patients. As with previous legislative years, bills regulating step therapy and biologics have received valuable consideration from state legislators, which has further built their correspondence with the CSRO, its Staff, and its partners.

The CSRO and its government relations team have been involved with every facet of the many legislative processes pertaining to biologics. This momentum has resulted in 31 states currently with some proper biologic regulations, with an additional two states, Maryland and Nebraska, which have passed legislation on to their Governors. Ideal legislation provides important pathways for patient access to these unique medications, while also mandating that a pharmacist that dispenses a biosimilar must communicate that dispense with the physician within typically three to five days. Iowa, Kansas, Montana, New Mexico and South Carolina have enacted legislation in this year alone, and through its own advocacy efforts the CSRO is optimistic that Connecticut and Nevada will soon move their respective bills.



*CSRO Board of Director & Rheumatology Association President Dr. Mark Box made the case for biological products at the Kansas State Legislature's Committee on Health and Human Services.*



*CSRO Board of Director & Rheumatology Alliance of Iowa President Dr. Michael Brooks advocates for step therapy legislation during Iowa's Advocacy Day.*

Step therapy, or fail-first, legislation has placed the CSRO and its partners in more legislative conflicts with health insurers. The CSRO advocates for bills that put preventive measures around step therapy protocols used by insurers that force patients into lengthy waiting processes for prescriptions. This effort can curb the worst of the situations that arise from this policy, especially to those patients living with chronic diseases. This uphill battle has seen only West Virginia and Iowa enact step therapy legislation in 2017, with Texas' SB 680 currently on the Governor's desk. The CSRO is also tracking legislation in Maine, Hawaii, Kansas, Maryland, Ohio, Utah, Georgia, and Florida. These bills will continue to receive support through physician testimony and factual letters of support.

The issue of non medical switching joined the legislative fray for the first time this year, as Florida, Tennessee, Colorado, Connecticut, Illinois, Maryland, Texas and Washington each drafted bills that looked well into the issue. However, the effort in 2017 has been focused on education of the policy, and the CSRO believes real legislative progress will come next year.

The CSRO is also advocating for prior authorization legislation across the country. The CSRO has core stipulations for the legislation it will support. With prior authorizations costing the health system \$728 million in 2012, the CSRO believes prior authorization processes must be more streamlined. To do this, prior authorization requests must use a single form, no more than two pages in length, and the forms must be available for access and submission electronically. Requests should be deemed approved if no response is received within 48 hours. Legislation has been moved in Minnesota, Indiana, West Virginia, New York and Georgia this year.

The CSRO will continue to endorse and help develop the resources and legislation needed to support rheumatology in a way that generates access, efficiency, safety and transparency for patients and physicians.



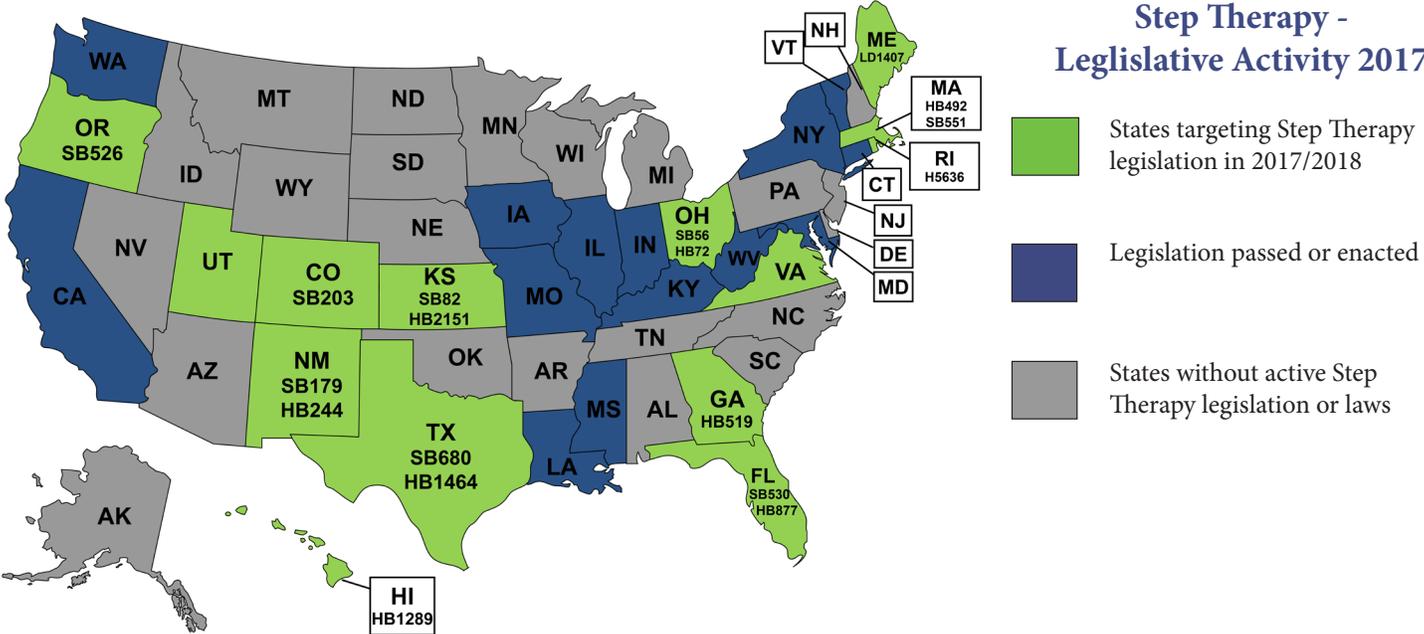
*CSRO Board of Director Dr. Josh Stolow met with legislators in Texas to advocate for a bill that would end non-medical switching.*

## STAY CONNECTED

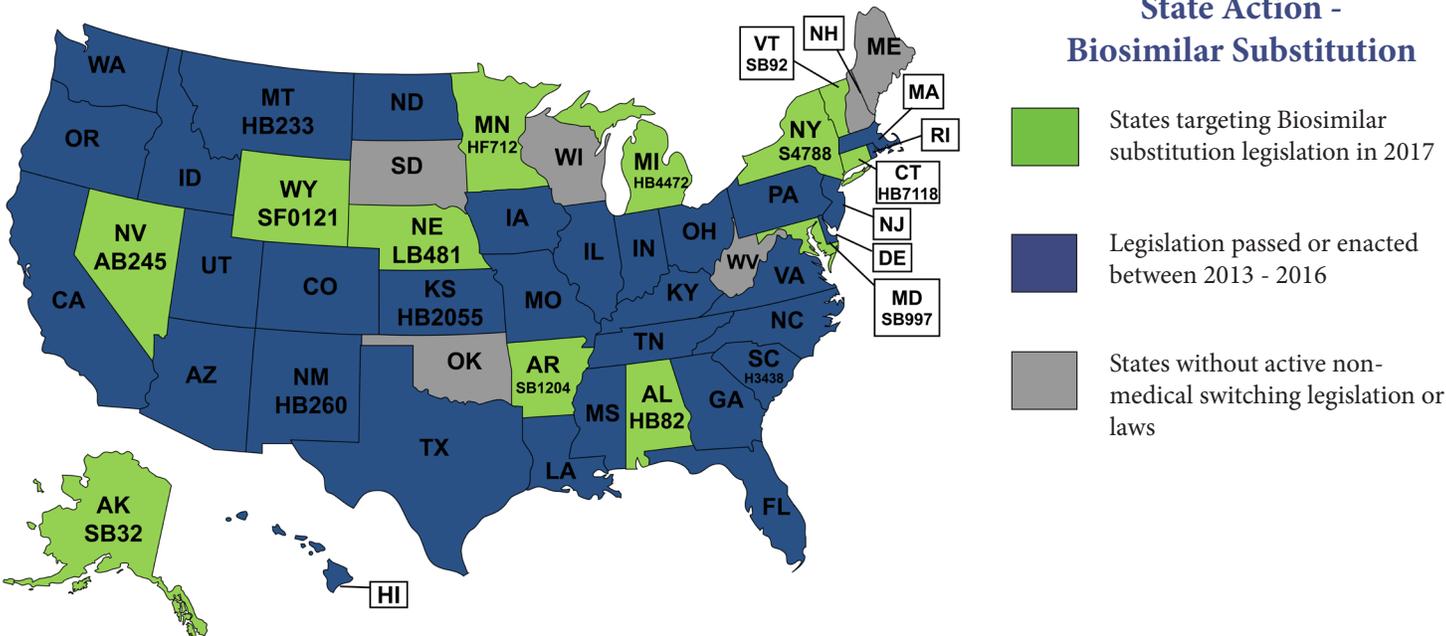
Stay connected with CSRO online via our website at [www.CSRO.info](http://www.CSRO.info),

# State Maps on Step Therapy & Biosimilars

## Step Therapy



## Biosimilars



## Fellows Assemble in San Francisco to Prepare for Next Step

The 2017 CSRO Fellows Conference presented all Fellows planning for clinical practice with information never taught in their training. At the Conference Fellows learned about various facets of practicing like the future outlook of rheumatology, the set up of clinical practices, the hiring process, the process of negotiating contracts with associates and insurers, the implementation of MACRA, and how to save for retirement. The various topics were presented by successful practitioners, lawyers, and administrators. Some even wrote the book on their subject.

The goal of the CSRO's Fellows Conference is to help young physicians gain a comprehensive perspective on all matters of practice management. The information received at these Conferences is very valuable for navigating the next phase of a young professional's career.



*2017 Fellows Conference San Francisco*

The 2018 CSRO Fellows Conference will be February 16 and 17 at the JW Marriot Union Square, in San Francisco, California. The CSRO faculty and staff will be available throughout this meeting, and they intend to be a resource for young rheumatologists throughout their careers. To register, contact Barbara Arango at (847) 264-5969 or [Barbara@wjweiser.com](mailto:Barbara@wjweiser.com).

Video of the 2017 Fellows Conference can be accessed by visiting the CSRO YouTube Channel at [youtube.com/user/CSROAdvocacy](https://youtube.com/user/CSROAdvocacy).

## The Alliance for Transparent and Affordable Prescriptions



*Members from ATAP meeting with MedPAC*

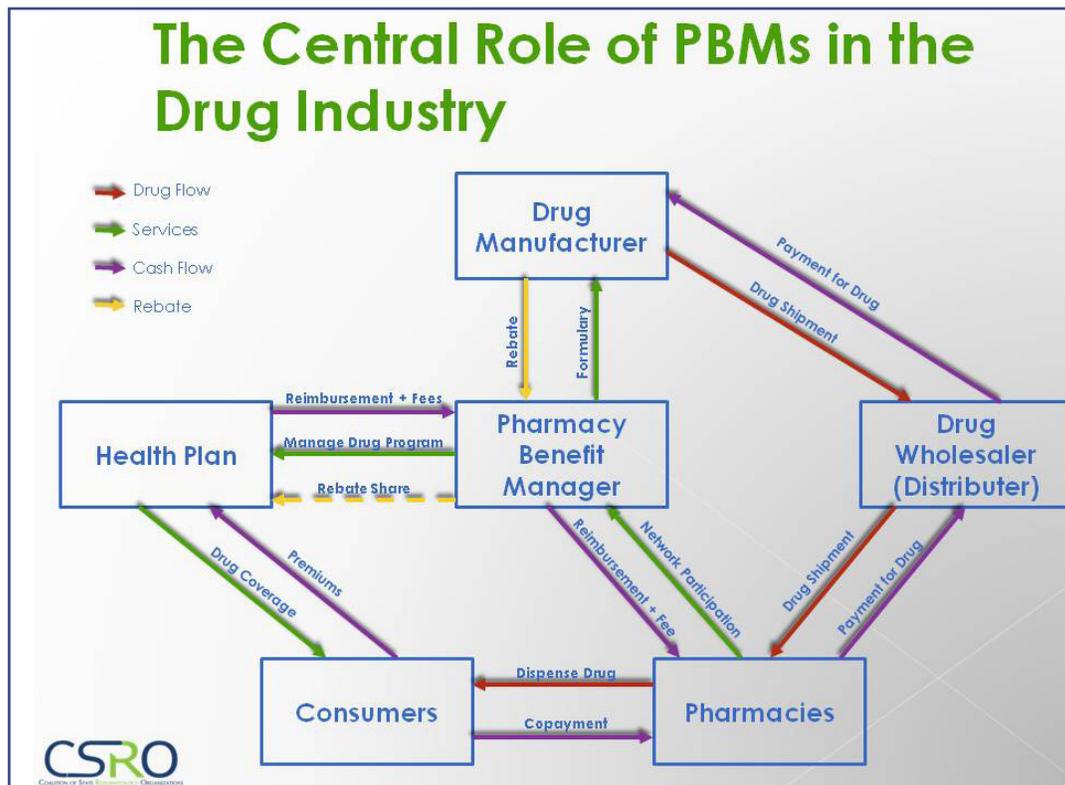
In our last newsletter, we introduced pharmacy benefit managers (PBMs) as our new advocacy initiative for this year, and our efforts to address this critical issue have since greatly increased. To that end, the CSRO is pleased to announce that we have joined forces with a number of other national patient and provider groups to form the Alliance for Transparent and Affordable Prescriptions (ATAP), a coalition dedicated solely to this PBM issue.

ATAP will work to ensure patients have access to effective and affordable medication therapies by developing and implementing a comprehensive advocacy plan that seeks to increase transparency and impose regulations on PBM practices through legislation and public policy at both the state and federal level. Eager to hit the ground running, ATAP has already undertaken outreach and advocacy efforts, including multiple meetings with the Medicare Payment Advisory Commission (MedPAC) on PBMs and the effect they have on Medicare patients and a number of meetings with Congressional Members on Capitol Hill. We have also begun engaging in proactive

discussions with the media in an effort to educate the public about PBMs and the direct impact they have on drug pricing and access to treatment.

A formal announcement of the Alliance and its participants will be issued later this spring. If you or your state society is interested in becoming a member please contact Kevin Daley at [kevin@wjweiser.com](mailto:kevin@wjweiser.com) or (847) 264-5937.

# The Rebate System: Why PBMs May Have a Bigger Say in Your Patient's Treatment Than You Do



Even in the face of the recently increased attention to the impossibly complex drug industry following the growing public outcry over rising drug costs, there is one industry player that has managed to stay for the most part, under the public's radar; pharmacy benefit managers (PBMs).

Acting as intermediaries between insurers, manufacturers, and pharmacies, PBMs play a uniquely central role in the prescription drug market, handling everything from negotiating prices with drug manufacturers and setting patient copay amounts to determining which drugs are covered by which insurers. And yet, despite their undeniable significance, PBMs and their effect on drug costs have managed to go largely unnoticed by the vast majority of Americans, allowing them to quietly influence not only prices and ultimately the amount patients pay for their prescriptions but also which drugs are available and accessible to the public.

The direct impact of PBMs on patients' ability to access effective and affordable treatment is perhaps best exemplified by the rebate system. Under this system, drug manufacturers pay retroactive rebates to PBMs in exchange for their drug's preferred placement on the PBM's tiered formulary. PBMs keep a portion of these rebates as profit and pass the rest back to insurers.

In theory, the system is supposed to lower costs for patients, but this is far from reality. Instead, it creates perverse financial incentives that motivate PBMs to develop their formularies based on the amount of the rebate they can obtain for a certain drug and ultimately drives up list prices (the higher the list price, the higher the potential rebate amount), both of which can have real consequences for patients.

Step therapy, prior authorization, and other utilization management requirements, which can delay patient access to effective and appropriate treatment, largely stem from the formulary restrictions caused by the rebate system. If a PBM decides to take a drug off formulary due to rebates, patients will lose coverage for that drug, forcing them to either switch to another potentially less effective medication or pay for the drug out-of-pocket. Moreover, because deductibles and coinsurance are calculated based on the undiscounted list price and not the rebated net price, out-of-pocket costs for the many patients with cost-sharing obligations are unfairly high.

In all, the rebate system gives PBMs a significant amount of control over drug coverage, and in turn access to affordable treatment, that physicians are for the most part powerless to oppose. This is especially true for rheumatologists, whose patients are especially vulnerable to the rebate system due to the complexity and high cost of biologics and other rheumatologic medications. For more information on this important issue, please visit the CSRO website.

## ARA: CSRO Vice President Presents on PBMs and the Rebate System



*Dr. Feldman presents at ARA*

The CSRO is pleased to report that CSRO Vice President Madeleine Feldman, MD, FACR, presented at the Arkansas Rheumatology Association (ARA), giving attendees an inside look at rising drug prices and the hidden rebate system controlled by pharmacy benefit managers (PBMs). In her presentation entitled "Exposing Rebate Systems," Dr. Feldman explained the role PBMs play in the drug industry, emphasizing how they use their intermediary position to reap profits, often at the expense of patients. Dr. Feldman's presentation focused particularly on the rebate system, under which manufacturers pay retroactive rebates to PBMs in exchange for favorable placement on their formularies. This system motivates PBMs to develop formularies based on how much profit they can earn from rebates and causes many patients to be denied coverage for their prescribed medication due to an unnecessary formulary restriction.

If your group is interested in learning more about PBMs and the rebate system or would like a CSRO Board Member to present a similar presentation at your state society's annual meeting, please contact the CSRO government relations staff, who can be found on the CSRO website.

## CSRO discusses Biosimilars, Drug Pricing, and PBMs with the California Rheumatology Alliance

The CSRO was delighted to join the California Rheumatology Alliance (CRA) in an informal presentation on the effect of biosimilars on rheumatology, and an inside look at rising drug prices and the hidden rebate system controlled by pharmacy benefit managers (PBMs). The panel that presented included Dr. Gregory Schimizzi on biosimilars, with Dr. Madelaine Feldman, Pharmacist Keith Bradbury, and Attorney David Balto on PBMs.

The panelists delved into the frequent legislative activity designed for biosimilars across the country, as the total states enacting legislation has raised to 31 and counting. The CSRO has given input to legislators to help them produce effective, proper bills in each state considering biologic regulations. Every state drafts a bill with different language, and it is the CSRO advocate's goal to ensure that every bill sufficiently protects communication between the patient and their prescriber, while enhancing access.

By extending its partnerships in discussion about PBMs and drug pricing, the CSRO hopes to bring about the education that fosters change, and ultimately more transparency within the drug pricing system. Panel presentations with partners like the California Rheumatology Alliance will help facilitate this effort.



*Dr. Gregory Schimizzi and Dr. Madelaine Feldman present at CRA*

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# CSRO Promotes Advocacy at 2017 CCR Conference



*Dr. Gregory Schimizzi and Dr. Michael Schweitz at the CSRO booth*

Over 600 attendees from 45 states gathered in Miramar Beach, Florida during the month of April for this year's 2017 Congress of Clinical Rheumatology Conference (CCR). Rheumatologists flock to this annual meeting as it is the largest outside of the American College of Rheumatology's (ACR) annual meeting.

The CSRO's Dr. Michael Schweitz (Florida) and Dr. Gregory Schimizzi (North Carolina) both were in attendance to speak to attendees about advocacy on the state and federal level. Issues included drug pricing, transparency within PBMs, non-medical switching, step therapy or fail-first, uniformed prior authorization and biosimilar substitution.

For more information about the Congress of Clinical Rheumatology please visit [ccrheumatology.com](http://ccrheumatology.com)

## CSRO Participates in 2nd Annual National Policy & Advocacy Summit on Biologics and Biosimilars

The Institute for Patient Access held its second annual National Policy and Advocacy Summit on Biologics and Biosimilars in Washington, DC in April. Patients, government representatives, physicians and advocates explored throughout the day-long event how more biological options present both new challenges and new possibilities for treatment.

CSRO's expert on biologics and biosimilars, Dr. Gregory Schimizzi, took part in a panel that discussed biosimilar labeling, the impact of distinct naming and what interchangeable biosimilars might mean for patients and policy.

Specifically, Dr. Schimizzi commended the FDA's work toward getting biologic and biosimilar agents approved. He added that "It would be nice to have statements about what is and is not an appropriate substitution."



*Dr. Gregory Schimizzi (3rd from the left) discusses FDA guidance on biosimilars*

For more information on the Annual National Policy and Advocacy Summit on Biologics and Biosimilars please visit [allianceforpatientaccess.org](http://allianceforpatientaccess.org).

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# REGISTER NOW!

## STATE SOCIETY ADVOCACY CONFERENCE

Register now for CSRO's State Society Advocacy Conference held on September 8 - 9, 2017, in Rosemont, Illinois. The conference provides rheumatologists and other practitioners the opportunity to learn from experts about advocacy best practices and get in-depth with the issues that affect you and your patients. To register, visit [tiny.cc/csrossac17reg](http://tiny.cc/csrossac17reg).

