A Letter from the President

Dear Rheumatology Community,

CSRO is proud to introduce the first issue of our new legislative newsletter, the CSRO Policy Update. This newsletter offers you a new resource to help track legislation updates and other news that affects practicing rheumatologists across the country.

Each month, the CSRO Policy Update will provide short articles on individual issues, news roundups, updates on CSRO advocacy efforts, as well as advice on how you can stay involved in advocating for your practice and your patients. To keep up-to-date on the latest news, individual bills and action alerts, please visit the CSRO website, www.CSRO.info. To obtain a login for the Members Only section, please contact our executive office.

We hope this newsletter will be a valuable resource that will help push forward your state organization advocacy efforts. If there is any information you would like to see added in future editions, or if you would like to ensure you are on our email list, please contact our staff.

Sincerely,

Michael Schweitz, MD
President, Coalition of State Rheumatology Organizations
Patient Safety at Center of Biosimilar Substitution Legislation

CSRO continues to take an active role at the state level regarding biosimilars. Regulation of biosimilar substitution continues to grow as a state issue. State legislatures are focused on notification, specifically, when prescribers should be notified regarding biosimilar substitutions.

The FDA is expected to approve the first biosimilar this year, but there are many unanswered questions. This year will be critical to deciding the future of biosimilars. The FDA still needs to strictly define interchangeability standards, how to name biosimilars and to determine regulations regarding labeling and substitutions.

At the state level, eight states currently have laws setting standards for substitution of a biosimilar product to replace an original biologic product, including requiring FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic, a physician’s ability to prevent a substitution and record-keeping. All existing state laws except one require prescriber notification. This legislative session, we have so far seen three of these states (OR, UT, VA) take on amendments to their laws and nine more states take on the issue. Additionally, Hawaii and Idaho have respectively introduced an exploratory committee and a Board of Pharmacy review of biosimilars.

Countering the Costs – Prescription Drugs and Out-of-Pocket Excess

Prescription formulary changes and rising co-pays prompted CSRO to make lowering patients’ out-of-pocket expenses a high priority. Highlighting that issue, a recent study from the New England Journal of Medicine found insurers may be using formularies to discriminate against patients with pre-existing conditions. These formularies specially selected certain drugs to be more costly in order to deter members using those medications from enrolling.

Although the study looked specifically at HIV medications, the researchers also noted that other analyses of insurance coverage nationwide showed similarly strong evidence for the same practice occurring with several other high-cost chronic conditions, including cancer and rheumatoid arthritis.

CSRO actively participates in the State Access to Innovative Medicine (SAIM) Coalition to fight for limiting patients’ out-of-pocket expenses and for proper management of specialty tiering in formulary selection. Five states already have existing laws and 13 more are being targeted by the coalition, including four that have already introduced bills this year. Kentucky, for instance, is considering capping copayments on specialty medications to $100 per prescription per month. CSRO and SAIM resources, as well as bill information, will be made available on the CSRO website.

Meanwhile, we continue to support federal efforts to address medication costs. Most notably, the Patient Access to Treatment Act which addresses Tier IV cost sharing, and will be re-introduced this year.
CSRO and Coalition Partners Campaign Against Fail First Policies

CSRO and the SAIM Coalition are also involved in advocating for limiting Step Therapy/Fail First policies. This is becoming a larger issue as we see an increasing number of insurance companies using Fail First policies as a cost control measure. In 2013, Fail First was a part of at least 75% of major employer healthcare plans. Research has shown Fail First protocols lead to higher health care costs, failure to halt disease progression, immunogenicity and adverse reactions. Health plans’ use of such policies also increases the administrative burden on physicians and their staff. The national time cost to practices of interactions with health plans is estimated between $23 billion to $31 billion annually.

CSRO is surveying rheumatologists across the country to gauge the impact of step therapy policies in their respective states. We hope to be able to use this data to drive the conversation going forward. A few states, including Connecticut and New York, have taken up the issue this session with wide-ranging step therapy restrictions including limited or physician-determined durations, as well as physician ability to bypass due to ineffectiveness, clinically predicted failure or adverse reaction. New Jersey, Utah and Washington have also introduced bills; however, their legislation is targeted at much narrower drug classes.

“...CSRO is surveying rheumatologists across the country to gauge the impact of step therapy policies in their respective states...”

Cutting Down Prior Authorization Paperwork

Rheumatologists are all too familiar with administrative burden on their practice. The national time cost to physician practices of interactions with health insurers, including seeking prior authorization for treatment and medications, is estimated between $23 billion to $31 billion annually. CSRO strongly supports state adoption of uniform prior authorization (UPA) policies to alleviate the burden.

State policies may require all providers and insurers to respectively use and accept a uniform prior authorization form or, at the least, provide a single short provider-wide form for all medications. California’s UPA form went into effect in the fall, while Illinois enacted a law requiring UPA forms. Several states will be considering similar legislation this session, including already-published bills in Virginia, New Jersey, New York and Arizona.

Signing in to Telemedicine

As technology continues to grow in its ubiquity, a number of states have begun to address the growing issue of providing consultations and medical appointments through the use of telemedicine. Last year, policy makers considered legislation requiring that services provided through telemedicine be covered in the same manner as if those services were provided in person. Such legislation became law in Hawaii; however, similar bills in Connecticut, Florida, New York, Washington and West Virginia did not make it out of session. A more limited bill requiring telemedicine reimbursement for home health monitoring if no other services are available became law in Mississippi. Meanwhile, in Maryland, the governor signed a law which extends coverage for telemedicine services to the Maryland Medical Assistance Program and managed care organizations.

This year there are already an impressive 22 states with legislation for the current session that address issues with telemedicine, modify existing telemedicine laws or institute telemedicine pilot programs. Six of these states, including Arizona, Oklahoma and Washington have also introduced legislation allowing the use of telemedicine in emergency or mental health situations. Eleven states also have legislation specifically looking to establish an Interstate Medical Licensure Compact which would make it easier for physicians from other states to practice in state through telemedicine.
A large number of medical liability bills have been introduced in 2015, many involving caps on damages. In New York, for example, AB 3130 limits non-economic damages to the greater of the amount awarded for economic damages, the amount calculated after applying a formula set forth in the legislation or $250,000.

Some bills relating to caps on damages are aimed at increasing those caps. It is likely they were introduced to prevent a court from later finding the caps too low or inadequate to be enforceable. Kansas enacted such a law last year, raising the state’s caps on non-economic damages. It was introduced in response to an earlier state Supreme Court decision which hinted that the state’s caps could be struck down at some point if they were too low.

This year another bill in Kansas similarly increases the limit on damages awarded for wrongful death from $250,000 to $500,000. Bills in Indiana and Oregon are also efforts to increase the damages caps in those states. In Maryland, two proposals essentially triple the state’s cap on non-economic damages in cases where there has been a “catastrophic injury.”

Stay connected with CSRO online via our website at www.CSRO.info and our Twitter account, @CSROAdvocacy (Twitter.com/CSROAdvocacy)