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PERSPECTIVES

Use 2022's advocacy successes and frustrations as a catalyst for the new year

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As we come to a close on 2022, let's take a look at the celebrations and frustrations of the past year's health policies so that they may act as a catalyst, encouraging us to engage with our representatives. Some of these policies include actions by major companies that rule our health care system, as well as the regulations and legislation passed (or not passed) by our governmental entities. And of course, we must consider how profits and politics influence these policies and often rule the roost!

Insurance

Once again, we are facing increased nonmedical switching of stable patients to different medications through ever-increasing formulary exclusions and higher tiering of less profitable drugs. There are some reports of patients being whipsawed back and forth yearly between reference infliximab and various biosimilars, depending on which is the most profitable to the health plan at the time. And now it's not just the copay accumulator or maximizer programs that are abusing patient assistance programs, there are new "alternative funding companies" that are carving out expensive and specialty drugs from coverage of employers' funded health plans. These alternative funding companies then obtain medications – sometimes from other countries – and other forms of assistance from manufacturers and foundations. There have been reports that they make the patient assign power of attorney to them and even pretend to be the patient to obtain the drug, assistance, and copay cards and then bill the employer for getting the free drug or assistance. This abuse of the system, along with copay maximizers, are causing drug manufacturers to rethink their assistance policies, with middlemen reaping the advantages of the assistance plans and not the truly needy patient.

Legislation and regulation

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.



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At the federal level, the Inflation Reduction Act

https://www.congress.gov/bill/117th-congress/house-bill/5376/text (IRA; H.R. 5376) was enacted in August and, like all major pieces of legislation, there are pros and cons

<https://www.mdedge.com/rheumatology/article/257497/businessmedicine/medicare-drug-changes-ought-benefit-rheumatology? channel=38029> . 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 <https://www.congress.gov/bill/117thcongress/house-bill/3173> (H.R. 3173) would reform prior authorization in Medicare Advantage

<https://www.mdedge.com/rheumatology/article/258050/businessmedicine/house-passes-prior-authorization-bill-senate-path?channel=38029>, 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 <<u>https://www.congress.gov/bill/117th-congress/senate-bill/464/text></u> (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.

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As noted above, PBMs escaped meaningful scrutiny or reform in the IRA, but the Federal Trade Commission took a different approach when it announced earlier in 2022 <https://www.ftc.gov/news-events/news/pressreleases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry> 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 <https://www.cms.gov/medicare/medicare-fee-for-servicepayment/physicianfeesched> 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 governmentreimbursed 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 problems in the Fee Schedule result from a combination of factors, but one overarching issue is the concept of "budget neutrality," which essentially requires CMS to make up for any new spending over a certain amount by a commensurate reduction across the whole Fee Schedule. This has the effect of turning the Fee Schedule into a fixed pie: If someone's slice gets bigger, someone else's slice must get smaller, but the pie itself never gets bigger. To make matters worse, the Medicare Access and CHIP Reauthorization Act of 2015 has not resulted in advancing value-driven care as the Congress had envisioned when it enacted that legislation. 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 https://www.congress.gov/bill/117th-congress/house-bill/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 valuebased care innovation, and safeguarding timely access to high-guality care by advancing health equity and reducing disparities.

Turning frustration into action

Much of the frustration for those of us who take care of patients is that many actions and policies are based on profits and politics and not on patient care.

It is unfortunate that money plays such an important role in politics. We are all aware of the power of the well-heeled lobbyist and how money can lead to legislation that is more beneficial to one for-profit company versus another in the health care sector. But then there is the party politics of health care legislation. We see examples of great legislation offered by one party being buried because it might be beneficial to the "other side" in the next election, in spite of the fact that both sides agree on the issue. Here is where we must fight our cynicism and remember our patients. Building and maintaining a relationship with our representatives, whether we agree with them are not, is a very important part of advocacy.

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As we come off the recent elections, it is important that we acquaint ourselves with our newly elected representatives and reacquaint ourselves with our reelected officials. Recently, the Coalition of State Rheumatology Organizations had an advocacy day asking rheumatologists to invite their legislator (city, state, or federal) to their office to witness first-hand the practice of rheumatology. The importance of asking your representative to visit your office cannot be overemphasized. First, you get to know the staffer who arranges these visits. Having a good relationship with your representative's staff is important in maintaining future communications. Having your legislator tour your office, while you share the daily challenges of getting the right medication for patients, is invaluable to their understanding of how the delay in care that utilization management tools such as prior authorizations and step therapy can cause. It is also helpful for you or your office manager to highlight how independent practices are small businesses that must be run efficiently to ensure they can stay open. Building a relationship with and educating your representatives on issues they may not be familiar with will encourage them to use you as a resource in the future.

CSRO has a legislator invitation template https://csro.info/non_cms_pages/advocacy-campaigns.php?

vvsrc=%2fCampaigns%2f97605%2fRespond>, and we can provide talking points if the invitation is accepted. Many state legislative sessions begin in January, so now is the time to get to know your legislator.

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!"

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