

#### Empowering rheumatology professionals to excel in their specialty

600 Maine Avenue, SW • 6th Floor • Washington, DC 20024 Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

# 2023 Advocacy Updates (Year 1 of the 118th Congress)

January 1, 2023 – December 31, 2023

# 118th Congress: Federal Legislative Activity

#### Barriers to Access

- Language to streamline the use of prior authorization is included in the current draft of the PBM reform bill being considered by the House.
- o The Safe Step Act, S. 652, HR 2630 to codify medical exceptions to step therapy protocols.
  - This language is included in the current draft of S. 1339, a PBM transparency package moving through the Senate.
- HELP Copays Act, HR 830, S. 1375 to require plans to apply third-party payments, financial
  assistance, discounts, product vouchers, and other reductions in out-of-pocket expenses toward
  a plan's cost-sharing requirements.

#### Workforce

- (Training Opportunities) The Resident Physician Shortage Reduction Act, HR 2389, S. 1302 To add 14,000 Medicare-funded GME positions
- (Student Loan mitigation) The Resident Education Deferred Interest Act, or REDI Act, HR 1202, S.
   704 To delay accrual of interest on student loans for physicians and dentists during residency.
- (Barriers to Practicing) The Conrad State 30 and Physician Access Reauthorization Act, S 665 To
  extend the program for 3 years which allows international physicians to remain in the U.S. upon
  completing their residency under the condition that they practice in areas experiencing doctor
  shortages.

### Medicare Reimbursement

 The Strengthening Medicare for Patients and Providers Act, HR 2474 - To adjust Medicare physician payments at the rate of inflation annually.

#### Drug Pricing:

- The Pharmacy Benefit Manager Transparency Act, S 127 To prohibit PBMs from charging a different amount than they reimburse the pharmacy and from clawing back reimbursements, or increasing fees or lowering reimbursements to pharmacies to offset changes to federally funded health plans unless they pass along 100% of price concession or discount to the health plan, and disclose costs, prices, reimbursements, fees, markups, discounts, and payments received.
- Pharmacy Benefit Manager Reform Act, S. 1339 to require annual reporting by PBMs including copay assistance from manufacturers, covered drugs, net spending by health plans on drugs, etc, prohibiting spread pricing, and requiring all rebates, fees, and discounts from a manufacturer be passed to the patient.
- o *Pharmacy Benefit Manager Sunshine and Accountability Act,* **HR 2816** to establish new, public reporting requirements for PBMs, to ensure that patients, providers, and employers are able to make informed, cost-efficient, and value-based PBM choices.

- Pharmacy Benefit Manager Accountability Act, HR 2679 to raise reporting requirements for PBMs to increase transparency in the drug supply chain.
- The HELP Copays Act, HR 830, S. 1375 To require third-party payments, financial assistance, discounts, product vouchers, and other reductions in out-of-pocket expenses apply toward plan cost-sharing requirements.

# Research Funding

National Defense Appropriations Authorization Act – After years of educating Appropriators, for the first-time dedicated arthritis funding in the Congressionally Directed Medical Research Program (CDMRP) has been included in the House Appropriations bill for the Department of Defense. Arthritis research has gotten funding from the general pool of peer-reviewed funds which change each year (decided on the Senate side).

#### <u>Letters to Policymakers</u>:

- January 23, 2023, Letter to Congressional leaders urging systematic of the Medicare reimbursement system.
- January 25, 2023, Letter to CMS urging them to revisit copay assistance policy.
- January 31, 2023, Letter to CMS on the use of step therapy in plans providing essential health benefits.
- March 3, 2023, Letter to Congress asking for \$732 million for NIAMS in FY2024.
- March 9, 2023, Thank You letter to the original co-sponsors of the REDI Act to combat medical student loan debts.
- March 13, 2023, Letter to Congress asking for \$50.924 billion for NIH in FY2024.
- March 13, 2023, Letter to CMS thanking them for and suggesting improvements for the proposed electronic prior authorization rule.
- March 15, 2023, Letter to Congressional leaders asking for legislation providing annual inflationbased payment updates to the Medicare Physician Fee Schedule (MPFS) based on the full Medicare Economic Index (MEI). Follow-up: Legislation filed April 3, 2023
- o March 16, 2023, Letter to Appropriations subcommittee on Labor, HHS, and Education leaders asking for **\$60 million for the CDC Arthritis research** program.
- March 21, 2023, Letter to Congressional leaders in support of permanent protections for "Dreamers" / DACA recipients, especially the 34,000+ currently serving in the medical workforce.
- o April 14, 2023, Letter to CMS on new **drug price negotiations** in the Inflation Reduction Act.
- April 24, 2023, Letter to Congress supporting funding for the Congressionally Directed Medical Research Program for FY 2024.
- May 3, 2023, Letter thanking members of the House of Representatives who introduced the Strengthening Medicare for Patients and Providers Act to adjust Medicare physician reimbursements for inflation annually.
- May 5, 2023, Letter to Medicare Payment Advisory Commission strongly opposing recommendations to eliminate the 6% add-on payments for acquisition of drugs.

- May 8, 2023, Letter to Congress endorsing the Resident Physician Shortage Reduction Act to fund additional graduate medical education training positions.
- May 10, 2023, Letter thanking members of the Senate who introduced the HELP Copays Act to include copay assistance towards plan cost-sharing requirements.
- May 11, 2023, Letter thanking members of the Senate who introduced the HELP Safe Step Act to codify medical exceptions to step therapy requirements.
- May 17, 2023, Letter to Congress requesting \$30 million for the pediatric subspecialty loan repayment program.
- o May 26, 2023, Letter to Senate leaders thanking them for the hearing "Examining Health Care Denials and Delays in Medicare Advantage" which highlighted the needed oversight of the use of **prior authorization** in these plans.
- May 30, 2023, Letter to Congress expressing concern regarding continued cuts to Medicare physician reimbursement payments.
- o May 30, 2023, Letter to Congress to protect access to treatments under Medicare Part B.
- June 6, 2023, Letter to Senate HELP Committee leaders in support of the REDI Act to combat medical student loan debt.
- o June 29, 2023, Letter to Congress urging action on the medical workforce shortage.
- July 11, 2023, Letter thanking original co-sponsors of the Safe Step Act for introducing legislation to codify exceptions to step therapy protocols.
- July 14, 2023, Letter urging Congress to include the HELP Copays Act in the anticipated PBM Reform Package.
- August 1, 2023, Letter thanking original co-sponsors of the Conrad State 30 and Physician Access Reauthorization Act for introducing legislation to support the medical workforce.
- August 4, 2023, Letter thanking appropriators for funding a new line item dedicated to arthritis research within the FY2024 DoD Appropriations Bill.
- September 6, 2023, Letter from cognitive care specialties to Congress supporting CMS implementing G2211 in the CY24 Medicare Physician Fee Schedule.
- September 7, 2023, Letter from broad coalition to Congress supporting CMS implementing
   G2211 in the CY24 Medicare Physician Fee Schedule.
- September 11, 2023, Comments on CY24 Medicare Physician Fee Schedule and Quality
   Payment Program Proposed Rule
- October 24, 2023, Letter in Support of the Protecting Patient Access to Cancer and Complex Therapies Act of 2023 to ensure providers can continue to acquire and administer complex therapies.
- October 27, 2023, Letter in support of passing the FY2024 Defense Appropriations Act to ensure full funding for the **Defense Health Research Programs**, including the CDMRP.
- October 31, 2023, Letter supporting legislation to reform the budget-neutrality policies that are destabilizing and eroding Medicare physician payments.
- o November 16, 2023, Letter supporting legislation to **stop the 3.37% reduction to Medicare physician payments** scheduled for January 1, 2024.
- o November 27, 2023, Letterer in support of the Specialty Physicians Advancing **Rural Care** (SPARC) Act to incentivize specialty physicians to practice in rural areas.
- o December 4, 2023, Letter responding to **FDA Laboratory Developed Tests Proposed Rule**.

### Other Congressional Actions:

- March 20, 2023, Senate Health, Education, Labor, and Pensions (HELP) Committee request for information (RFI) response.
- Asked to "provide feedback on the causes of our current healthcare workforce shortages and potential legislative solutions."

# **Federal Regulatory Updates**

- Biosimilars
  - Patient-facing fact sheet and video produced in conjunction with the ACR's Rheumatic
     Disease Awareness Month (RDAM) campaign.
  - o Dedicated website to serve as a comprehensive resource on biosimilars and ACR's positions.
  - Communication with the FDA regarding new educational activities and opportunities
  - Discussions with manufacturers to understand patient programs.
- Medicare Payment Advisory Commission
  - Communications with MedPAC providing comments and concerns regarding their policy recommendations on add-on payments for Part B drugs and biologics.
    - Three recommendations were proposed:
      - Establish a fixed payment for Part B drugs and biologics, based on the Average Sales Price
      - Reduce the add-on payment for high-cost drugs.
      - Eliminate add-on payments for Part B drugs and biologics that are based on the wholesale price.
- Drug Shortages
  - Ongoing communication with the FDA Drug Shortage team to address methotrexate drug shortages.
- OSTP Zero Embargo
  - Collaborate with the journals' staff on policy options for the OSTP's Zero Embargo policy.
- Medicare Drug Pricing Negotiation Program
  - ACR submitted comments on CMS Drug Pricing Negotiation Program guidance document that highlighted the need to provide greater patient and provider perspective and cautioning against activities that may diminish further innovation.
- Medicare Physician Reimbursement
  - Ushered in the passage of the G2211 evaluation management code to increase reimbursement for in-office care of complex patients.
    - Based on the CY 24 conversion factor and related work relative value units, the reimbursement for G2211 will be around \$16.08.
    - G2211 will better capture the time, intensity, and practice expense costs necessary for ongoing comprehensive care of patients with a chronic or complex condition.
  - The ACR advocated for CMS to include G2211 in the CY24 Medicare Physician Fee Schedule and continues to work with Congress and related agencies to support the rheumatology specialty in providing high-quality care to Medicare beneficiaries.
  - ACR developed guidance to support members in understanding the Medicare G2211 code.

## **State Activity of Note**

- Prior Authorization
  - o Virginia (SB 1261/HB 1471)-enacted
  - West Virginia (SB 267)- signed by Governor
  - o Arkansas (HB 1271-Gold Card legislation)- enacted
  - California (SB 598-Gold Card legislation)-passed Health Committee July `11<sup>th</sup>, referred back to Appropriations)

#### PBM Reform

- o Licensing, registration and basic regulation bills
  - Oklahoma (HB 1843)- enrolled
  - Montana (HB 379)-transmitted to Governor
  - Wyoming (SF 151)- enacted
- o Rebate Pass Through
  - Arkansas (SB 94)- enacted
  - Indiana (SB 8)-enacted
  - California (SB 873)- passed Senate
- o Florida
  - Gov. Desantis-backed drug pricing reform legislation that includes PBM reform measures as well as regulations on manufacturer price increases.
  - (SB 1550)-enacted
  - (HB 1509)-enacted
- White Bagging
  - o Texas (HB 1647)- enacted
  - North Dakota (SB 2378)- enacted
    - 9 other states considered white bagging legislation.
- Step Therapy
  - o Washington (HB 1356) (specific to biosimilars)- in House committee
  - o Colorado (HB23-1183)- enacted
  - o Missouri (SB 268)-in Senate committee
  - Maryland (SB 0515)- enacted
  - o Nevada (SB 194)- enacted
  - o Oklahoma (HB 1736)- enacted
- Copay Accumulator
  - o Colorado (SB 195)- enacted
  - o New Mexico (SB 51)- enacted
  - o Texas (HB 999)- enacted
  - North Dakota (HB 1413)-reported back from conference committee awaiting senate approval.