CSRO

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Town Hall

Federal & State Advocacy Update

November 20, 2024

Presentation Overview

- Political Update
- Federal Legislative Update
- Federal Regulatory Update
- State Legislative Update

Political Update

Matt Duckworth
Vice President, Government Relations
Hart Health Strategies Inc.

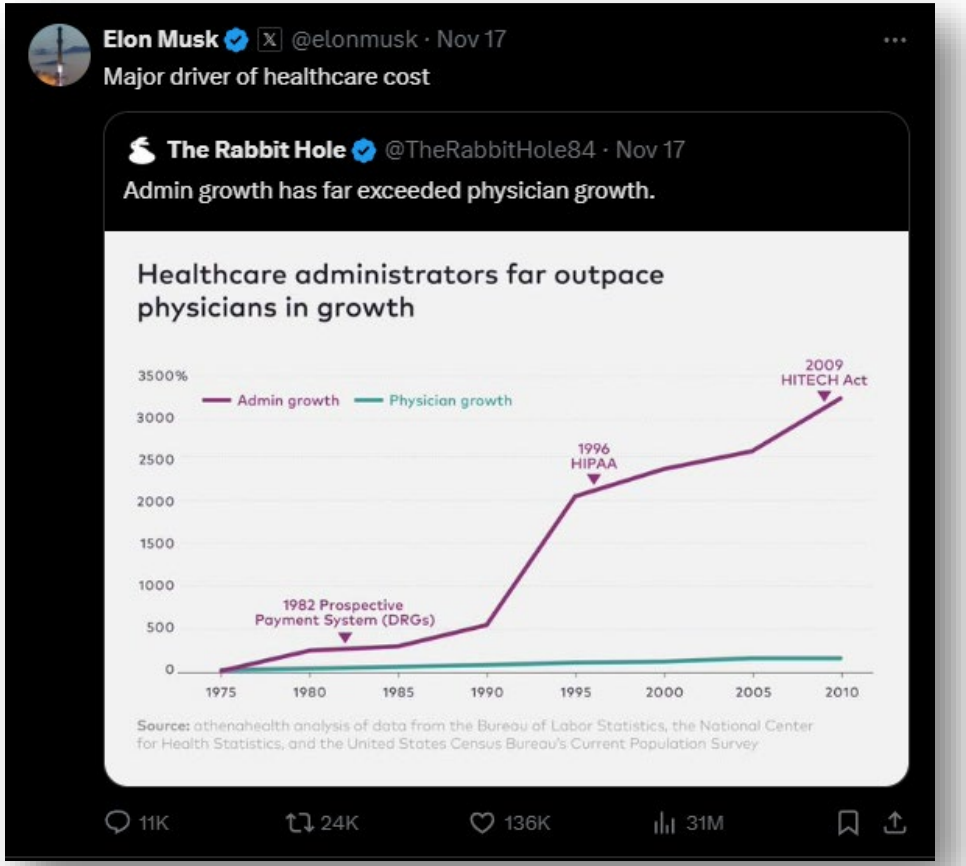
The New Washington

Federal Legislative Update

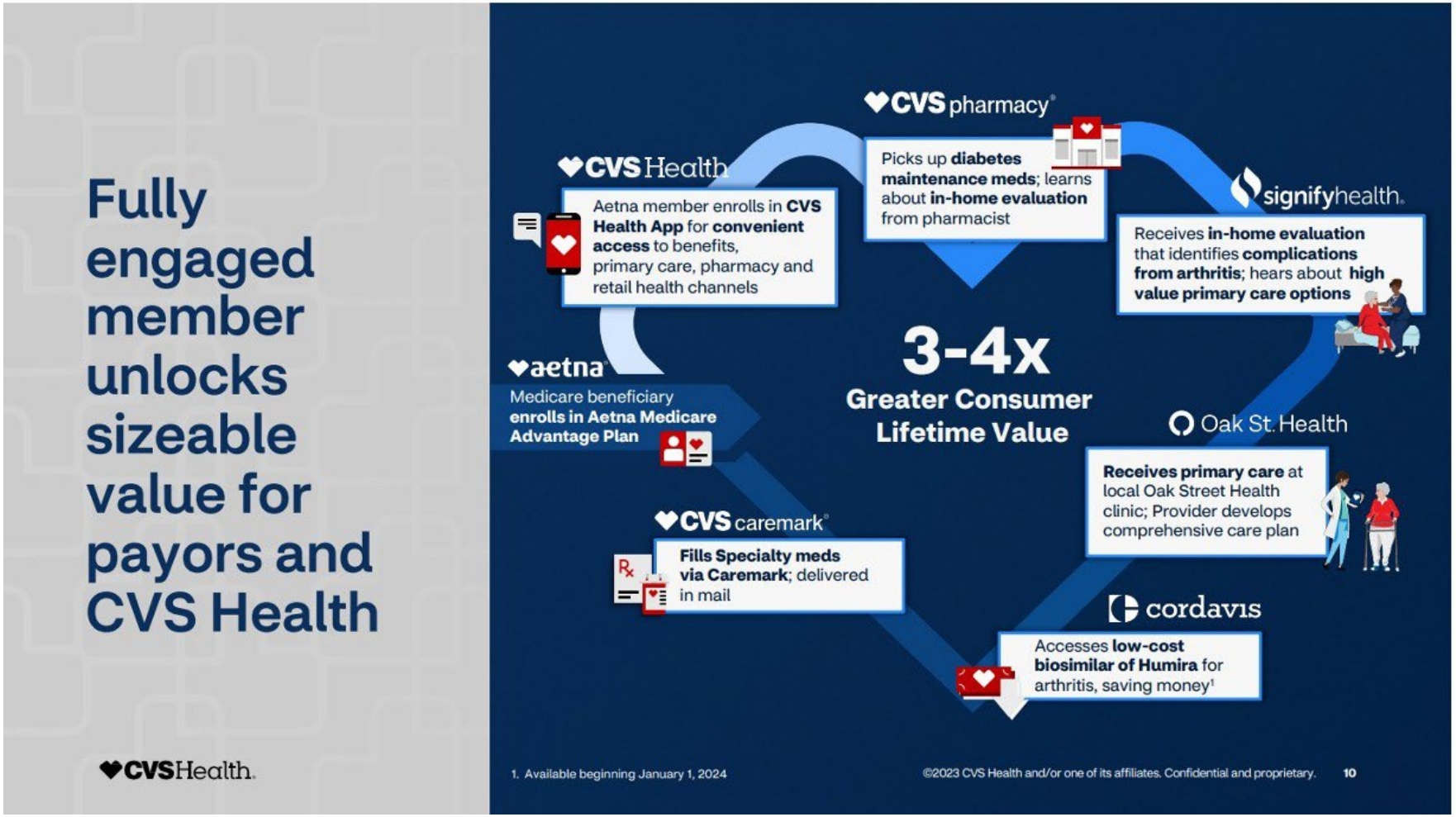
Jessica Frasco
Vice President, Federal & State Drugs and Biologics Policy
Hart Health Strategies Inc.

Medicare Physician Fee Schedule

- Bipartisan support to address cuts to the Physician Fee Schedule
  - When?
  - By how much?
- **Short Term:** Address the impending cut
  - Medicare Patient Access and Practice Stabilization Act of 2024 (H.R.10073)
- **Long Term:** Stop annual cuts
  - Physician Fee Stabilization Act (S.4935)
  - Strengthening Medicare for Patients and Providers Act (H.R.2474)
  - Provider Reimbursement Stability Act (H.R.6371)
  - Physician Fee Schedule Update and Improvements Act (H.R. 6545)



Pharmacy Benefit Manager (PBM) Abuses



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PBM Reform

- CSRO's main PBM principles:
  - Delink PBM Compensation from Drug Prices
  - Pass Manufacturer Rebates Directly onto Patients
- Several bills have advanced by congressional committee in the 118th
  - Modernizing and Ensuring PBM Accountability Act (S.2973, Section 2), as reported out of Senate Finance
  - Accelerating Kids' Access to Care Act (H.R.4758, Section 3), as passed by the House
  - Protecting Patients Against PBM Abuses Act (H.R.2880, Section 2), as marked up in House Energy & Commerce
  - Delinking Revenue from Unfair Gouging (DRUG) Act (S.1542/H.R.6283), as reported out of House Oversight and Accountability Committee
  - Better Mental Health Care, Lower-Cost Drugs, and Extenders Act (S.3430, Section 203), as reported out of Senate Finance
  - Share the Savings with Seniors Act (S.2474/H.R.5376)

Prior Authorization Reform – MA Plans

- Improving Seniors' Timely Access to Care Act (S.4532/H.R.8702)
  - Senate cosponsors: 54
  - House cosponsors: 228

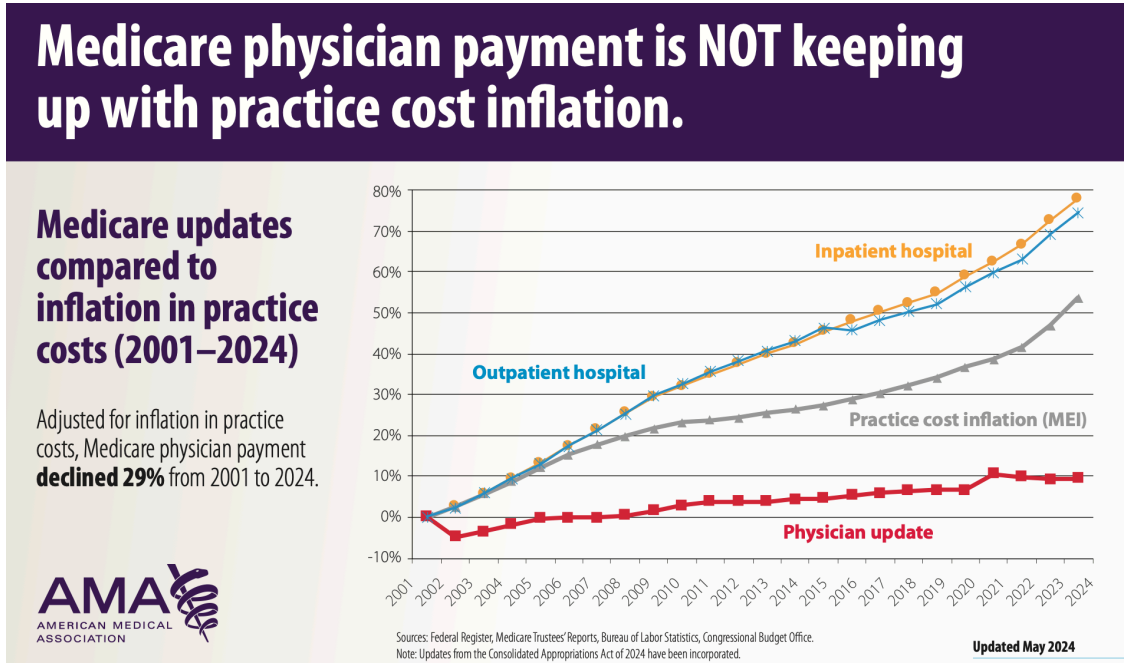
- About the bill:
  - Create uniform electronic PA standards to streamline MA approvals
  - Limit time the plan can review PA request
  - Improve transparency
  - Encourage MA plans to adopt policies that adhere to evidence-based guidelines

Federal Regulatory Update

Emily Graham, MSHIM, RHIA, CCS-P
Vice President, Regulatory Affairs
Hart Health Strategies Inc.

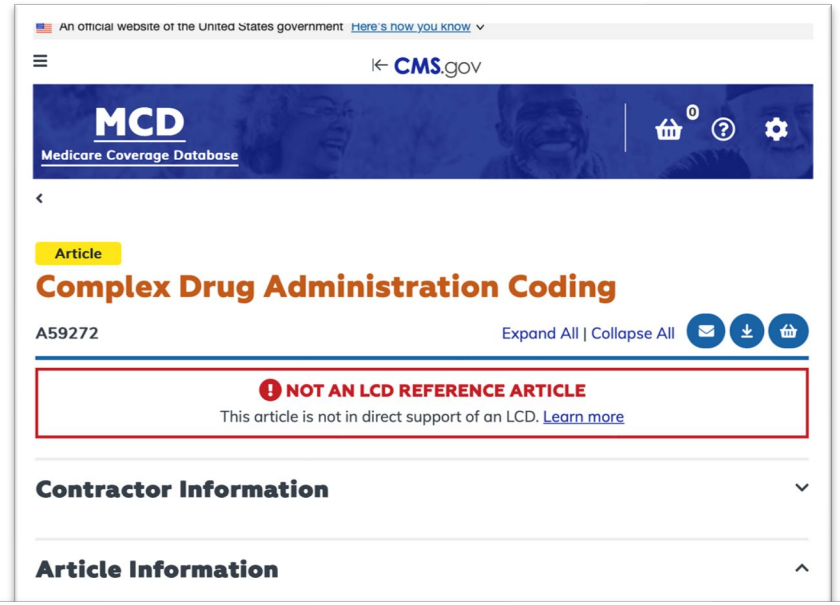
Medicare Physician Payment

- Medicare physician payments slated to **drop by 2.83%**, resulting in a conversion factor of **$32.3465** starting on January 1, 2025
- Congress is considering legislation to address the CY 2025 cut and provide a modest update to address rising inflation
- Other challenges in Medicare Physician Fee Schedule (PFS) payments are under consideration as part of recent legislative efforts, including:
  - Inclusion of an inflation adjustor (i.e., MEI)
  - Revision to budget neutrality requirements
  - Requirement to update key data inputs (e.g., practice expense data)



Down Coding

- MACs previously issued ”billing and coding” articles that directed practices to use “therapeutic” admin codes when infusing/injecting several rheumatology drugs rather than “complex” admin codes
- CSRO argued this was inconsistent with:
  - Statute: *Medicare Prescription Drug and Modernization Act of 2003*
  - CMS’ long-established payment policies
  - AMA coding guidance
- CMS action:
  - Technical Direction Letter (TDL)
  - Program Transmittal
  - Request for Information
  - Finalized policy to update criteria outlined in CMS’ Internet Only Manual (IOM)
- All MAC policies have been retired; new policies could emerge based on new criteria in the IOM

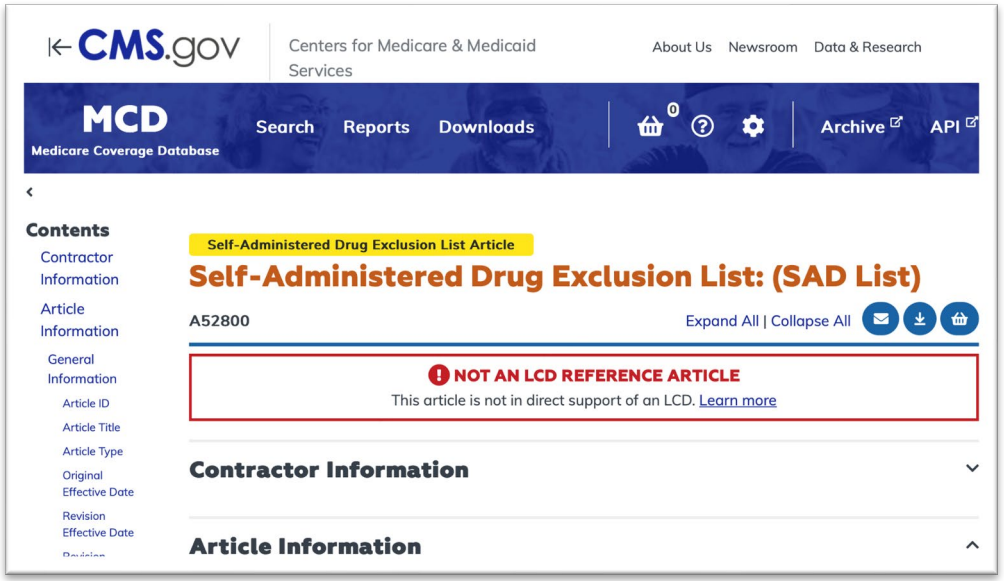


SEC. 304. EXTENSION OF APPLICATION OF PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS TO OTHER PHYSICIAN SPECIALTIES.

Notwithstanding section 303(j), the amendments made by section 303 shall also apply to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

Self Administered Drug (SAD) Exclusion List ("SAD List")

- Drugs on the SAD List are *excluded* from Medicare Part B; beneficiary is liable for full cost of these drugs, regardless of disability, etc.
- SAD List policy stems from CMS' interpretation of the *"not usually self-administered by the patient"*
- CSRO argued the SAD List:
  - Uses incomplete data; results in flawed analysis
  - Violates HHS' nondiscrimination regulations
- CMS action:
  - Request for Information
- CSRO request to HHS/CMS:
  - Remove dual formulation drugs from the SAD List; postpone including additional dual formulation drugs
  - Establish inclusion criteria that account for clinical, other factors
  - Address data issues, improve transparency



“Underwater” Biosimilars

- Joint coalition of patient and provider organizations led by CSRO/ACR has been working to address challenges facing infusion providers with “underwater” biosimilars
- Multi-pronged approach:
  - Agency
    - Letters to CMS leadership
    - Meetings with CMS’ Deputy Administrator, White House Office of Management and Budget (OMB)
  - Congressional
    - Letter to Congressional Leaders
    - Meetings with Congressional offices, Medicare Payment Advisory Commission (MedPAC)
  - CMS acknowledged concerns in recent CY 2025 PFS final rule; ramp up legislative efforts in the new Congress

Other PFS Topics: Payment Provisions

- **Complex Add-on Code G2211**
  - CMS finalized an **exception to the Modifier ~25 billing prohibition for G2211** "to allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code reported by the same practitioner on the same day as an AWV, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting." CMS confirmed that this policy includes the "Welcome to Medicare" visit.
  - CMS may consider expanding use of G2211 to services other than office and outpatient E/Ms where the practitioner is the "continuing focal point."
- **Telehealth**
  - Through 2025, CMS will **continue to permit practitioners to use their currently enrolled practice location instead of their home address** when providing telehealth services from their home.
  - CMS will **allow for direct supervision via virtual presence using audio/video real-time communications technology on a permanent basis for a subset of "incident to" services** when:
    - (1) the service is provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; or
    - (2) the service is an office or other outpatient E/M visit for an established patient that may not require the presence of a physician or other qualified healthcare practitioner (i.e., CPT 99211).
  - For all other services, CMS finalized its proposal to continue to allow for direct supervision via virtual presence using real-time audio and visual interactive telecommunications technology through 2025.

Other PFS Topics: Quality Provisions

- **MIPS Cost Measures.**
  - CMS finalized the Rheumatoid Arthritis (RA) Cost Measure for implementation in the Merit-based Incentive Payment System (MIPS) starting in 2025.
  - CMS rebuffed the concerns raised by CSRO and other commenters.
  - **CSRO strongly urges rheumatology practices to become familiar with the RA cost measure specifications to avoid scoring poorly on this measure in the cost category.**
- **Rheumatology Specialty Set.**
  - CMS made substantive changes to 4 of the quality measures in the Rheumatology Specialty Set, including:
    - RA: Glucocorticoid Management
    - RA: Functional Status Assessment
    - RA: Periodic Assessment of Disease Activity
    - Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy
- **Rheumatology MVP**
  - CMS finalized modifications to the existing Advancing Rheumatology Patient Care MIPS Value Pathway (MVP).

State Legislative Update

Kevin Daley
Vice President, State Government Affairs
Hart Health Strategies Inc.

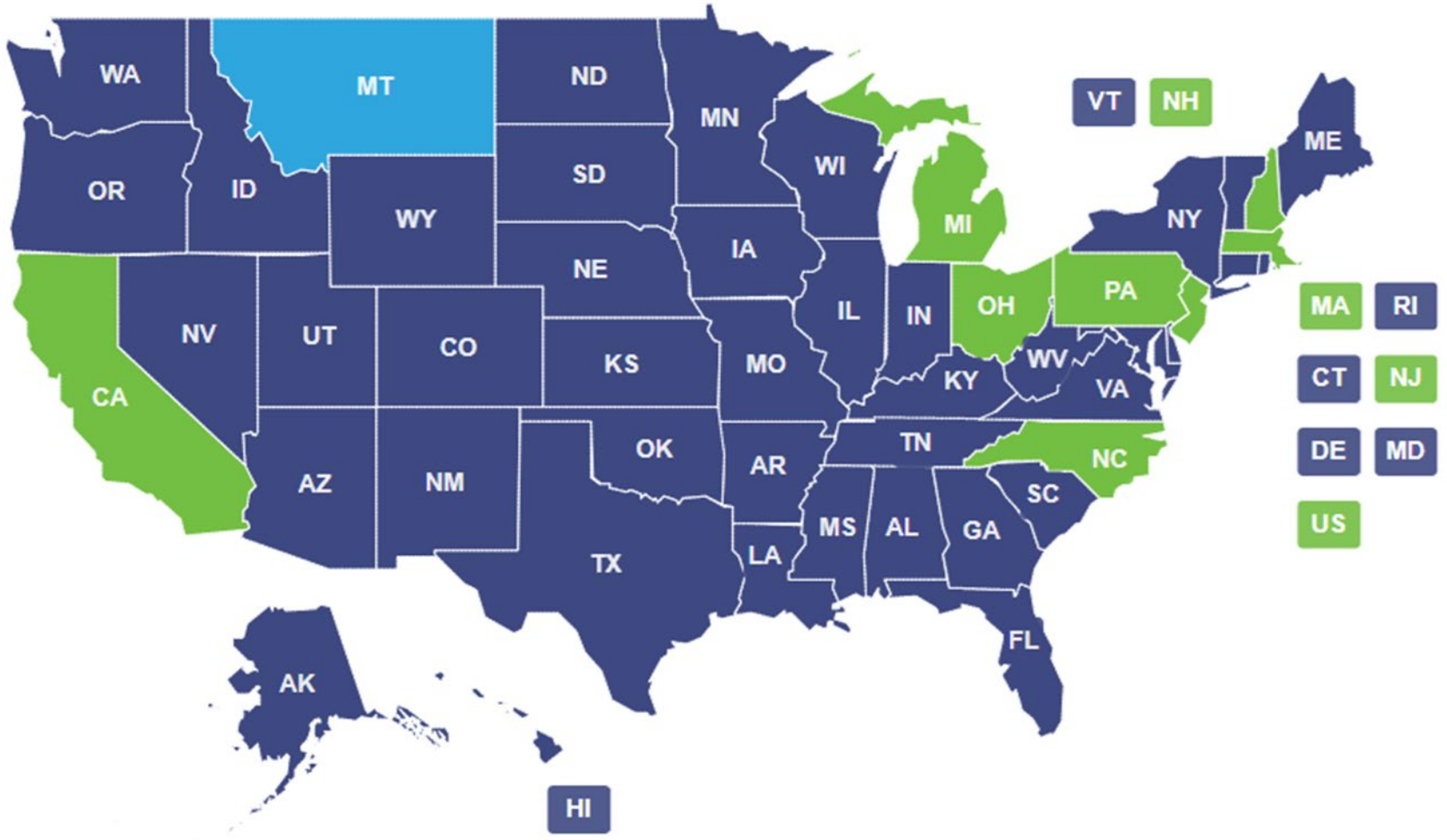
Priority Issues for 2025

- Prescription Drug Affordability Boards (PDABs)
- 340B
- Accumulators, Maximizers, and Alternative Funding Programs
- PBM Reform
- Specialty Pharmacy Mandates
- Biomarkers
- Utilization Management
  - Step Therapy
  - Non-medical switching
  - Prior Authorization
    - Gold Cards

New Laws to Know

- **Colorado** – Gold Card HB1149 (**January 1, 2026**)
- **Iowa** –
  - Non-Medical Switching HF 626 (**January 1, 2025**)
  - Biomarker Coverage HF 2668 (**July 1, 2024**)
- **Indiana** – Biomarker Testing SB 273 (**July 1, 2024**)
- **Kentucky** – White Bagging HB 190/SB 188 (**January 1, 2025**)
- **New Mexico** – Step Therapy SB 135 (**January 1, 2025**)
- **Oregon** – Accumulator Ban HB 4113 (**January 1, 2025**)
- **Rhode Island** – White Bagging S 2096 (**January 1, 2025**)
- **Vermont** – PDAB S 98 (**July 1, 2024**)
- **Wyoming** – Step Therapy/Gold Card HB 14 (**January 1, 2025 & January 1, 2026**)

We need your help in 2025!



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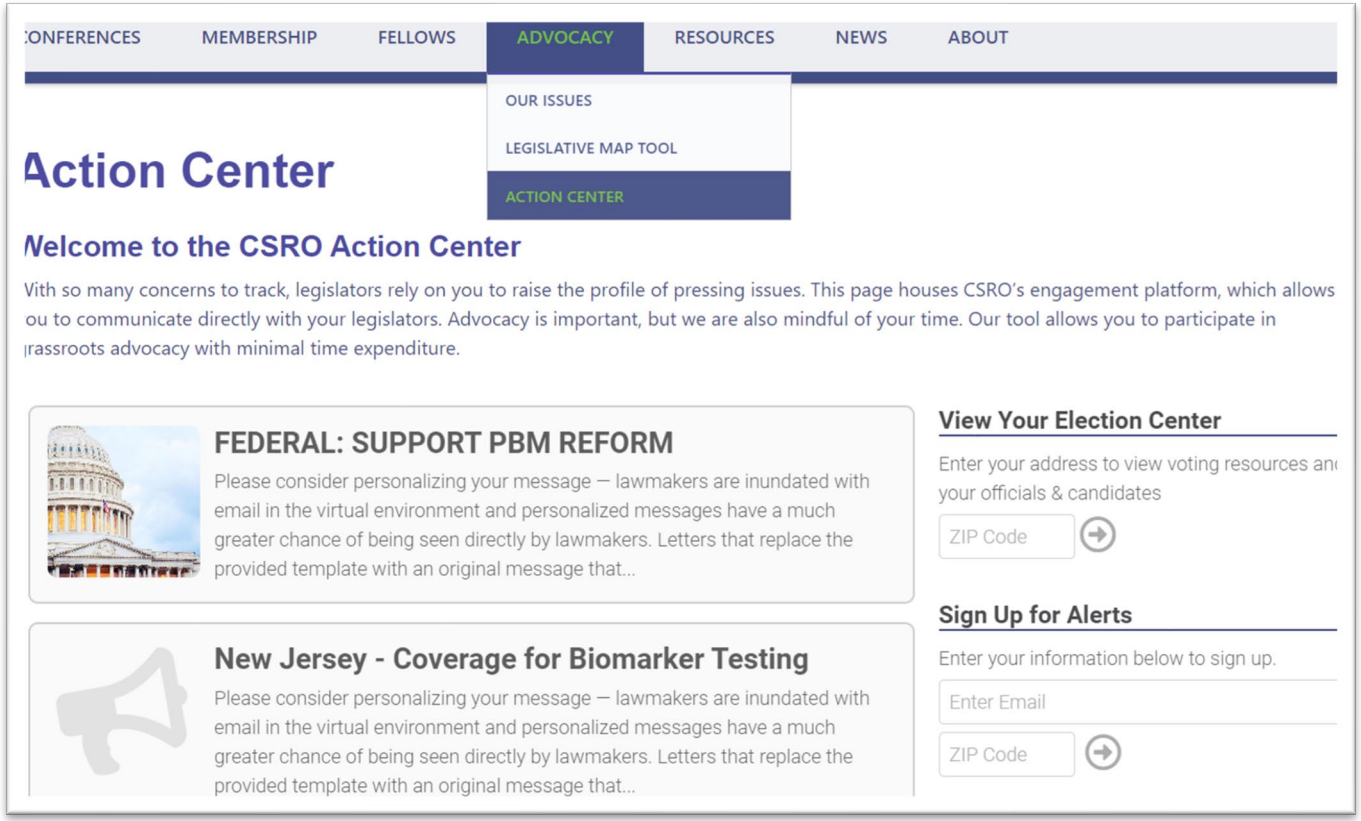
How can you help?

- CSRO Action Center
- Committee Testimony
- Op-eds
- Capitol Day



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