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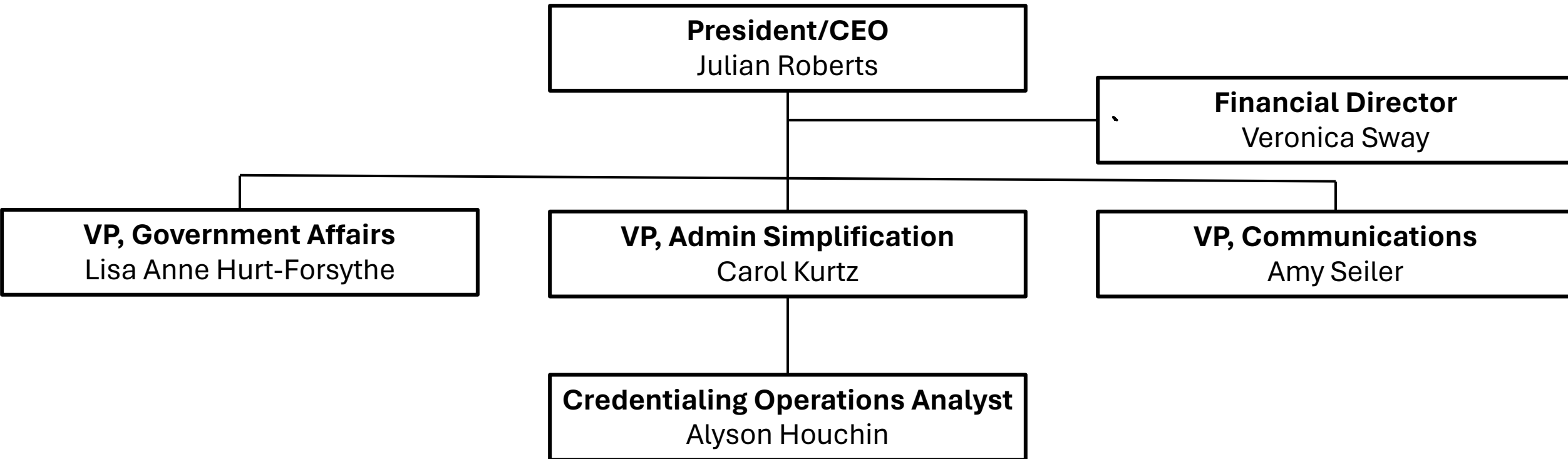
Focus Areas

ADVOCACY

COLLABORATION

**ADMINISTRATIVE
SIMPLIFICATION**

2024 Organizational Chart



Federal and State Update

Brought to you by:



Federal Update

Bob Wood
BGR Group



Overview

- Congressional Agenda
- Administration/Regulatory Update
- 2024 Elections



Congressional Agenda



Key Deadlines for 2024

September 30	Government funding bills
December 31	Community health centers
December 31	National Health Services Corps
December 31	Teaching hospitals
December 31	Disproportionate Share Hospital cuts
December 31	Physician payment bonuses expire
December 31	Medicare COVID telehealth flexibilities

Congressional Health Care Agenda

- Five key health care issues have advanced in the House and Senate:
 - Pharmacy benefit manager (PBM) reforms
 - Provider and payer transparency (House)
 - Privacy and cybersecurity
 - Physician payment reform
 - ERISA reforms

House Health Care Transparency Package

- In December, the House approved the Lower Costs, More Transparency Act (H.R. 5378) by a vote of 320-71, which includes PBM reforms, price transparency, hospital drug administration site-neutral pay, and extenders.
- It would require providers and insurers to disclose health care price information, require plans and PBMs to disclose negotiated drug rebates and discounts, establish site-neutral payments for physician-administered drugs, and end Medicaid PBMs from spread pricing.
- **Outlook:** Despite concerted efforts by the bill's champions, it was not included in the most recent package. Supporters are now looking to the lame duck to get these items across the finish line. Given the opposition and the separate effort in the Senate on PBMs, these reforms may stall but are likely to be picked up next Congress.

Senate PBM Reform Activity

- The Senate Health, Education, Labor, and Pensions (HELP) Committee, Senate Finance Committee, and Senate Commerce Committee have each advanced packages that include a variety of PBM reforms. They all include transparency requirements as well as more substantive reforms.
 - **HELP Committee:** Approved the Pharmacy Benefit Manager Reform Act (S. 1339), which would expand oversight and enforcement; ensure that PBMs remit 100 percent of rebates, fees, alternative discounts and other remuneration from drug makers; and increase transparency.
 - **Commerce Committee:** Approved the bipartisan Pharmacy Benefit Manager Transparency Act (S. 127), which would prohibit PBMs from engaging in spread pricing and reimbursement clawbacks and require PBMs to report annually to the FTC information about payments received from health plans and fees charged to pharmacies.

Senate PBM Reform Activity

- **Finance Committee:** Approved legislation that would increase transparency and restrict certain practices of PBMs. The Modernizing and Ensuring PBM Accountability (MEPA) Act (S. 2973) would prohibit PBM compensation in Medicare from being tied to the sticker price of a drug; increase transparency by creating independent audit and enforcement measures; and standardize pharmacy contract terms and metrics.
- **Outlook:** All three Senate reform bills are awaiting a vote on the Senate Floor. In early April, Senate Majority Leader Chuck Schumer (D-NY) outlined the Senate's upcoming agenda, which listed several priorities, but these PBM reforms were not included. Given the differences between the House and Senate packages, final enactment of a PBM reform package may be pushed to next Congress.

Health Care Privacy

- Advances with respect to generative AI, have resulted in increased Congressional attention on privacy.
- On April 7, Senate Commerce Committee Chair Maria Cantwell (D-WA) and House Energy and Commerce Committee Chair Cathy McMorris Rodger (R-WA) released a bipartisan draft data privacy bill. The draft legislation would:
 - Set clear national data privacy rights and protections
 - Establish enforcement mechanisms, including a private right of action
 - Authorize FTC to enforce privacy requirements, including those related to health information
 - Require business associates partnering with medical entities to comply with HIPAA
 - Allow individuals to opt out of a company's use of algorithms to make decisions about health care, credit opportunities, education, insurance, or access to places of public accommodation
 - Not preempt state laws and regulations that protect the privacy of health information, medical information, medical records and HIV status or testing
- **Outlook:** The Committee is expected to mark up the bill in May and supporters are pushing for passage in the lame duck. If the bill cannot clear the finish line this year, we expect this effort will pick back up next year.



Cybersecurity

- A recent cyberattack that led to a widespread outage impacting provider payments, claims processing, and coverage determinations has increased attention on the issue of cybersecurity.
- Several members of Congress have called for mandatory health cybersecurity requirements as well as payer and provider accountability as a result of the outage.
- The House Energy and Commerce Health Subcommittee held a hearing on cybersecurity. The hearing was focused on what needs to be done to secure sensitive health information and to protect the health care sector from disruption.
- The Senate Finance Committee is also planning on holding a hearing on the lessons learned from the cyberattack.
- **Outlook:** Congressional action seems unlikely in the near-term; however, this issue will continue to receive significant attention.

Physician Payment Reform

- In March, lawmakers struck a deal to mitigate a Medicare physician pay cut that went into effect in January. Congress agreed to reduce the 3.34 percent cut by roughly half, 1.68 percent. The payment was not retroactive, it covers March 9-December 31.
- During the debate on the second spending package, there was a significant push to include broader permanent Medicare physician payment reforms.
- Working groups have been established in both the House and the Senate on this issue.
- The Senate Finance Committee recently held a hearing on physician pay and how it affects the care of patients with chronic conditions, and Chair Ron Wyden (D-OR) said he wants to jump-start the debate on payment reform.
- Prominent physician lawmakers, Reps. Michael Burgess (R-TX) and Larry Bucshon (R-IN) have announced their retirements and would like to see Congress enact payment reform as a legacy issue.
- **Outlook:** A permanent fix faces some challenges given the Congressional calendar and the challenges around these issues. However, there is strong bipartisan support to limit further cuts.

ERISA Preemption

- In January, House Education and the Workforce Committee Chair Virginia Foxx (R-NC) announced efforts to strengthen the Employee Retirement Income Security Act of 1974 (ERISA) and released a RFI to seek feedback from stakeholders.
- The Education and Workforce Subcommittee on Health, Employment, Labor, and Pensions held a hearing to explore options to ensure employers can continue to offer uniform benefits across states lines, hold service providers accountable when they manage workers' premium dollars and data, and expand access to telehealth.
- **Outlook:** This is currently a Republican exercise, but staff has said they would like it to be bipartisan. The committee is considering legislation to strengthen and clarify ERISA preemption and if it can't get accomplished this year, they would pursue it next Congress.

Medicare Advantage

- MA enrollment is now 51% of the Medicare population.
- Bipartisan lawmakers are increasingly concerned with prior authorization denials and plan restrictions.
- In March, the HHS OIG released a report that found that 13 percent of prior authorization denials should have been approved. Other research has shown that over 80 percent of denials were overturned on appeal.
- There is also concern about how plans market themselves to beneficiaries, with some members going as far as to call the practices predatory.
- Additionally, several Democratic members of Congress have raised concerns that CMS pays plans on average 6 percent more per enrollee than what it would have cost in traditional Medicare. These members have called for the end to these “overpayments” and quality bonuses.

Regulatory Agenda

Regulatory Update

- Under divided government, when advancing legislation becomes more challenging, the Administration tends to rely on an aggressive regulatory agenda to achieve its policy objectives.
- The Biden Administration has announced several initiatives aimed at lowering health care costs and improving the quality of care.
- CMS has been working to implement the Medicare drug price negotiation process and ensure that Medicare plans comply with those prices.
- Additionally, the Administration is continuing to implement the No Surprises Act and has proposed changes to the mental health parity regulations.

MA and Part D Rulemaking

- **Prior Authorization:** In January, CMS released the Interoperability and Prior Authorization Final Rule, which requires MA, Medicaid and CHIP managed care plans, and Qualified Health Plans to streamline the prior authorization (PA) process. It requires plans to send PA decisions within 72 hours for expedited requests and 7 days for standard requests for medical services (starting in 2026). It also requires payers to provide a specific reason for denying a PA request.
 - CMS Administrator Chiquita Brooks-LaSure recently commented that the agency is thinking about ways to address PA for prescription drugs in the future.
- **MA and Part D Technical and Policy Changes:** CMS issued a final regulation updating rules for MA and Part D plans in 2025. CMS is putting new constraints on insurance broker compensation and limiting how third-party marketing organizations can share data. The rules also give more flexibility to Part D plans to make formulary changes mid-year when biosimilars come to market.

MA and Part D Rulemaking

- **Rate Announcement:** CMS issued the final Rate Announcement for MA and Part D for 2025. CMS is projecting that the finalized policies will result in a 0.16% decrease in expected MA plan payments in 2025.
- **Part D Redesign Guidance:** CMS released new guidance for Part D plans related to the major overhaul of the Part D program required by the Inflation Reduction Act (IRA). The IRA significantly redistributed the financial liability of the Part D program between the government, plans, and manufacturers.

MA and Part D Rulemaking

- **RFI on MA Transparency:** CMS released a RFI to solicit feedback on how best to enhance MA data capabilities and increase public transparency. Comments are due on May 29, 2024. CMS is seeking data-related input from the public related to all aspects of the MA program, including:
 - access to care
 - prior authorization
 - provider directories and networks
 - supplemental benefits
 - marketing
 - care quality and outcomes
 - value-based care arrangements and equity
 - healthy competition in the market, including the effects of vertical integration and how that affects payment

No Surprises Act Implementation

- The implementation of the Federal Independent Dispute Resolution (IDR) process had a rocky start and has been mired in litigation.
- Several of the regulations have been vacated, including the calculation for the qualifying payment amount (QPA).
- CMS said it has been swamped with claims. For the first six months of 2023, the number of disputed claims was 13 times higher than was initially estimated for the entire year.
- In August 2023, the IDR portal closed after a court vacated provisions in the rules. It was partially reopened in October for single disputes.
- On December 15, HHS, DOL, and Treasury announced that the federal IDR portal reopened to process all dispute types. The departments also granted extensions to the IDR deadlines.



No Surprises Act Implementation

- On December 18, the Departments released a final rule setting the fees for the federal IDR process. The administrative fee was set at \$115 per party and the certified IDR entity fee range of \$200-\$840 for single determinations and \$268-\$1,173 for batched determinations.
- CMS released data in February that found that IDR payouts to providers were well above Medicare and most in-network private insurance rates.
- Last week, HHS, Labor, and Treasury announced a new process by which the Federal IDR portal will send disputing parties a unique webform to resubmit disputes that were originally improperly submitted, instead of receiving a request from a certified IDR entity.
- CMS said this new resubmission process will be automated in the Federal IDR portal and will streamline Federal IDR operations.



Health Care Competition and Consolidation

FTC and DOJ

- **Proposed Changes to Premerger Notification Rules:** In June 2023, the FTC and DOJ announced proposed changes to the premerger notification form as well as the premerger notification rules implementing the Hart-Scott-Rodino (HSR) Act. The proposed changes would increase the amount of information that would need to be provided ahead of a merger and increase costs. The final rule has not yet been released.
- **New Merger Guidelines:** In December, the FTC and DOJ released new Merger Guidelines. The new guidelines include 11 principles that the agencies will use when determining whether a merger is unlawfully anticompetitive under the antitrust laws.
- **Enforcement Activity:**
 - FTC has taken action against a dialysis provider requiring the sale of certain facilities and requiring prior approval for mergers.
 - FTC and DOJ sued and eventually settled with a pharmaceutical manufacturer.
 - FTC has taken legal action against hospitals and major health systems across the country.
 - FTC has sued a large anesthesia provider group and its private equity partner over its alleged anticompetitive acquisitions.

Health Care Competition and Consolidation

FTC, DOJ, and HHS

- **RFI on Corporate Ownership in Health Care:** The RFI is requesting comments on deals conducted by health systems, private payers, private equity funds, and other alternative asset managers that involve health care providers, facilities, or ancillary products and services. The agencies are interested in how these types of market transactions may increase consolidation and generate profits at the expense of patients. Comments are due May 6.
- **Public Portal:** FTC, DOH, and HHS have announced the launch of a new online portal for the public to report concerns about anticompetitive behavior in health care markets.

HHS

- **Competition Office:** HHS announced the appointment of a Chief Competition Officer that will work with the FTC and DOJ to promote competition in health care markets.



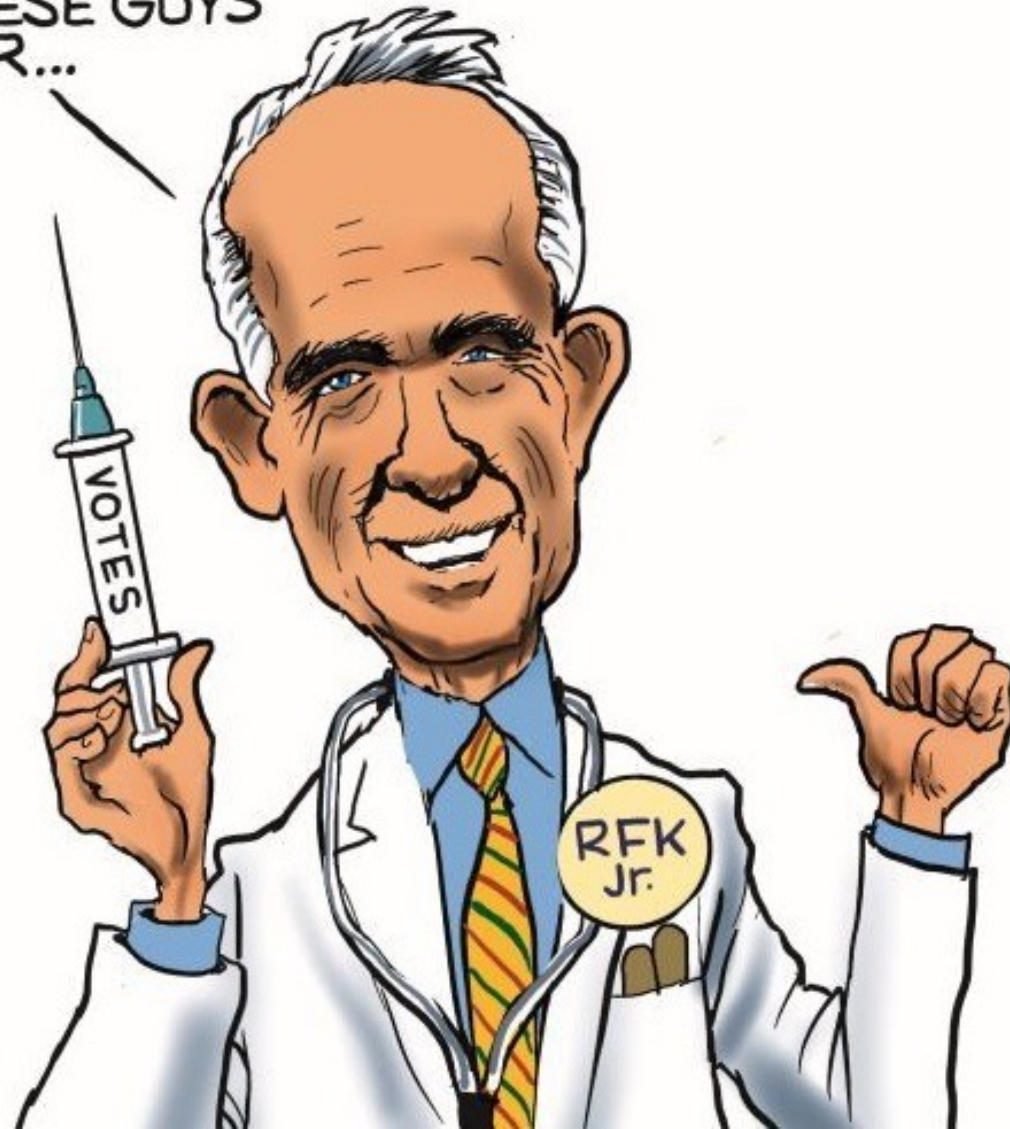
Mental Health Parity Proposed Rules

- In August 2023, DOL, HHS, and Treasury released proposed rules that amend regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).
- These rules focus on implementing the nonquantitative treatment limitation (NQTL) comparative analyses. These proposed rules:
 - Amend the existing NQTL standard to prevent plans from using NQTLs to place greater limits on access to mental health and substance use disorder benefits.
 - Require plans and issuers to collect and evaluate relevant data to assess the impact of NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits and sets forth a special rule with regard to network composition.
 - Set content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available.
- AAPAN submitted comments on the proposed rule.

2024 Elections



I'LL GIVE ONE OF THESE GUYS
A BOOSTER...



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Looking Ahead to 2024: National Landscape

- 2024 looks to be a rerun of 2020 (Trump/Biden) as well as a repeat of 2016, where the two most unpopular candidates are at the top of the ticket (Trump/Clinton).
- Polls show that the race for the presidency is tightening. Nationwide polling shows Trump leading Biden by one percentage point. Trump is leading in five states Biden won in 2020 (Arizona, Georgia, Michigan, Nevada, and Wisconsin). Biden is maintaining a slight lead in Pennsylvania.
- Out of the last 12 elections, 10 have been change elections where party control has switched in the House, Senate, or White House.
- On Inauguration Day in 2025, Biden would be 82 years old, and Trump would be 78.
- Third-party candidates, such as Robert F. Kennedy, Jr., Cornel West, and Jill Stein could play a role.
- With Donald Trump as the figurehead of the party, the GOP has experienced a number of reversals, starting with losing the White House, Senate, and House in 2020. Republicans have also had setbacks in states, losing legislative control in Michigan, Minnesota, and Virginia.

Key Political Dates:

~~January 15: IA GOP Caucus Trump win~~

~~January 23: NH Trump win~~

~~February 6: NV Trump win~~

~~February 24: SC Rep Primary~~

~~February 27: MI~~

~~March 4: Trump Federal Election Trial Start Date~~

~~March 5: Super Tuesday AL, AK, AR, CA, CO, IA (Dem),~~

~~ME, MA, MN, NC, OK, TN, TX, US, VT, and VA~~

~~March 7: State of the Union~~

~~March 12: GA, HI, MS & VA Primaries~~

~~March 20: Trump Appeal due on Carroll~~

~~April 15: Trump NY Hush Money Trial Start Date~~

May 20: MAL Classified Documents Trial begins

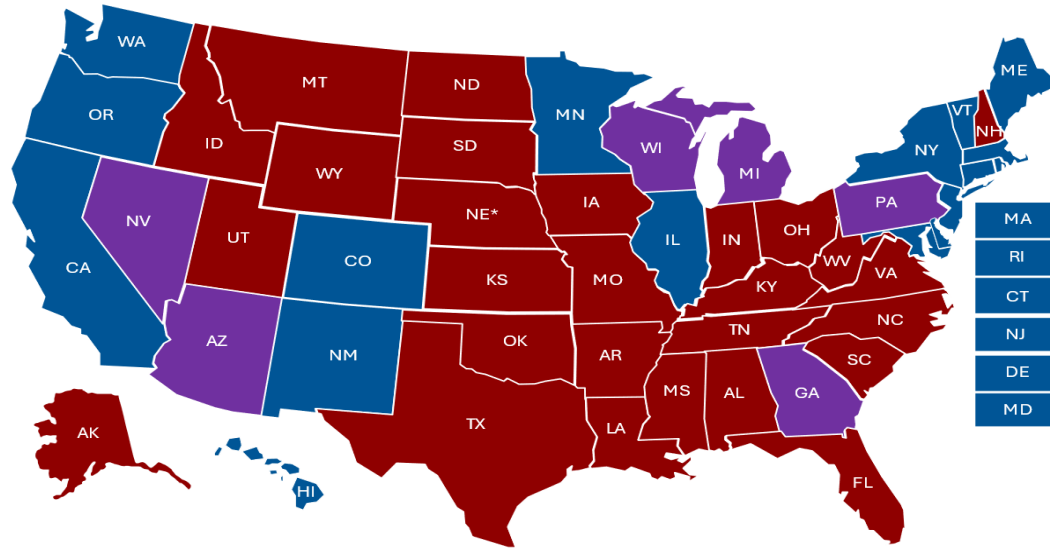
July 15-18: RNC Convention

August 5: Trump GA proposed trial start date

August 19-22: DNC Convention



Road to 270



PENNSYLVANIA

Electoral Votes: 19

TRUMP SAFE + PA = 254

NEED 16-> 270

BIDEN SAFE + PA = 245

NEED 25-> 270

NEVADA

Electoral Votes: 6

TRUMP SAFE + NV = 241

NEED 29-> 270

BIDEN SAFE + NV = 232

NEED 38-> 270

MICHIGAN

Electoral Votes: 16

TRUMP SAFE + MI = 251

NEED 19-> 270

BIDEN SAFE + MI = 242

NEED 28-> 270

GEORGIA

Electoral Votes: 14

TRUMP SAFE + GA = 249

NEED 21-> 270

BIDEN SAFE + GA = 240

NEED 30-> 270

ARIZONA

Electoral Votes: 10

TRUMP SAFE + AZ = 245

NEED 25-> 270

BIDEN SAFE + AZ = 236

NEED 34-> 270

WISCONSIN

Electoral Votes: 10

TRUMP SAFE + WI = 245

NEED 25-> 270

BIDEN SAFE + WI = 236

NEED 34-> 270

Congressional Races

Senate

- Current Senate Ratios: 51- 49.
- 34 Senate seats are up: 21 Democratic Seats, 11 Republican, and 3 Independents who Caucus with Democrats
- The Senate has flipped six times since the 1994 elections.
- Key Vulnerable Senators Include: Joe Manchin's open seat (D-WV), John Tester (D-MT), Sherrod Brown (D-OH), Kyrsten Sinema (I-AZ), Jacky Rosen (D-NV), and Tammy Baldwin (D-WI).
- New Senators in safe states will be elected in California, Delaware, Indiana, Maryland, Michigan, and Utah.
 - However, former Governor Larry Hogan (R) announced his bid for the Maryland Senate seat, instantly shaking up the race.
- Eight Senators have announced their retirements (5 D/3 R).

House

- Current Party Ratios: 218 Republicans to 213 Democrats (3 R/1 D vacancies).
- The House has flipped five times since the 1994 elections.
- 18 Republican seats are up in districts that Biden won. 12 of those are in CA, NJ, and NY.
- Democrats are defending 5 seats in districts Trump won.
- There are 22 toss-ups (11 R/11 D) races, according to the Cook Political Report.
- Forty-six House members have announced their retirements, are running for other office, or lost their primary (25 D/21 R).

Vulnerable Senate Seats

The following Democratic seats are up for reelection in states where either former President Donald Trump won by large margins in 2020 or was barely defeated by President Biden.



Retiring Senator Joe Manchin

West Virginia 2020: Trump +39



Incumbent Jon Tester (D)

Montana 2020: Trump +16



Incumbent Sherrod Brown

Ohio 2020: Trump +8



Incumbent Kyrsten Sinema (I)

Arizona 2020: Biden +0.3



Incumbent Tammy Baldwin

Wisconsin 2020: Biden +0.63



Incumbent Jacky Rosen (D)

Nevada 2020: Biden +2.4

2024 Innovation Retreat

Zachary Cook Esq., Senior Director



2024 Legislative Session

- States Adjourned Sine Die

- Arizona
- Florida
- Georgia
- Idaho
- Indiana
- Iowa
- Kansas
- Kentucky
- Maine
- Maryland
- Montana*
- Nebraska
- Nevada*
- New Mexico
- North Dakota*
- Oregon
- South Carolina
- Texas*
- Utah

*Did not meet this year

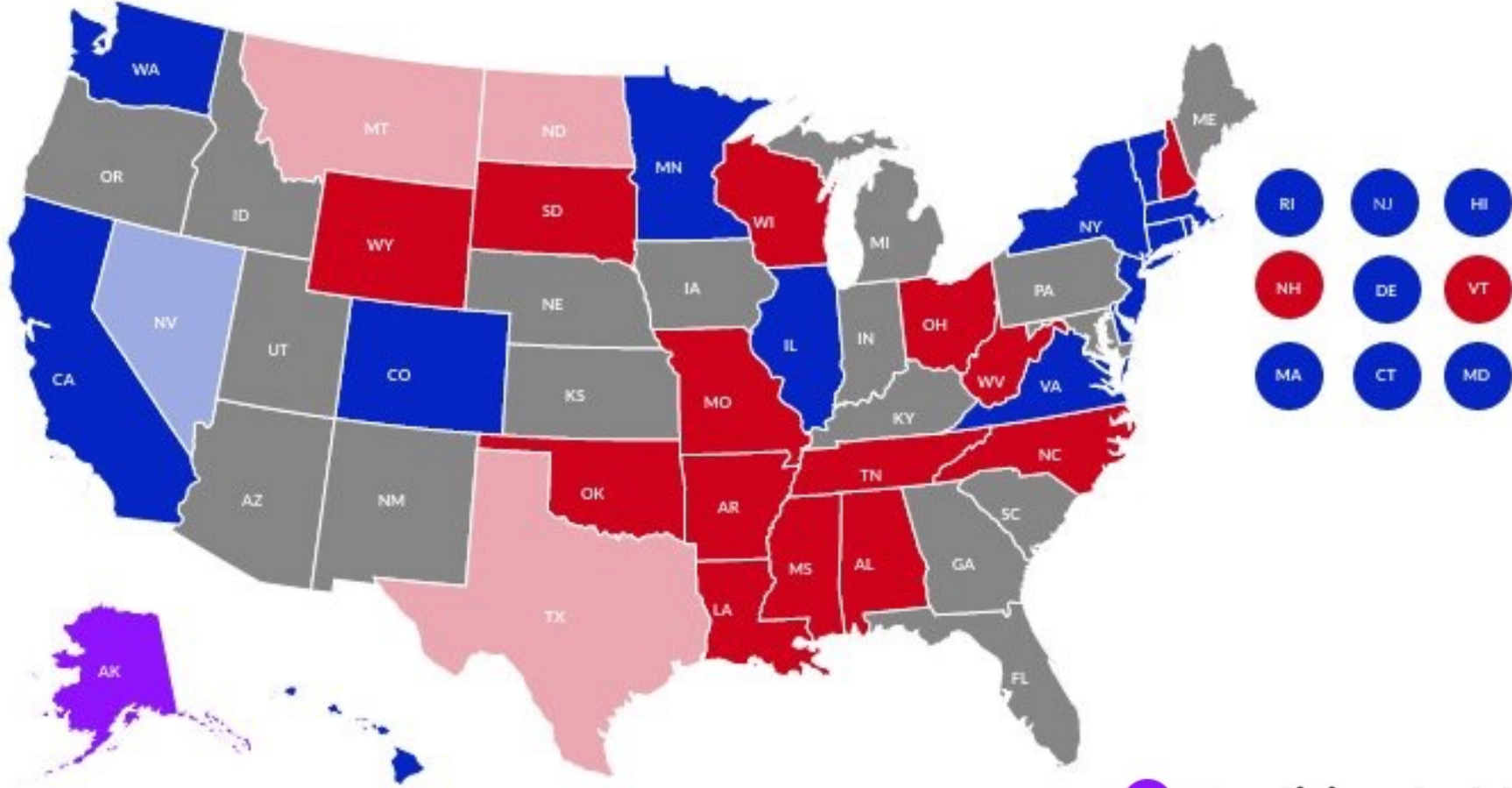
- States Still in Session

- Alabama
- Alaska
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Hawaii
- Illinois
- Louisiana
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- New Hampshire
- New Jersey
- New York
- North Carolina
- Ohio
- Oklahoma
- Pennsylvania
- Rhode Island
- South Dakota
- Tennessee
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming



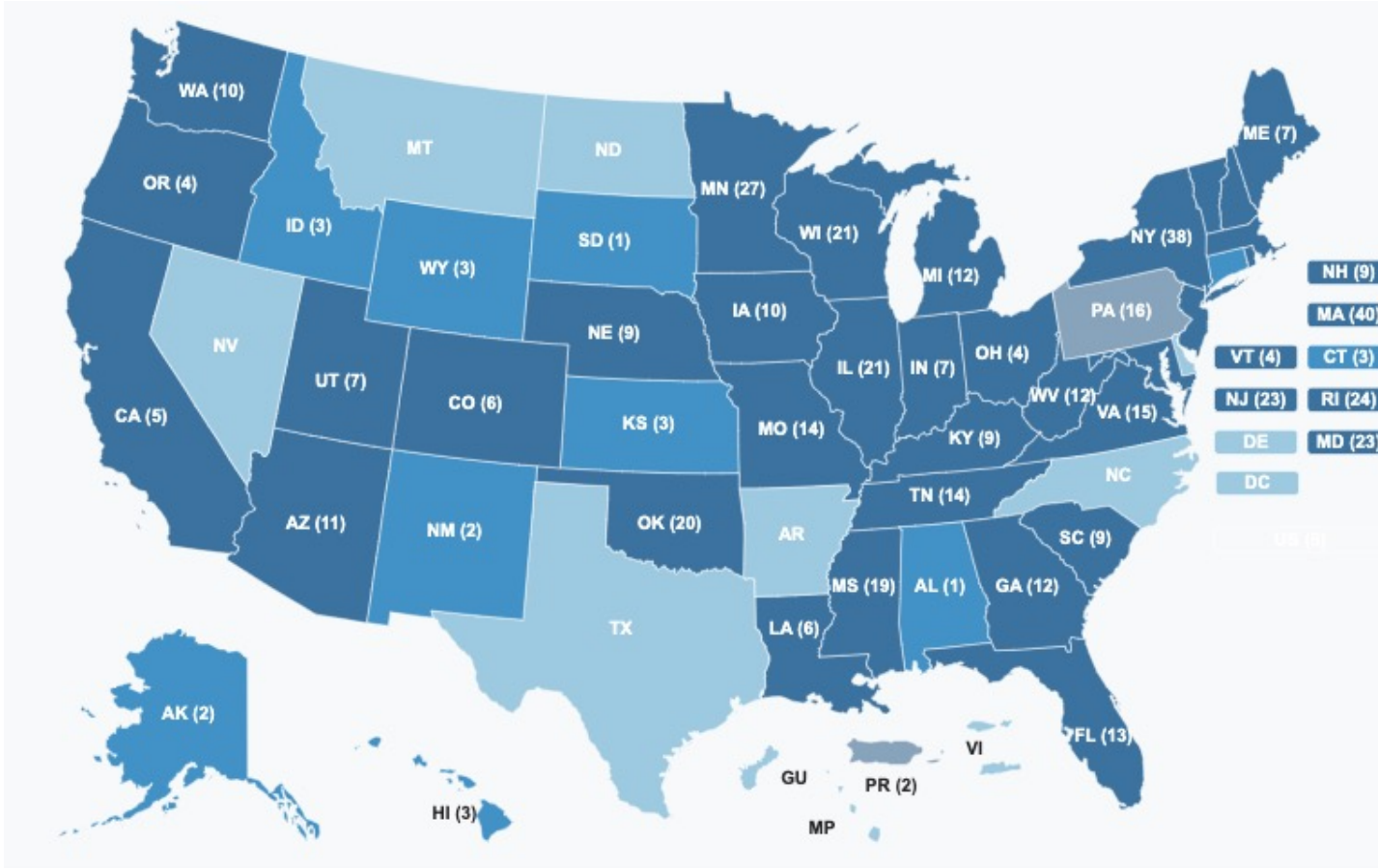
2024 Legislative Session Map

States holding legislative sessions are in bold colors



 **Coalition-held Chamber**

Legislative Trends and Movement



- We are currently tracking 3,433 bills.
- About 600 are bills that are priorities.
- These include:
 - WC Fee Schedules
 - PBM Issues
 - Pharmacy Issues
 - Direction of Care
 - Physician dispensing
 - Many others

Auto/PIP Work Group

- New Council Centered on Auto Issues
- Notable Trends Stateside has Encountered
 - Requirements for Insurance on Electric Bicycles
 - Minimum Liability Coverage Amounts
 - Insurance for Self-Driving Vehicles
 - Insurance Fees and Reimbursement Rates



California

- **Convened:** 1/3/2024
- **Adjourns:** 11/30/2024

Legislation & Rulemakings

Stateside monitored legislation and rulemakings with updates concerning workers' compensation:

- Legislation for coverage and benefits, provider directories, MPNs, and definitional changes
- Regulatory amendments for fee schedules, opioid guidelines, and qualified medical evaluators



New York

- **Convened:** 1/3/2024
- **Adjourns:** 6/6/2024

Legislation & Rulemakings

- PBM Rules
- A.1219 - WC Pharmacy Choice Bill
 - State Advocacy and Comments
 - Bill Sponsor Engagement



Oklahoma

- **Convened:** 2/5/24
- **Adjourns:** 5/31/24

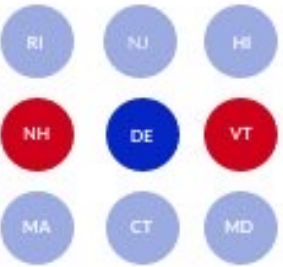
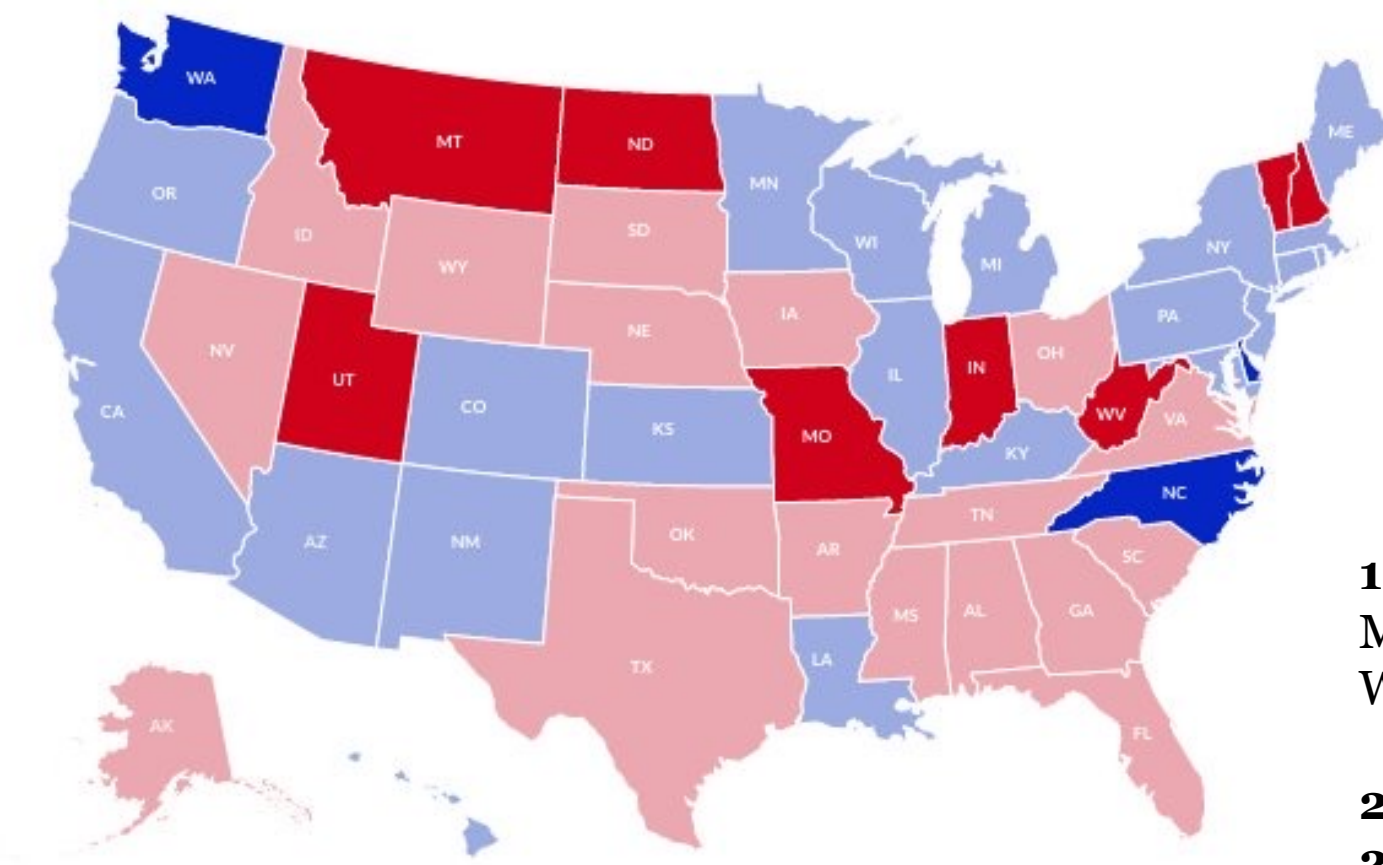
Legislation & Rulemakings

- Engaged with AG on WC compliance
- Achieved potential common ground



2024 Gubernatorial Election Map

States with elections are in bold colors

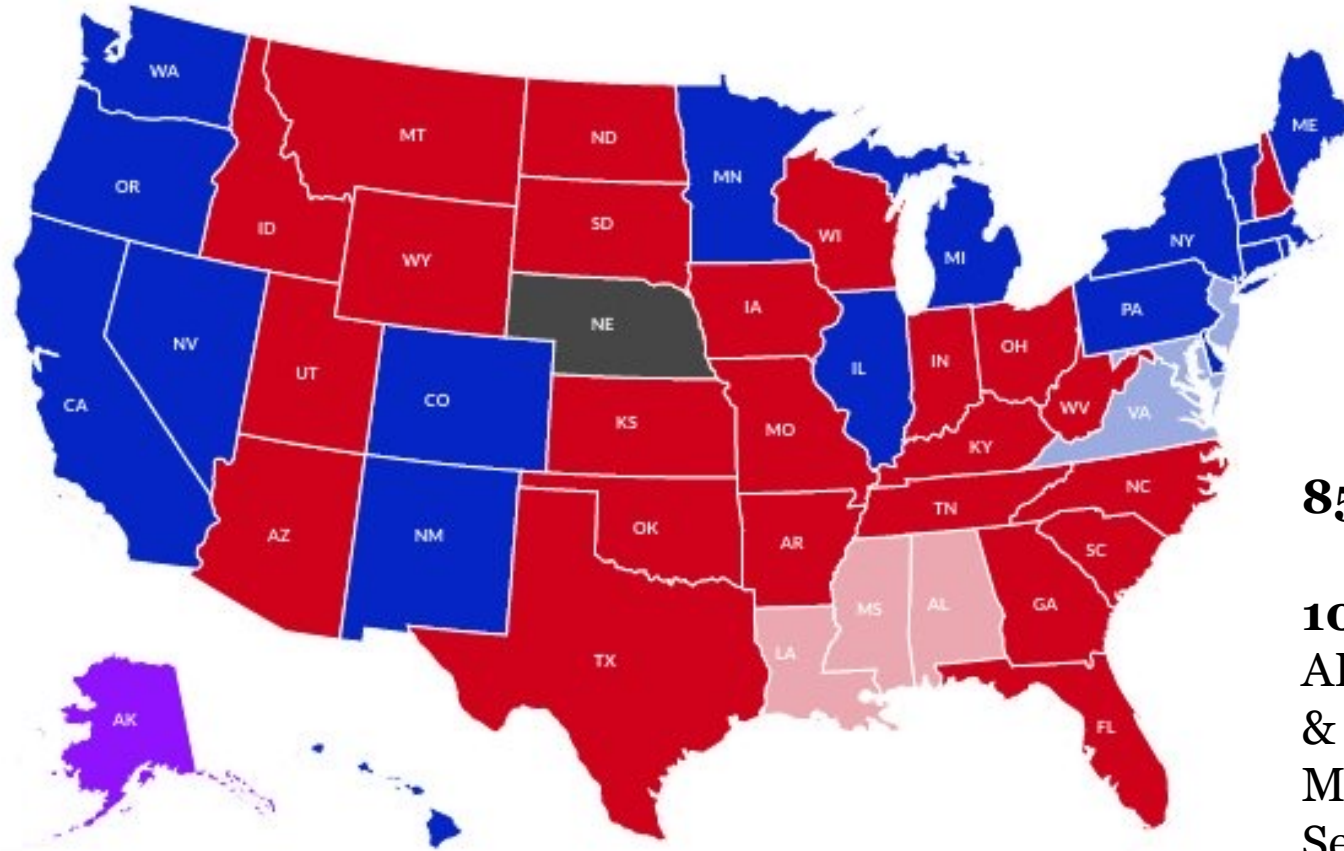


11 Races | DE, IN, MO, MT, NC, ND, NH, UT, VT, WA, WV

2 Competitive 2024 Contests | NH, NC

2024 Lower House Election Map

States with elections are in bold colors



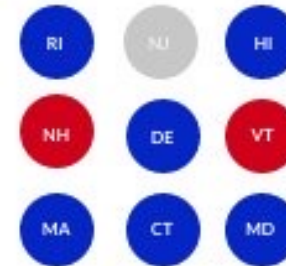
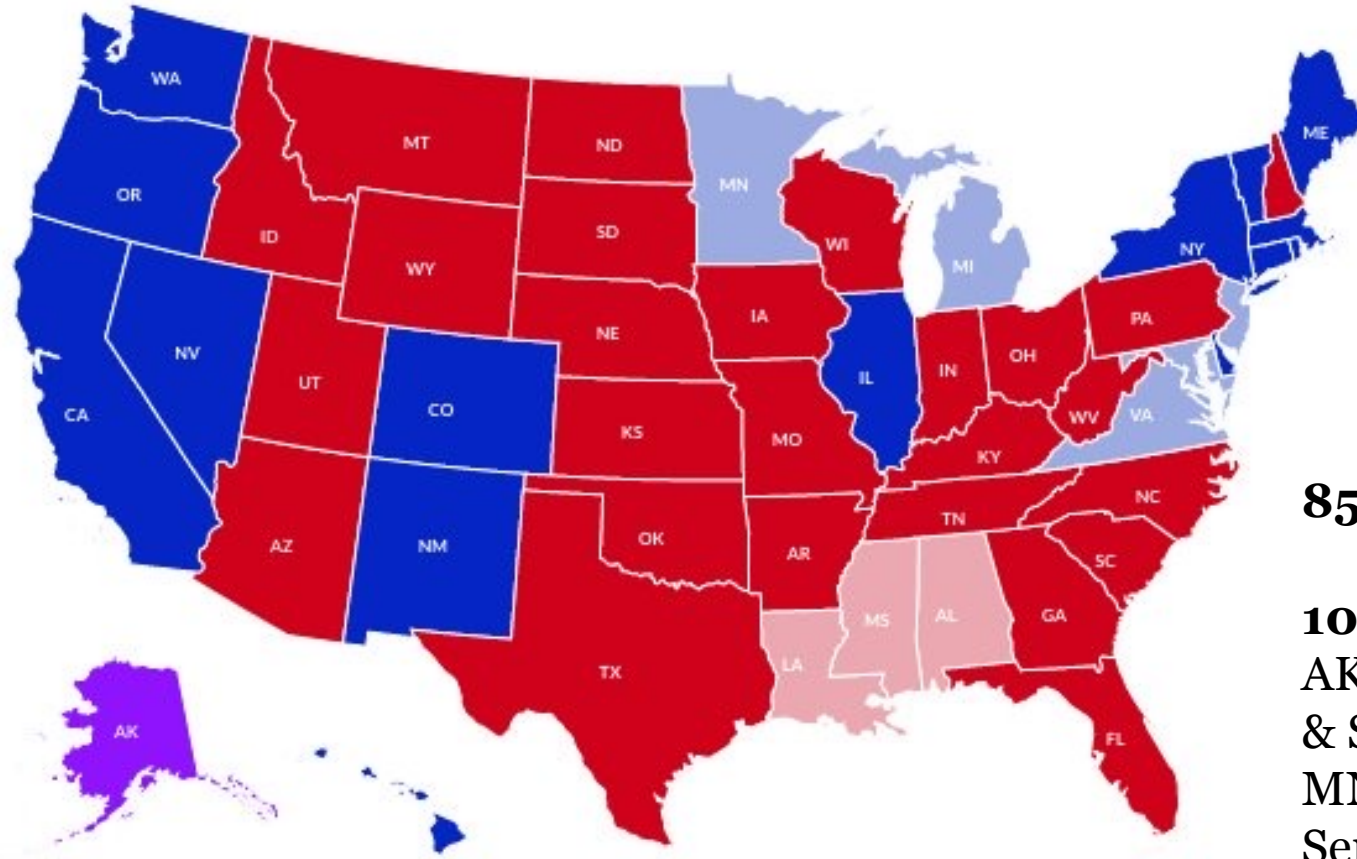
85 Chambers Up

10 Chambers Competitive |
AK House & Senate, AZ House & Senate, MI House, MN House, NH House & Senate, PA House & Senate

 **Coalition-held Chamber**

2024 Upper House Election Map

States with elections are in bold colors



85 Chambers Up

10 Chambers Competitive |
AK House & Senate, AZ House & Senate, MI House, MN House, NH House & Senate, PA House & Senate

Coalition-held Chamber