CSRO

CELEBRATING 20 YEARS

State Legislative & Policy Update

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Utilization Management Reform

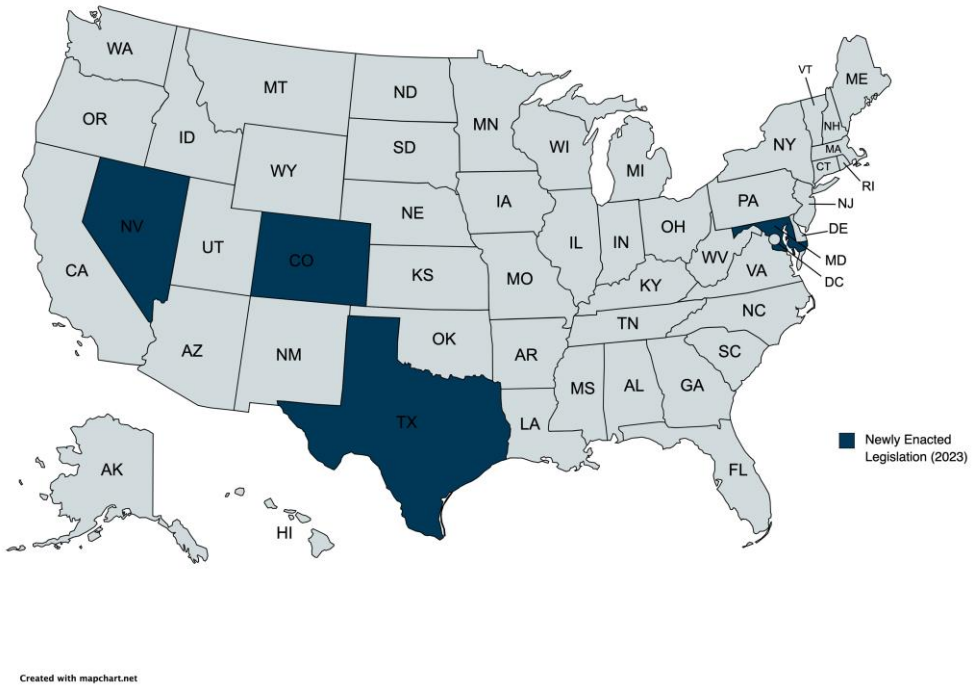
Step Therapy

Generally

- Provider can override a step therapy protocol under certain circumstances
- 24/72 hour determination timeframe (varies)
- Minimum evidentiary standard for creating a protocol

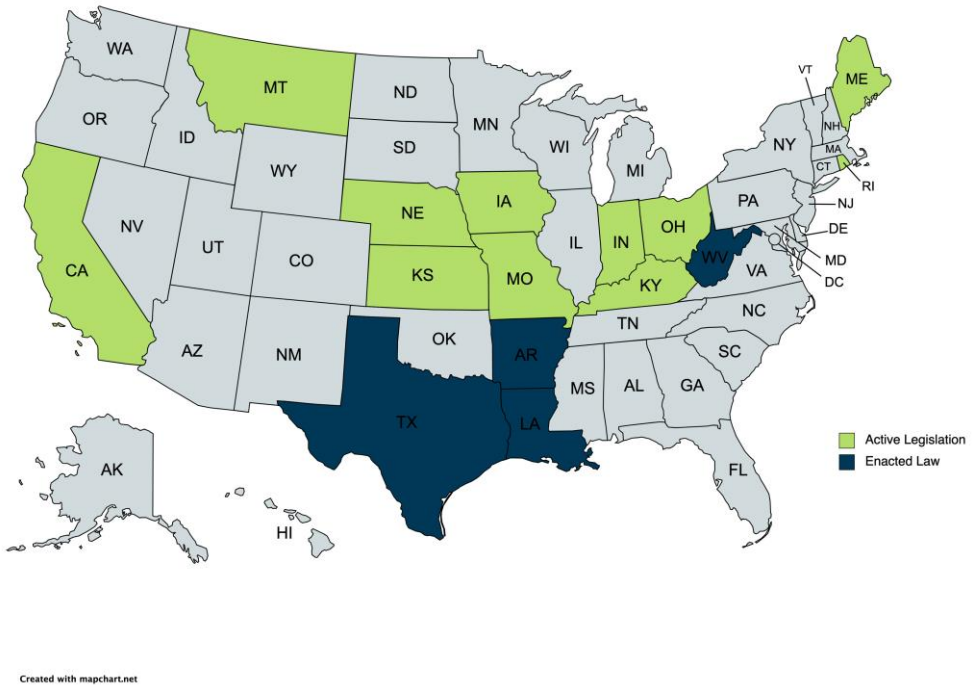
Key Challenges

- Awareness, use, application
  - CSRO Resources
  - New Education Campaigns
  - Interaction between



Prior Authorization – Gold Cards

- In general:
  - Exempts physicians from prior authorization requirements for a *specific service* if a certain percentage of authorizations are approved (80-95%) *for that service, for that insurer or health maintenance organization*
  - Requires peer to peer consultation *prior* to issuing a denial
  - Appeals process for inappropriate denial of exemption
  - Prohibition on retroactive claw backs on exempted physician services except in case of fraud



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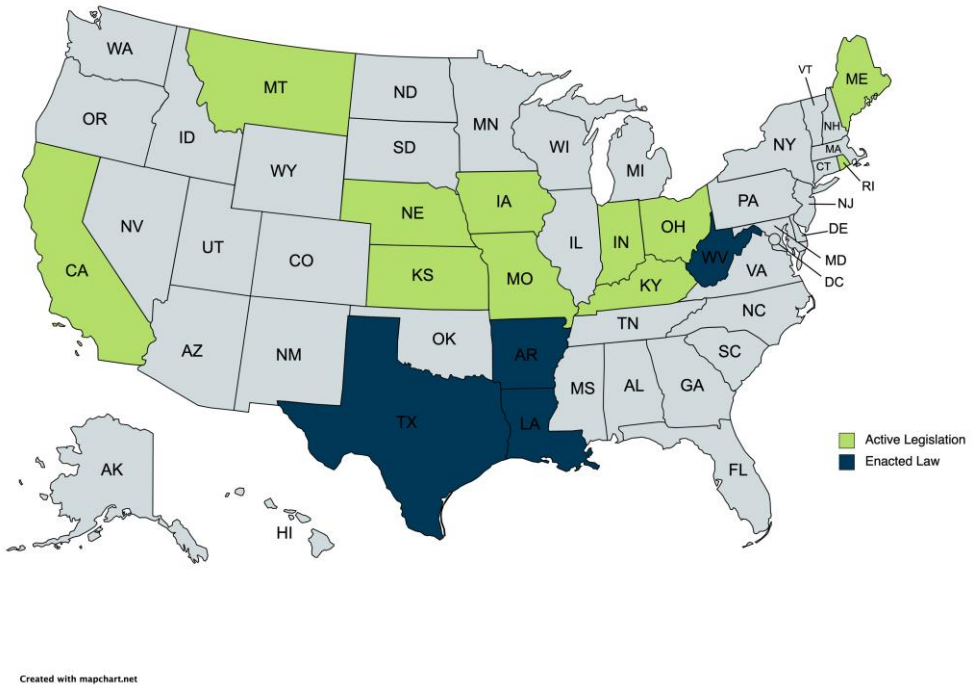
Prior Authorization – Gold Cards

Qualifying for an exemption:

- Initial determination: All requests analyzed, but no fewer than five
- Re-evaluation: Random sample of 5 – 20 requests from prior 6 months
- One provider cannot rely on another provider's exemption
- Consideration of practice level vs. individual physician or service grouping instead of individual service
  - Exemption based on drug class or by indication?



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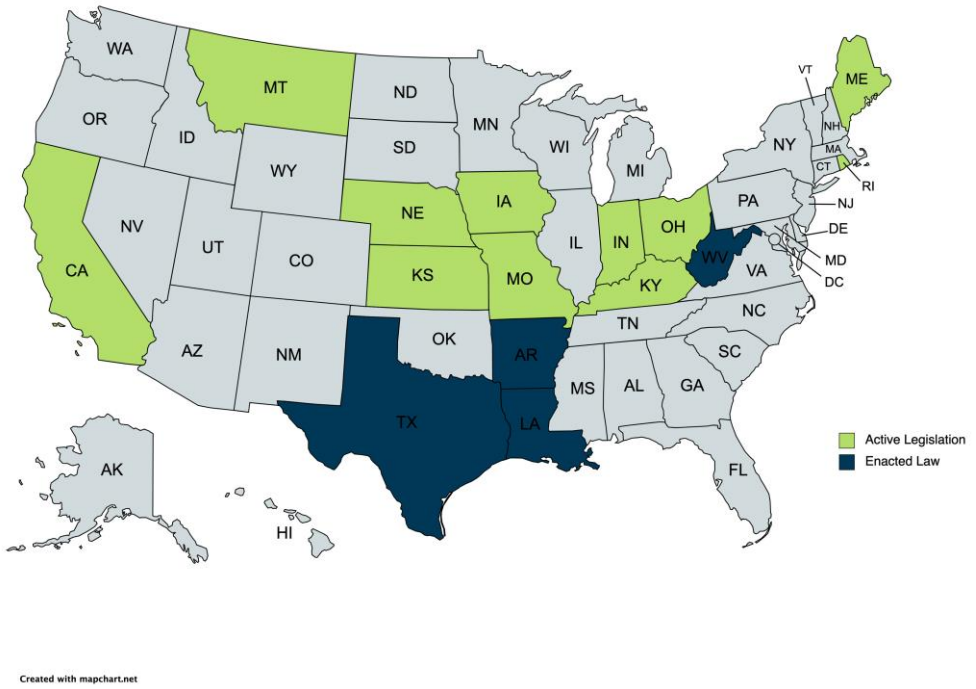
Prior Authorization – Gold Cards

CSRO Survey (TX):

- 88% did not receive any exemption
- Of those receiving an exemption:
  - 3/7: Did reduce burden
  - 3/7: Did not reduce burden
  - 1/7: Somewhat reduced burden
  - 4/7: keeping track of exemptions was itself burdensome
  - 7/7 lack of clarity on whether non-prior authorization utilization management was still required.

Key Challenges:

- Treatment interval, variety, volume
- Variety of insurers
- Tracking exemptions
- Concurrent utilization management requirements (step therapy)



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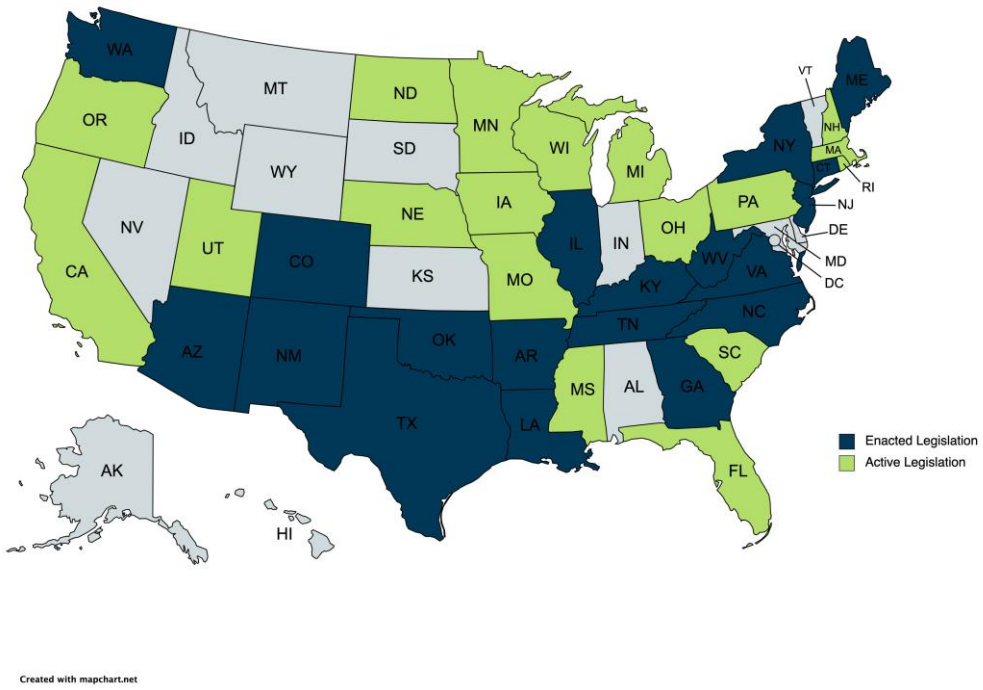
The War on Copay & Other Assistance

Accumulator Adjustment Programs:

- Payers: Not counting third party assistance towards a patient's deductible
- Key Challenges:
  - Patient OOP increases
  - Non-medical switching
- Policy:
  - Require insurers to count third party payments towards patient deductibles and other OOP obligations
  - Carveout for generics/interchangeable biosimilars
  - Carveout for HSS eligible HDHPs



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The War on Copay & Other Assistance

Maximizer Programs:

- Payers:
  - Ascertaining amount of copay assistance available
  - Altering patient benefits to conform to available assistance
  - Distributing new cost sharing obligations over the year
- Key Challenges:
  - Avoids copay “surprise”
  - Challenges sustainability of assistance programs
  - Increased patient OOP costs
- Policy:
  - Must close federal loophole, potential state level activity to fix

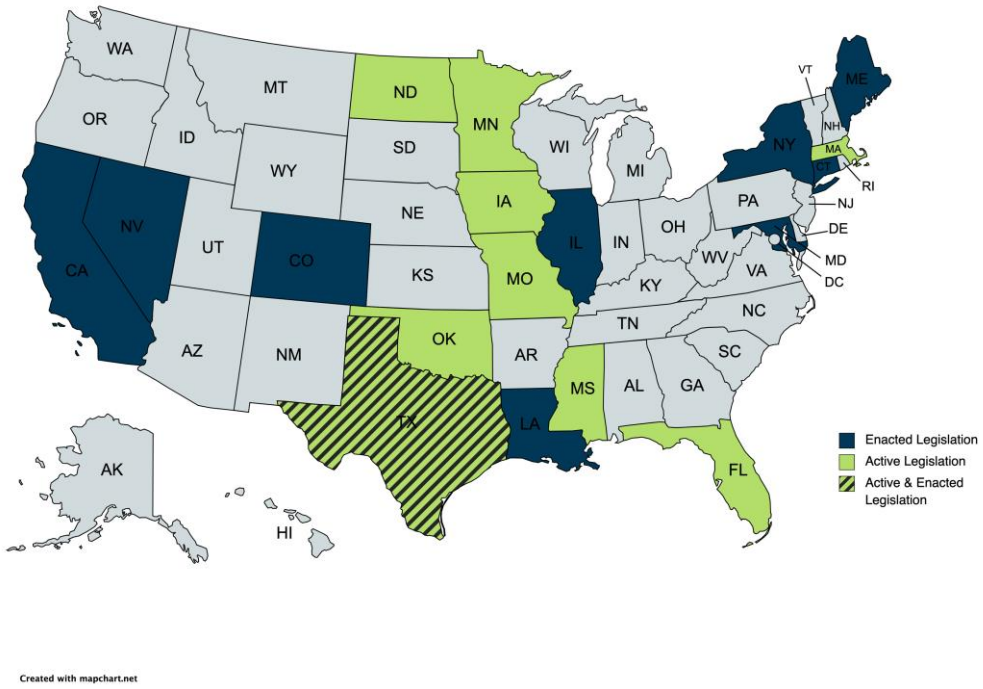
The War on Copay & Other Assistance

Alternative Funding Programs:

- Third Party Administrators:
  - Employer: carves out specialty drug(s) from coverage under plan
  - Third Party Administrators: apply for manufacturer or charitable foundation assistance to cover drug costs
  - Patient: may or may not receive assistance to cover drug cost
- Key Challenges:
  - Patient access/ OOP costs
  - Challenges sustainability of assistance programs
  - Drug importation
- Policy:
  - Potential legislation to prevent spillover of these programs
  - TX HB 4800 allowing Alternative Funding programs

Non-medical Switching

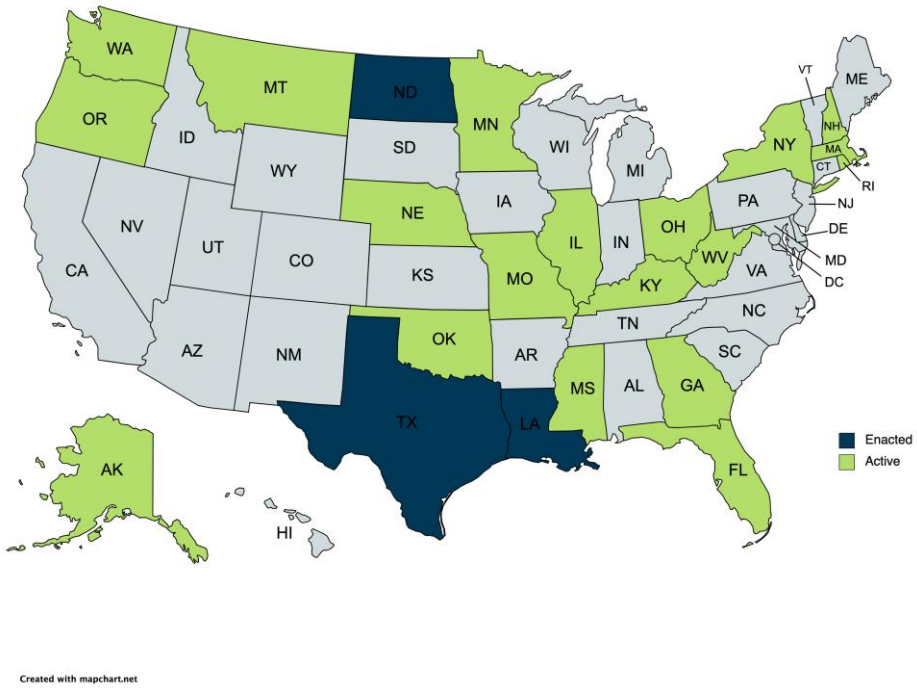
- Two policies:
  - Year-over-year (Grandfathering)
  - Mid-year switching protection



White Bagging

White Bagging

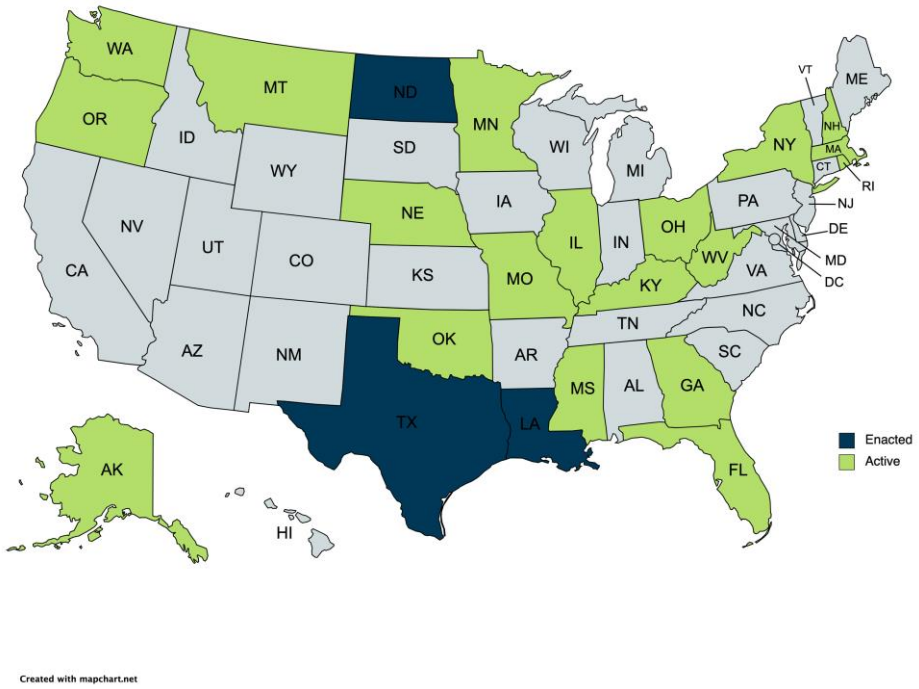
- Three main types of bills:
  - Safety and logistics guidelines
  - Protecting patient choice of provider, coverage, and OOP costs
  - Patient choice, coverage, OOP costs, authorization for service, provider reimbursement, prohibition on requirement to dispense from a selected pharmacy



White Bagging

Two new wins!

- North Dakota
- Texas:
  - Excludes hospitals
  - Prohibits switching from medical benefit to pharmacy benefit



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White Bagging

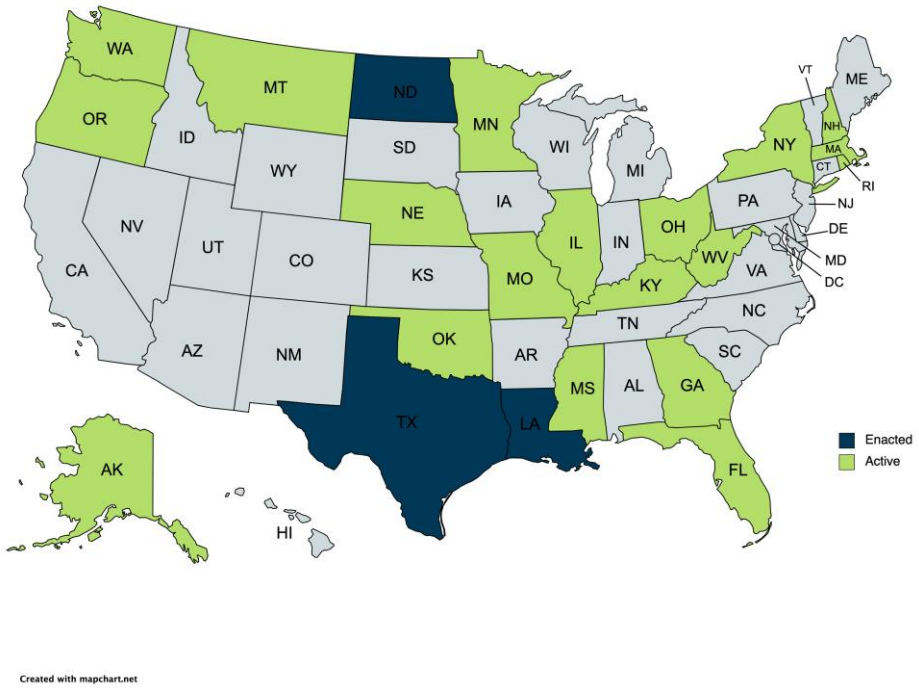
Additional policy evolutions:

New Hampshire:

- Reimbursement consistent with “similarly situated” network participants

Oregon:

- Choice between participating as a specialty pharmacy or accepting white bagging



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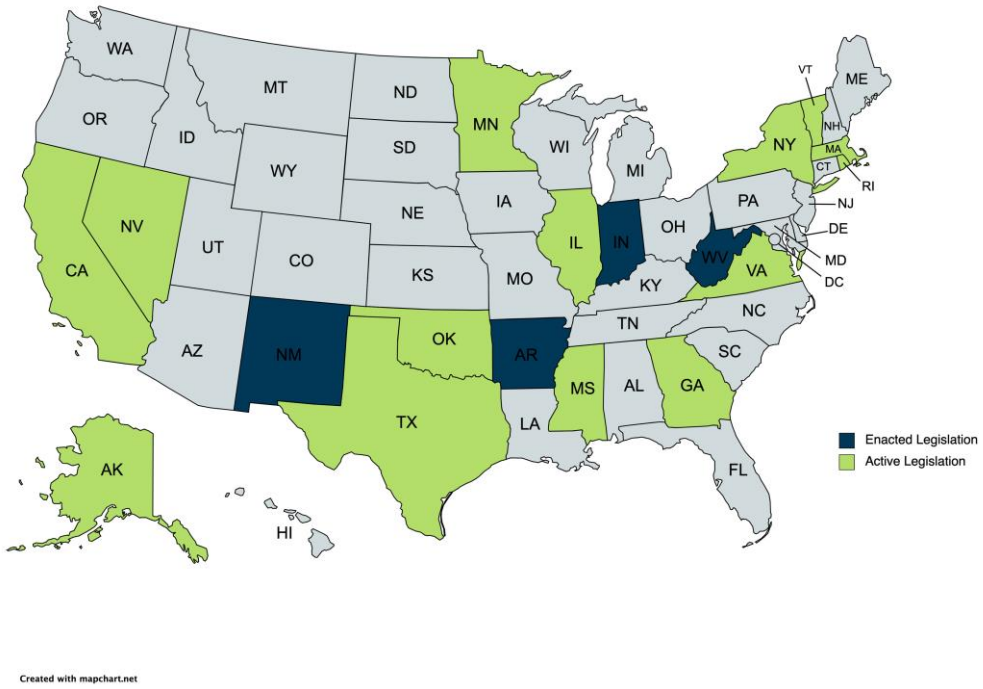
PBM Reform

Rebate Pass Through

Policy:

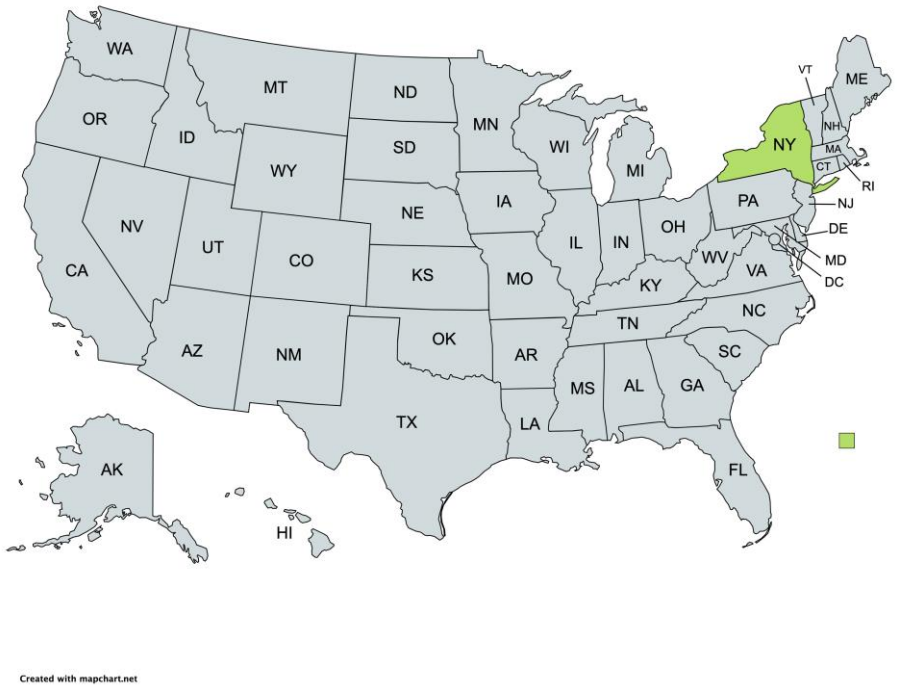
- Patient cost shares reduced by percentage of rebates received in conjunction with their utilization (50 -100%)
- Some legislation only requires pass through of rebates to plan sponsor/insurer



Transparency

New Policy Evolution:

- Legislation to extend transparency to PBM affiliated/owned organizations
- Rebate aggregators



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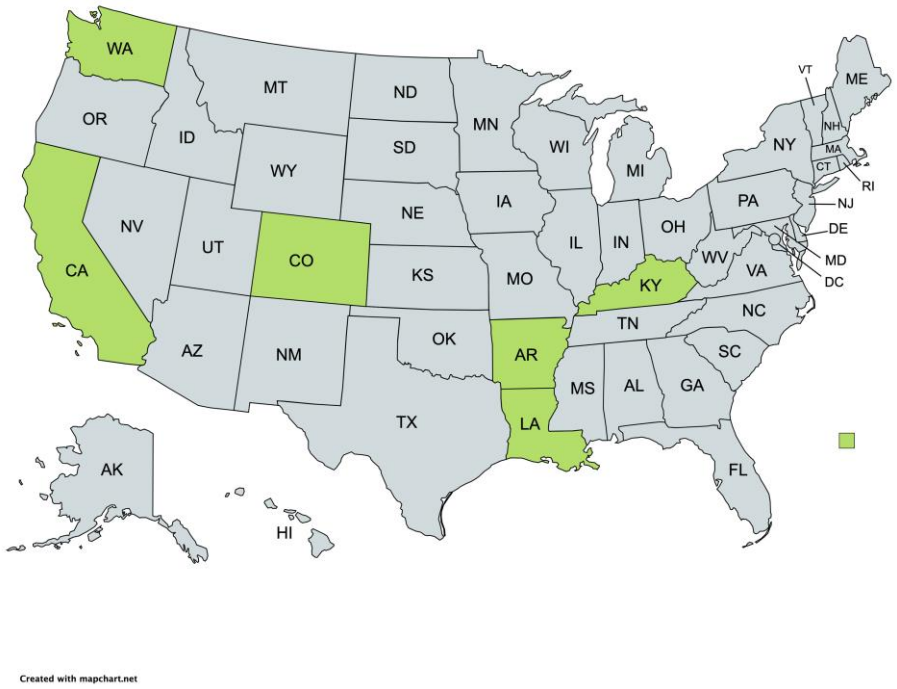
Biosimilars

Biosimilars

- Step Therapy
  - Allow insurer to require trial and failure of a non-interchangeable biosimilar product even when patient qualifies for an exception (stable provision)
- Pharmacy Level Substitution
  - Allow pharmacist to substitute non-interchangeable product
- Eliminate separate designations (Federal)
  - Automatically confer interchangeability status to all biosimilars



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Drug Affordability

Drug Affordability Boards

- Upper Price Limit
  - Limitation on both purchase and reimbursement for a prescription drug

- Maximum Fair Price
  - State imports MFP negotiated by federal government
  - Provider cannot seek reimbursement at a rate higher than the MFP
  - MFP *does not* include administration payment

Biomarker Testing

Biomarker Testing

- Coverage of a biomarker test required under certain circumstances:
  - CMS or MAC NCD or LCA
  - Nationally recognized clinical practice guidelines
  - Labeled indications