



# AMCP

Optimizing medicine.  
Improving lives.

## AMCP Legislative & Regulatory Briefing

**November 17, 2021**

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# Presenters



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AMCP

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# Federal Legislation

# Bipartisan Infrastructure Framework

- H.R.3684, Infrastructure Investment and Jobs Act
- \$1.2 trillion w/ \$550 billion in new spending over 5 years
- Passed Senate 69-30 & House 228-206
- President Biden signed into law Nov. 15
- Health Care Offsets
  - Sequester (\$21b/10 years) – restores 2% cut through 2031
  - Rebate Rule (\$52b) – effective date delay to 2026
  - Vial Size (\$3.2b) – beginning in 2023, requires drugmakers to refund Medicare quarterly for unused medication in single-dose/single-use packages under Part B outpatient
  - COVID Relief (\$210b) – repurposes unused relief dollars

# Build Back Better Act (BBBA)

- \$1.75 to \$1.85 trillion/10 years
- White House framework (10/28) + House legislative text (11/2)
- Health Care Provisions (as of 11/16)
  - Medicare hearing coverage
  - Premium reduction for ACA coverage (\$600/person for 9 million covered)
  - Home and community-based services investment
  - Closes “Medicaid gap” by expanding coverage to 4 million under ACA
  - Medicare Part D redesign
  - Questionable
    - PBM transparency
    - Rebate rule pass through
    - Rx price reforms

# The NOVEL Act

- The New Opportunities for Value that Extend Lives Act (S. 2416)
- Bipartisan bill designed to speed patient access to certain novel therapies by allowing manufacturers to apply for an HCPCS code as soon as the therapy receives breakthrough designation
- Requires CMS to begin the coverage determination process for these therapies as soon as they receive an HCPCS code

# 21<sup>st</sup> Century CURES 2.0 Act

- Provisions
  - Long COVID research & future pandemic response
  - Patient/caregiver education; clinical trial diversity & standards
  - FDA: digital and novel therapies; real-world evidence; accelerated approval pathway
  - CMS: telehealth and breakthrough therapies; reporting; access and coverage
  - Creates ARPA-H
- AMCP's recommendations
  - § 303 (cell and gene therapies): include language codifying FDA's 2018 guidance on pre-approval information exchange (PIE)
  - § 309 (confirmatory studies for accelerated approval): incentivize confirmatory study completion through higher rebate penalties or sunseting authorization
  - § 404 (breakthrough devices): create a benefit category for prescription drug digital therapeutics, allowing Medicare coverage



# Provider Status Bill

- Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 2759/S.1362)
- Adds pharmacists to the list of providers whose patient care services, when delivered to patients in medically underserved communities, are covered by Medicare Part B
- Ensures pharmacists are fairly compensated for the patient care they provide to beneficiaries in underserved areas

# Government Funding & Debt Ceiling

- Continuing Resolution to fund government at current levels through Dec. 3, 2021
- Debt Ceiling
  - Temporarily raised through Dec. 3\*
  - Republicans want Democrats to raise via reconciliation
  - Failure to raise = federal default (& economic catastrophe)
  - Combined funding & debt ceiling showdown in Congress come December

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# Federal Regulation

# Medicare Coverage of Innovative Technology (MCIT)

- Proposed establishing a coverage pathway for new, innovative medical devices approved by FDA, granting Medicare beneficiaries faster access to breakthrough technologies (Nov. '20)
- Proposed repeal (Sept. 13)
- Final rule repealing MCIT (Nov. 12)
- CMS committed to future efforts to accelerate approval of innovative technologies, including DTx
  - Future pathway should not focus on breakthrough designation
  - Ensure adequate safety protections
  - Improve data standards on device benefit for Medicare population
  - Incentivize generating new evidence

# Biosimilars

- On Oct. 15, FDA approved first interchangeable biosimilar monoclonal antibody for immunosuppressant, Humira®
  - Because of its designation as interchangeable, product may be substituted for the reference product at the pharmacy counter, without intervention of the prescriber
- All 50 states have laws allowing for pharmacy-level substitution of interchangeable biosimilars

# Drug Importation

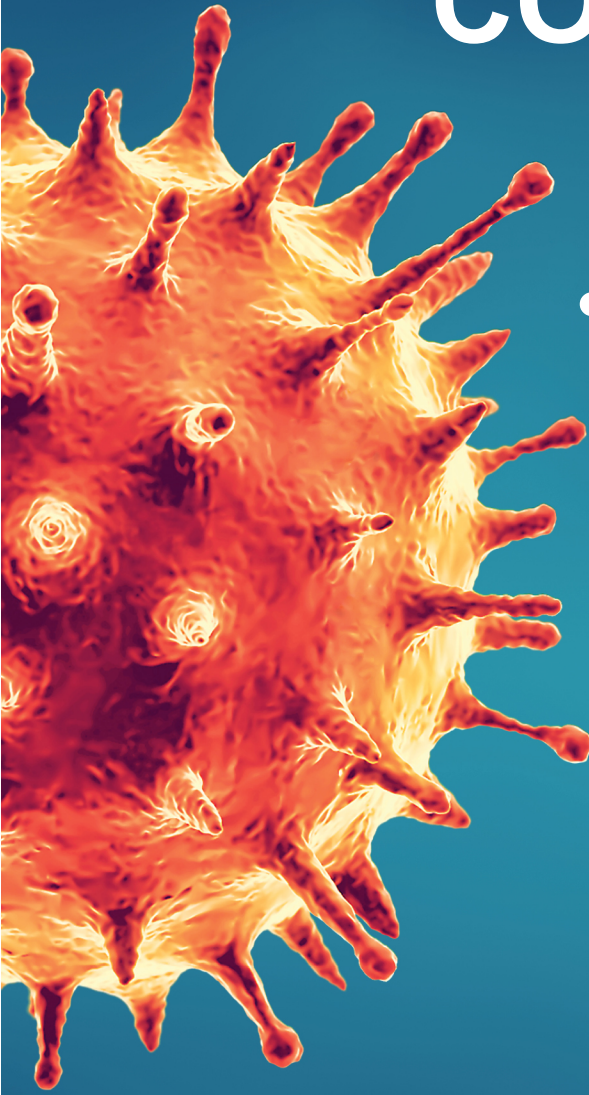
- FDA Issued Final Rule in Sept. 2020 permitting FDA-authorized programs to import specific drugs from Canada
  - Importation plans would be administered by states or Indian tribes after authorization by the FDA and would specify the drugs eligible for importation
- Colorado, New Mexico, Florida, Maine, Vermont, and New Hampshire have submitted importation plans for approval
  - None have been approved at this point
  - Numerous other states have introduced legislation to create importation programs
- Biden administration has been supportive of drug importation, but it is unclear how it will proceed on these state importation plans

# HHS Comprehensive Plan for Addressing High Drug Prices

- Released Sept. 9<sup>th</sup>
- Guiding principles for drug pricing reform: make drug prices more affordable and equitable, promote competition throughout prescription drug industry, foster scientific innovation
- Potential actions
  - Legislation authorizing CMS to negotiate prescription drug prices in Medicare Parts B and D
  - Legislation speeding entry of biosimilar and generic drugs
  - CMMI models to test using value-based payments for Part B drugs



# COVID Rules & Regulations

- 
- Under PREP Act authority, HHS has permitted pharmacists/pharmacies to:
    - Order and bill Medicare for COVID testing
    - “Order vaccine”
    - Administer vaccine
    - Administer COVID post-exposure prophylaxis
    - Preempts state laws that would effectively prohibit this



# Dr. Robert Califf Nominated as FDA Commissioner

- Served as FDA Commissioner in former President Obama's final year (February 2016 to January 2017)
  - Confirmed by Senate 89-4
  - Democrats Manchin, Blumenthal, Markey, and Ayotte opposed
- Previously Deputy Commissioner of the Office of Medical Products and Tobacco at FDA
- Cardiologist by training with pharmaceutical research background



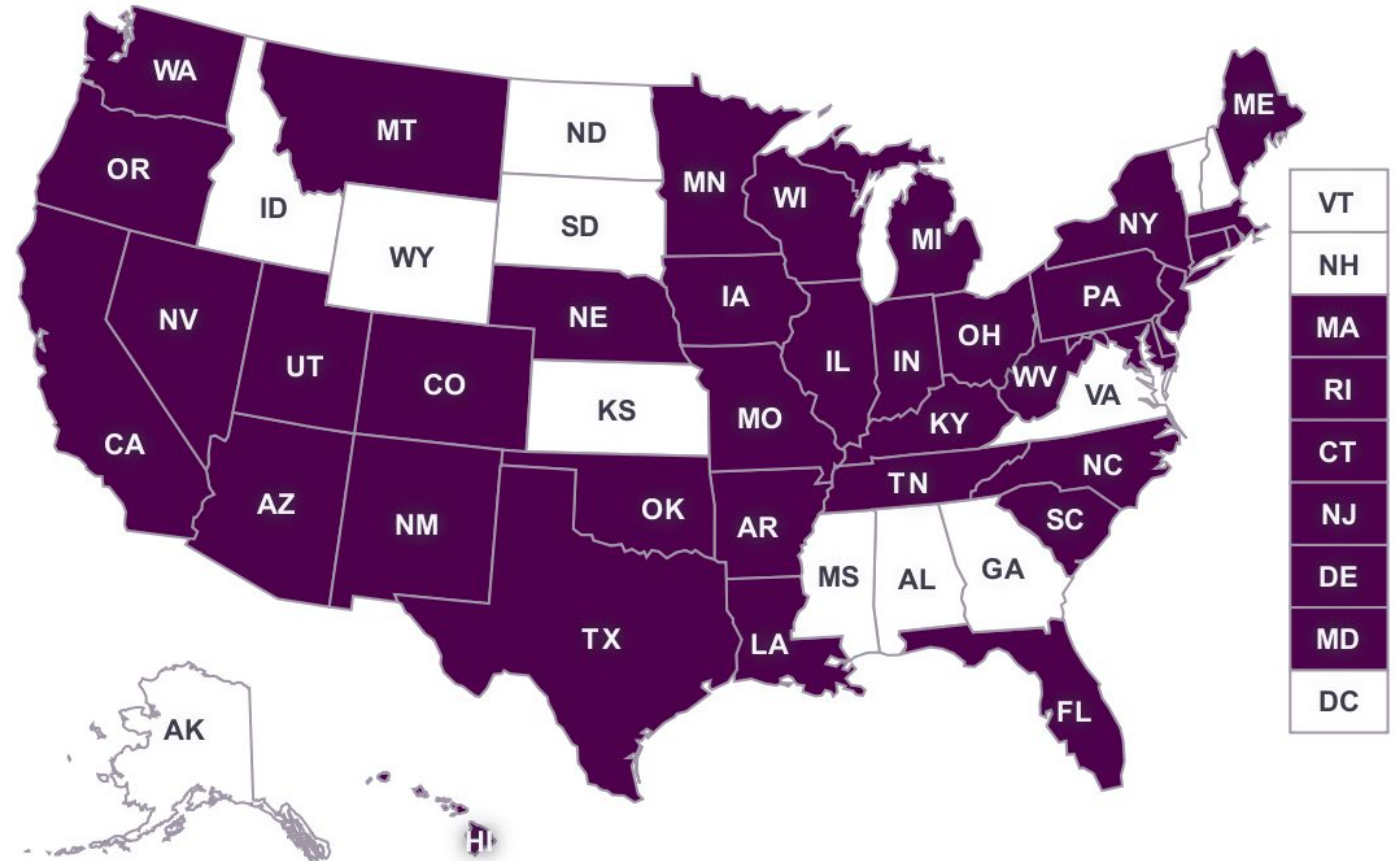
# State Affairs

# State Priorities

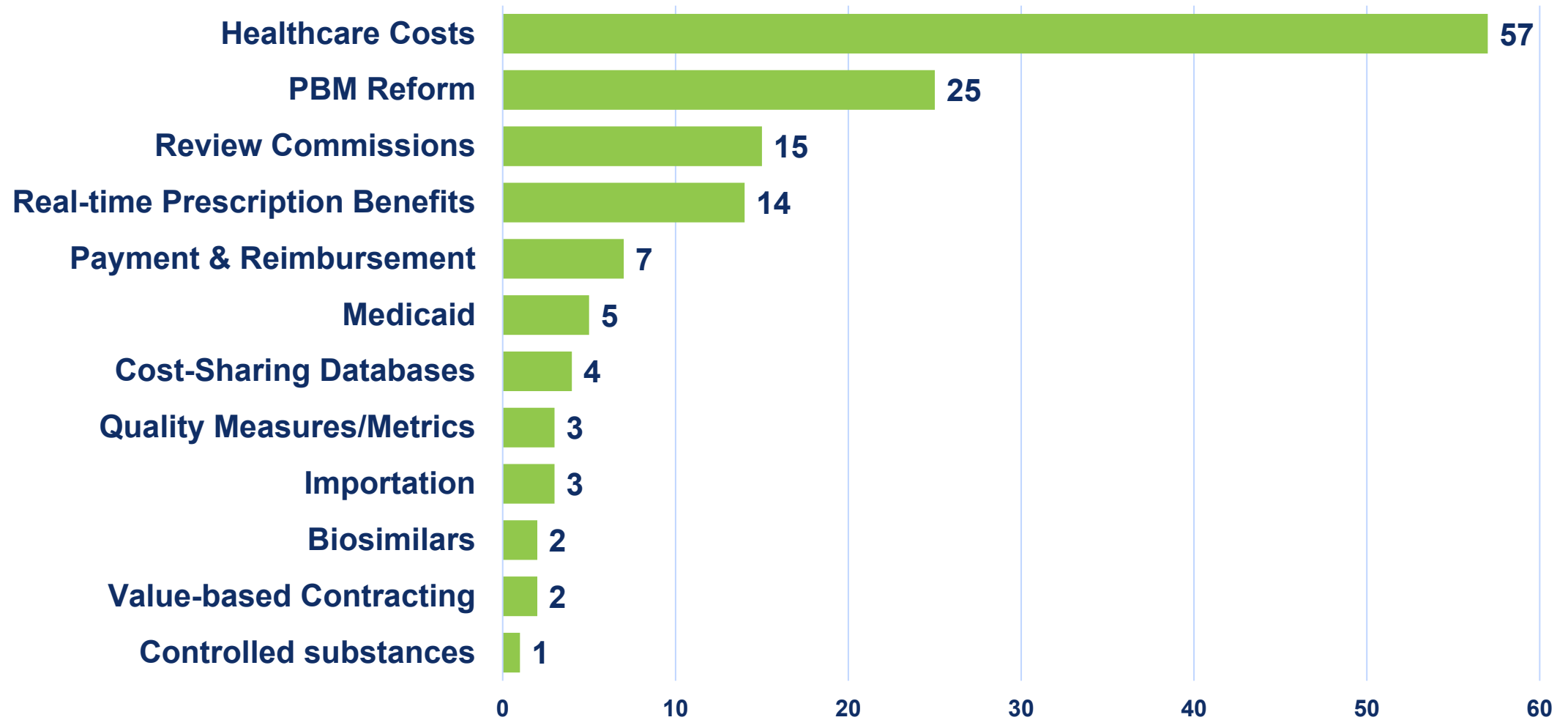
- Promote meaningful transparency on drug pricing and patient cost-sharing
- Advocate for the development of clear metrics to shift pharmaceutical payments to value-based care
- Encourage data sharing and interoperability of electronic health records
- Promote AMCP's position on formulary requirements, tier restrictions, and coverage mandates
- Support the use of managed care tools

# Pricing Transparency

Legislation  
introduced  
in 38 states

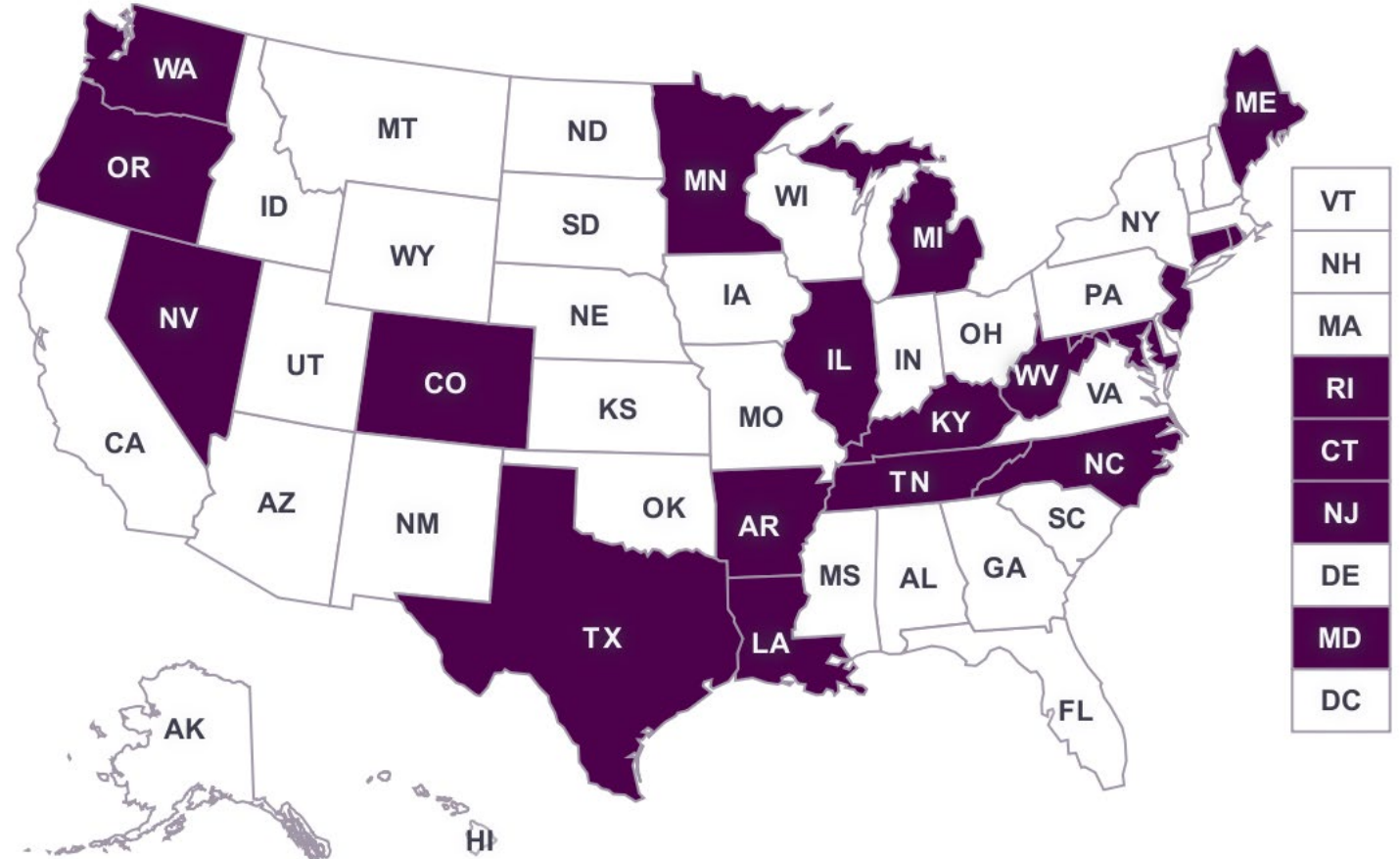


# Pricing Transparency

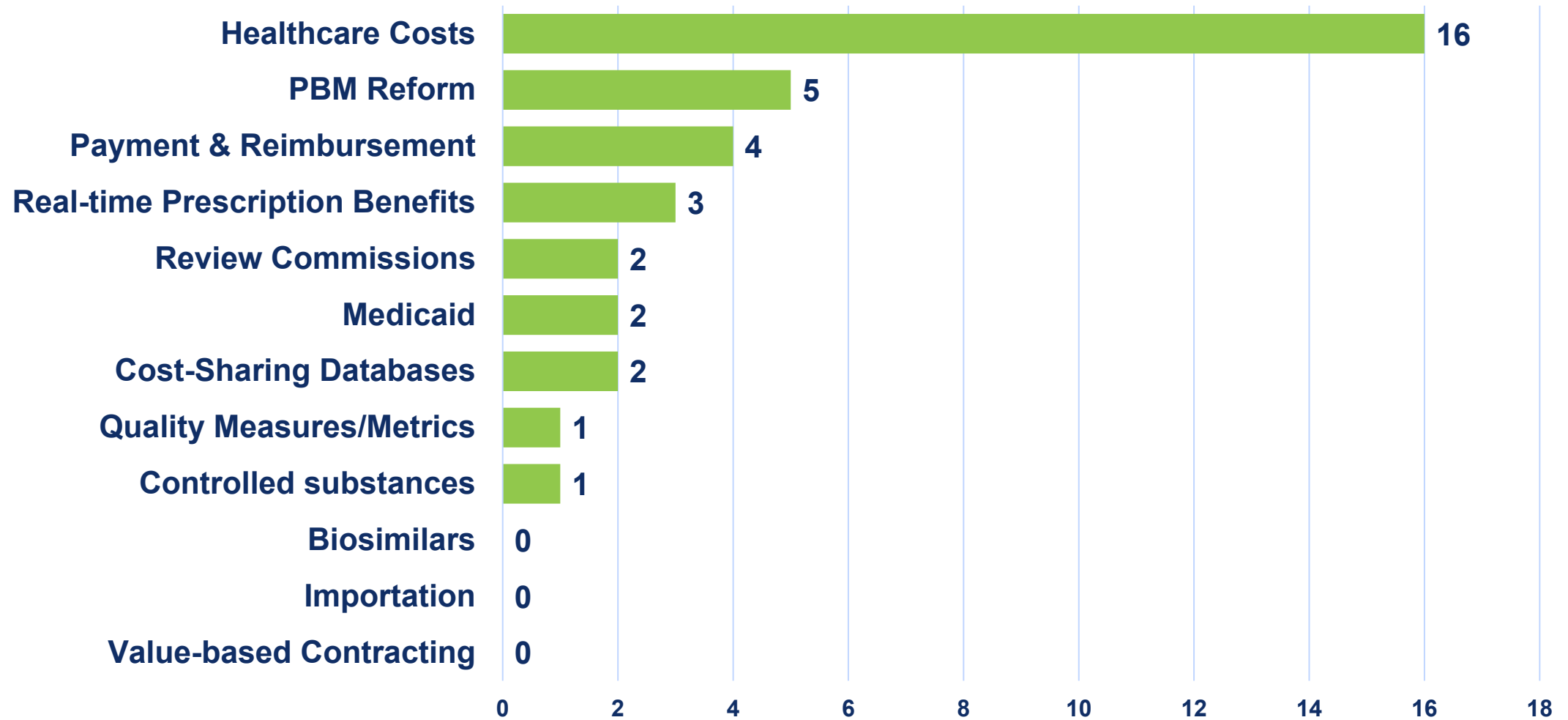


# Pricing Transparency

**Legislation  
enacted  
in 19 states**

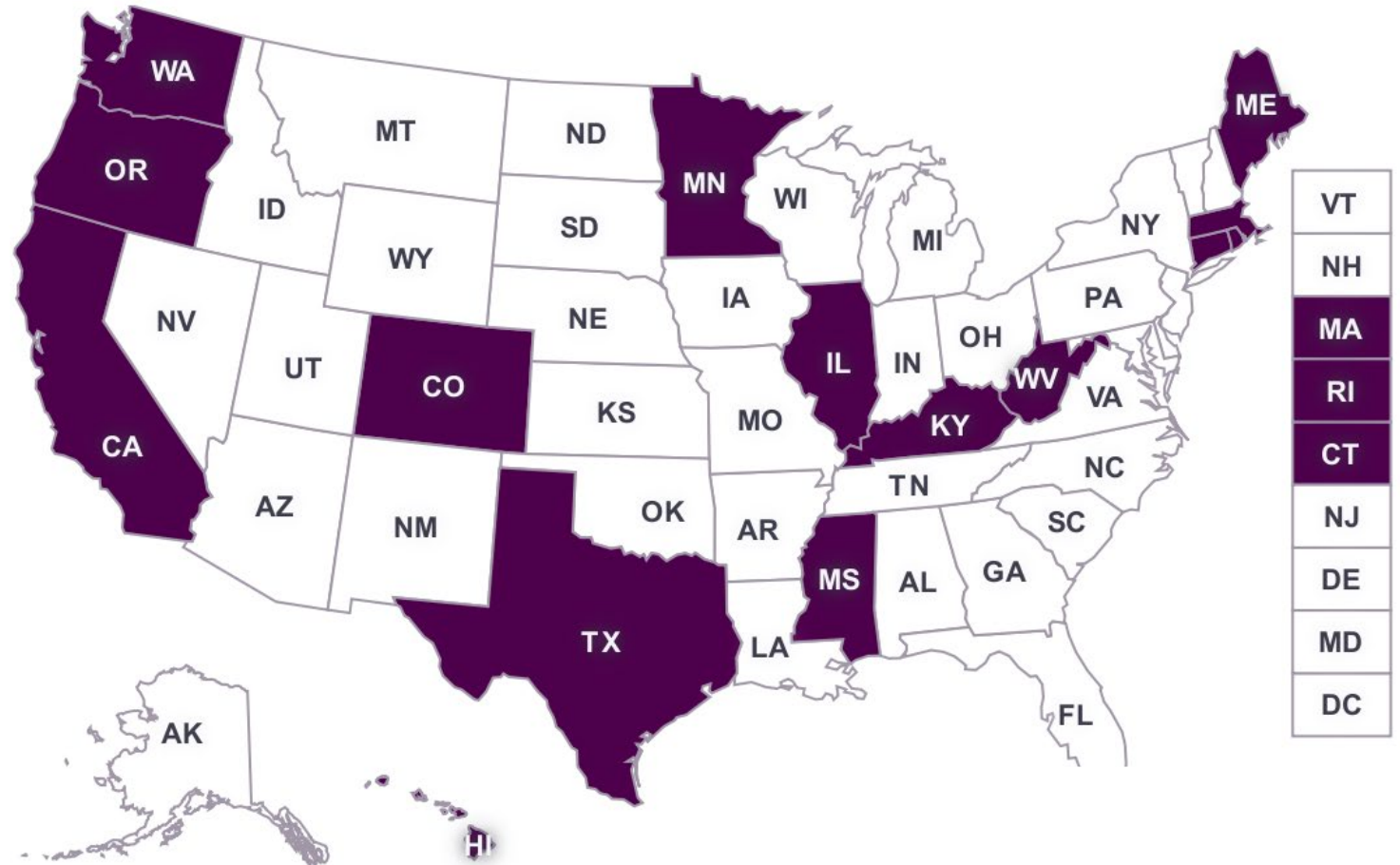


# Pricing Transparency



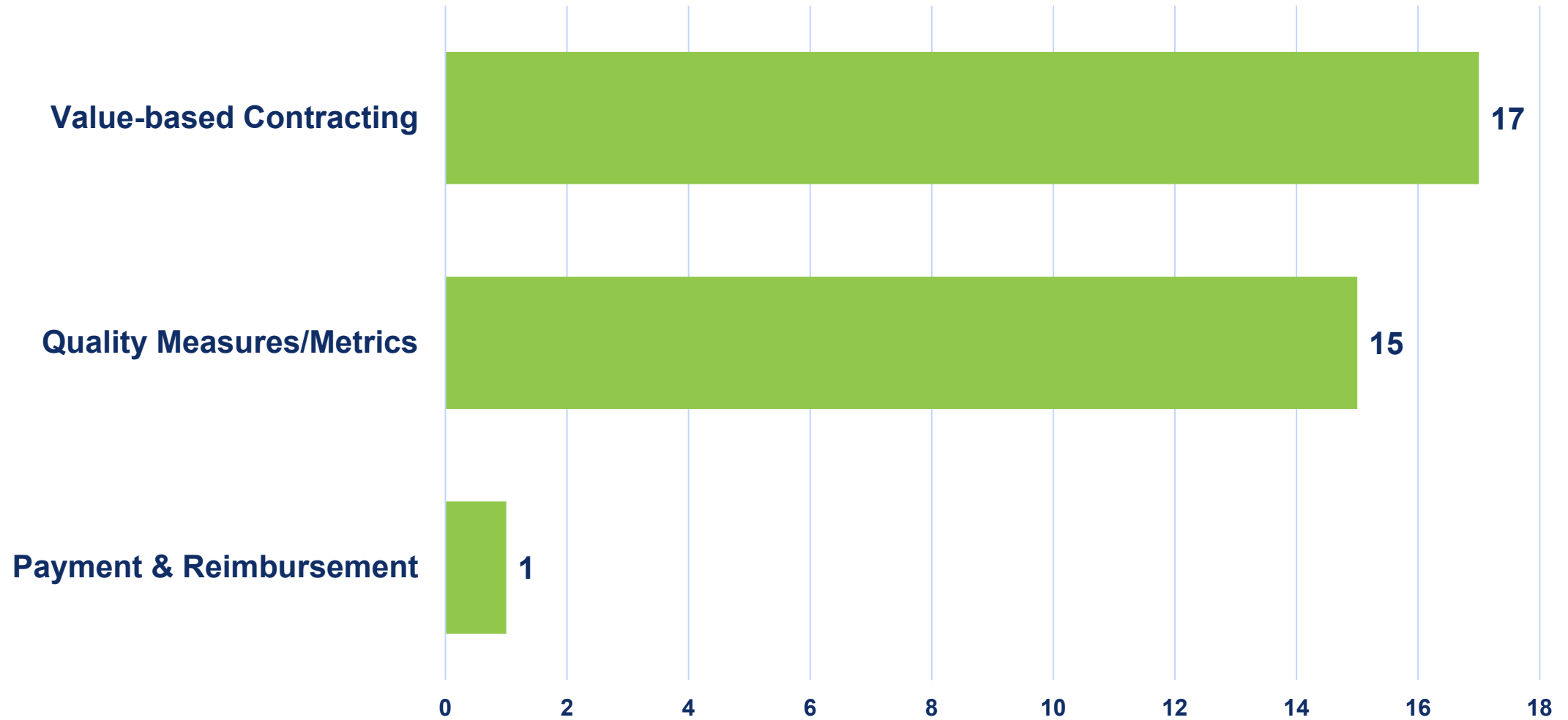
# Value-based Care

Legislation  
introduced  
in 15 states



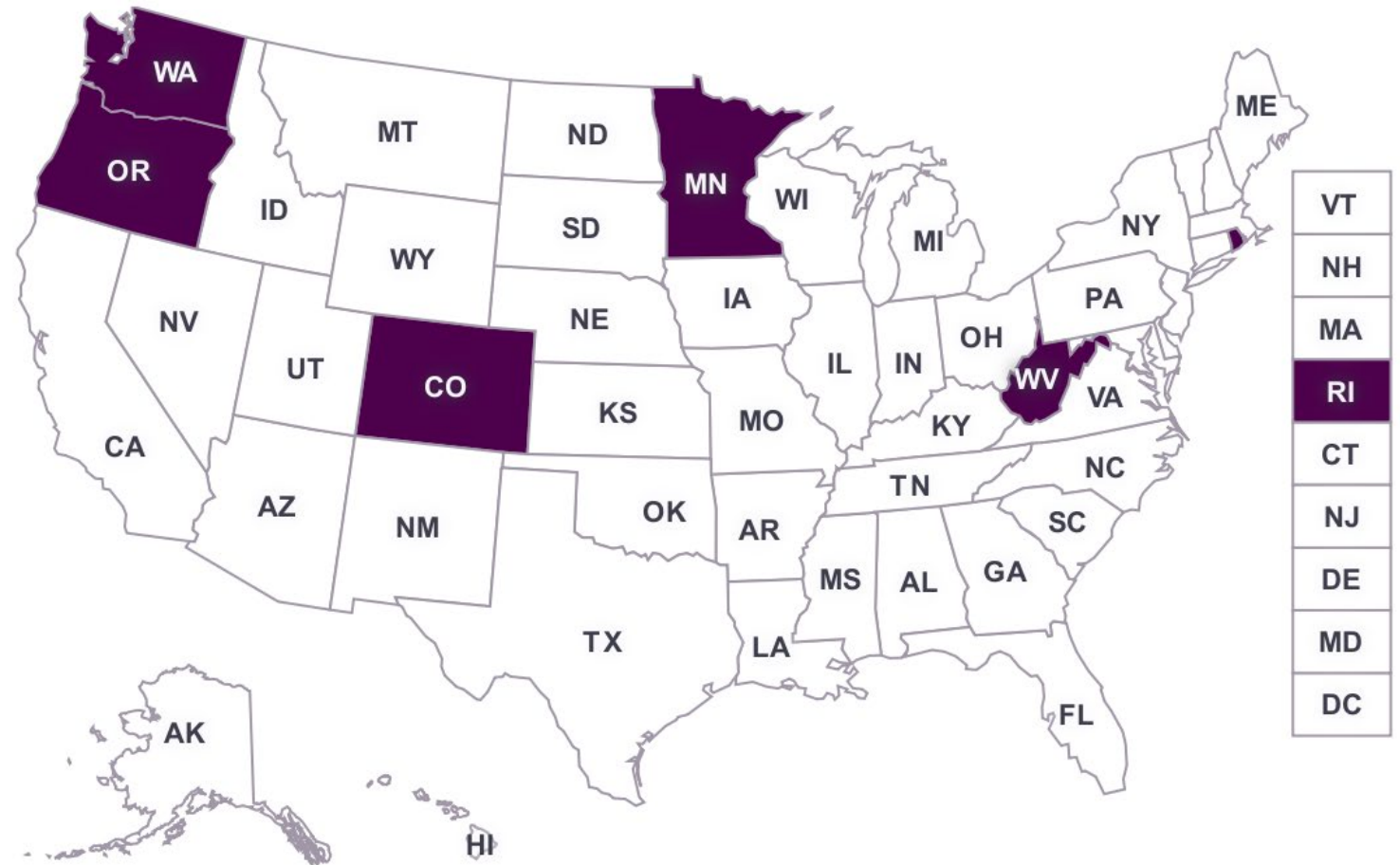


# Value-based Care

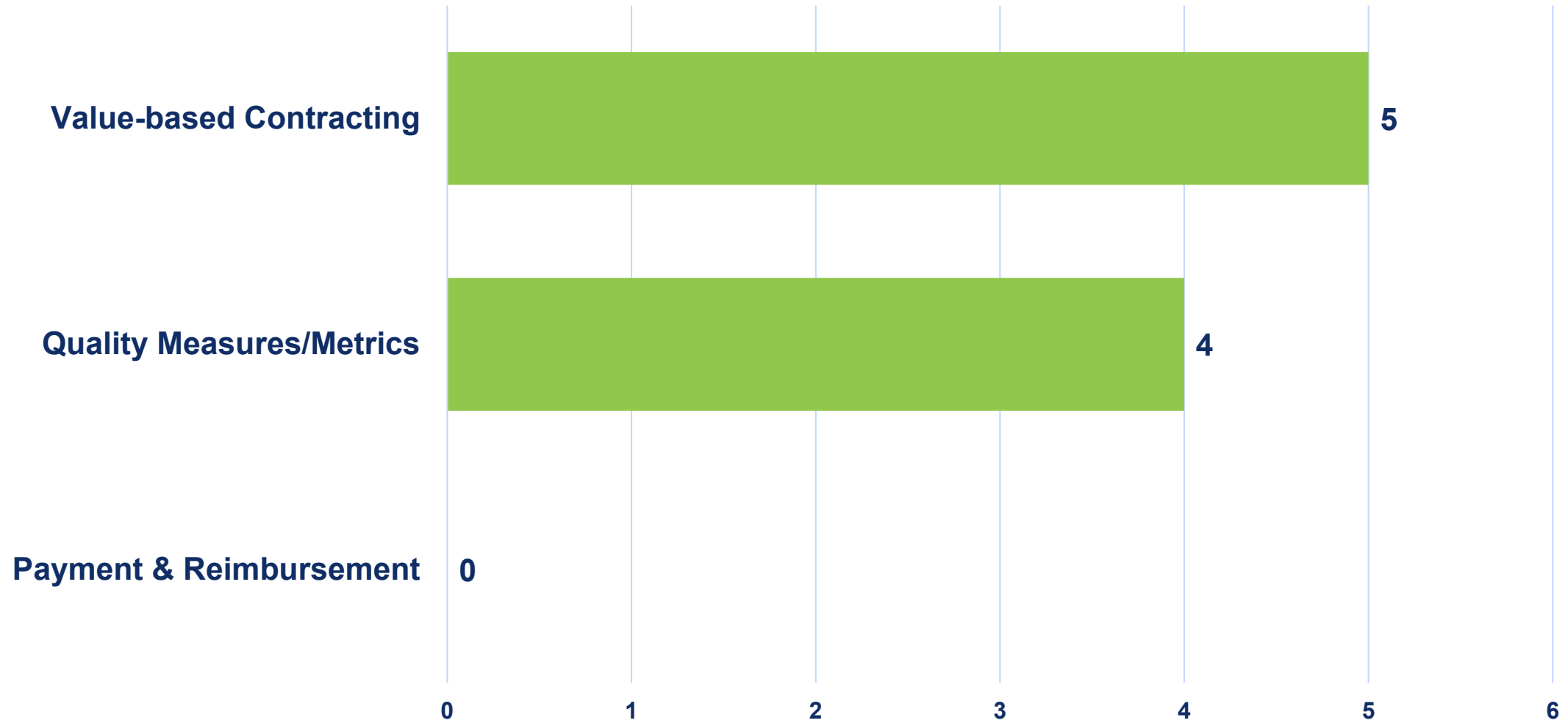


# Value-based Care

Legislation  
enacted  
in 6 states

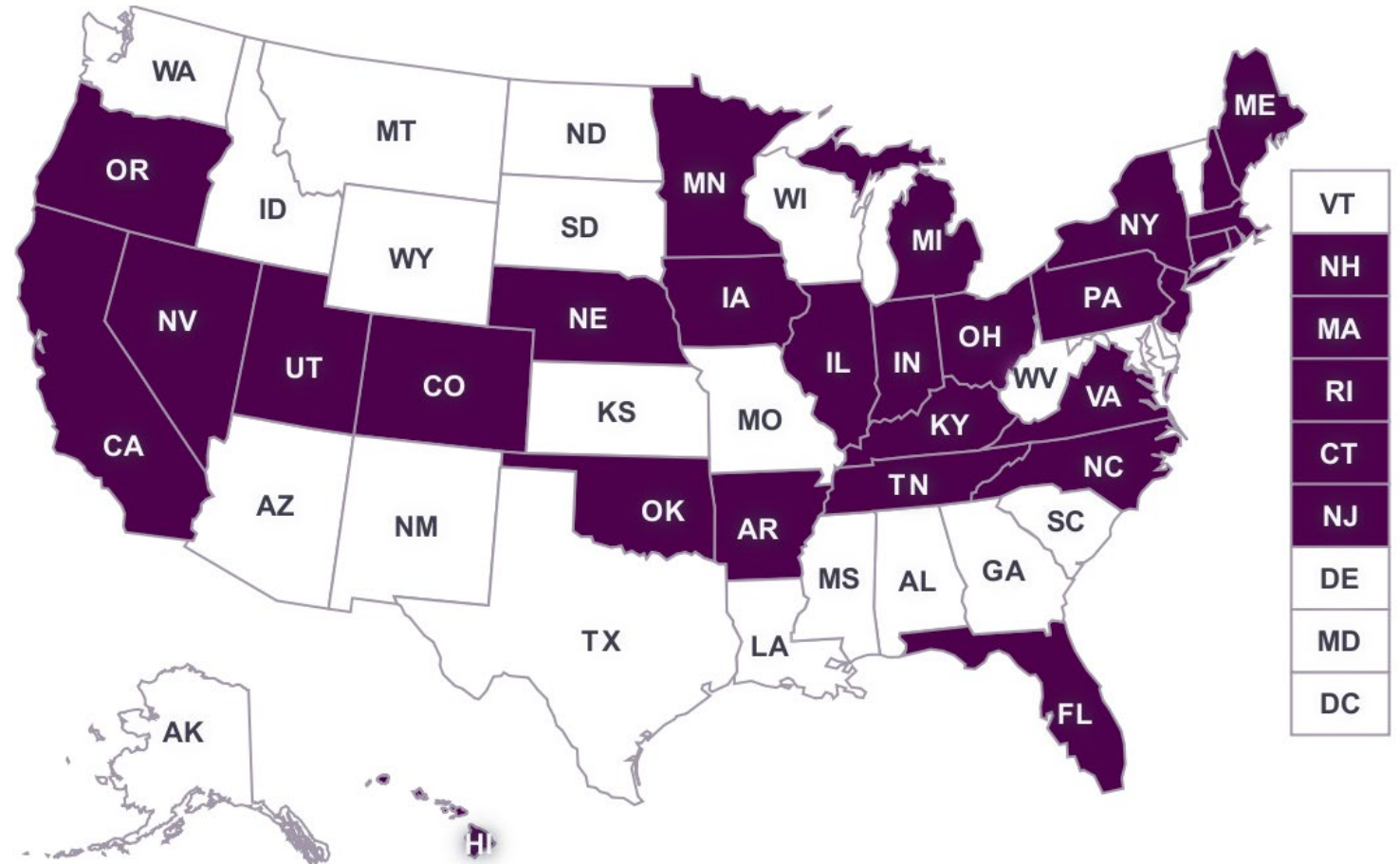


# Value-based Care

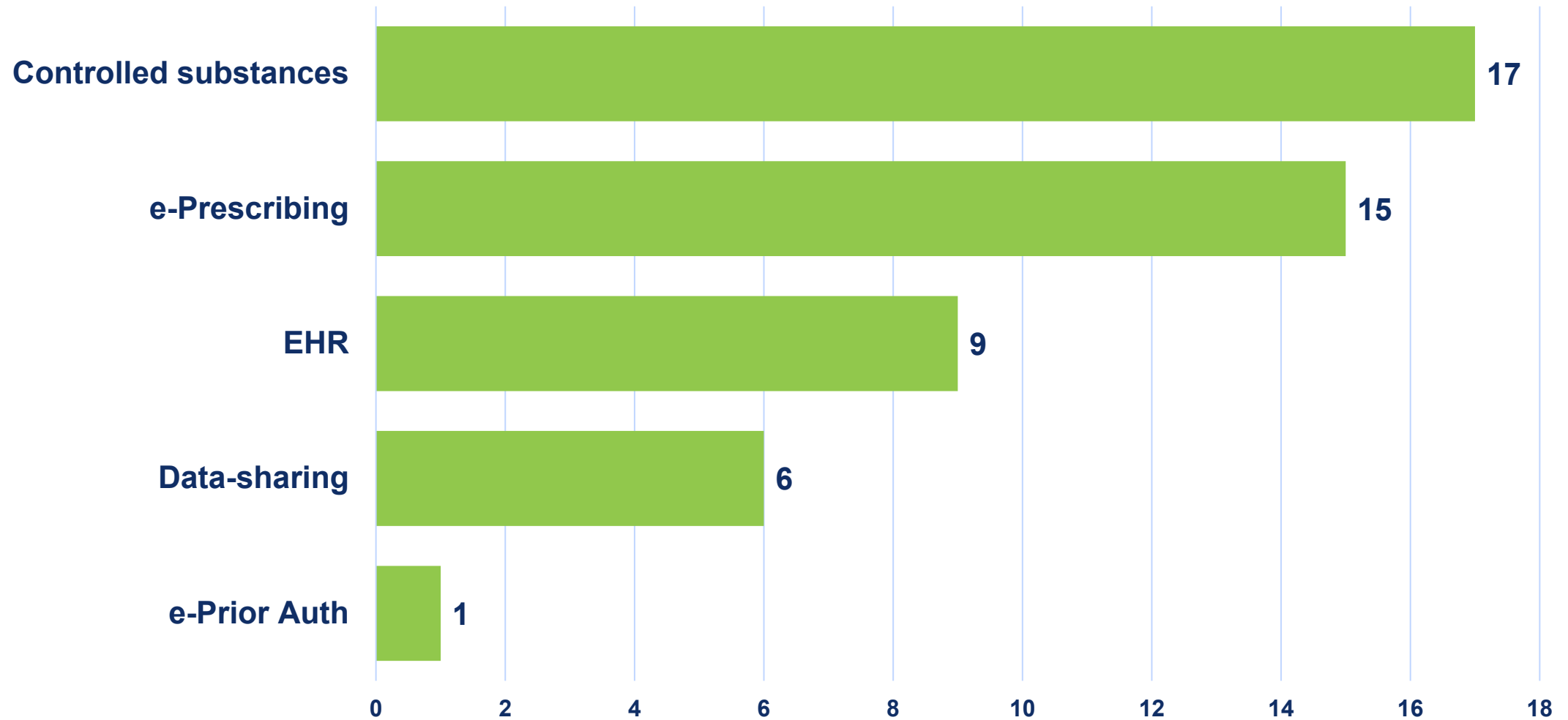


# Data-sharing and EHR

**Legislation  
introduced  
in 28 states**

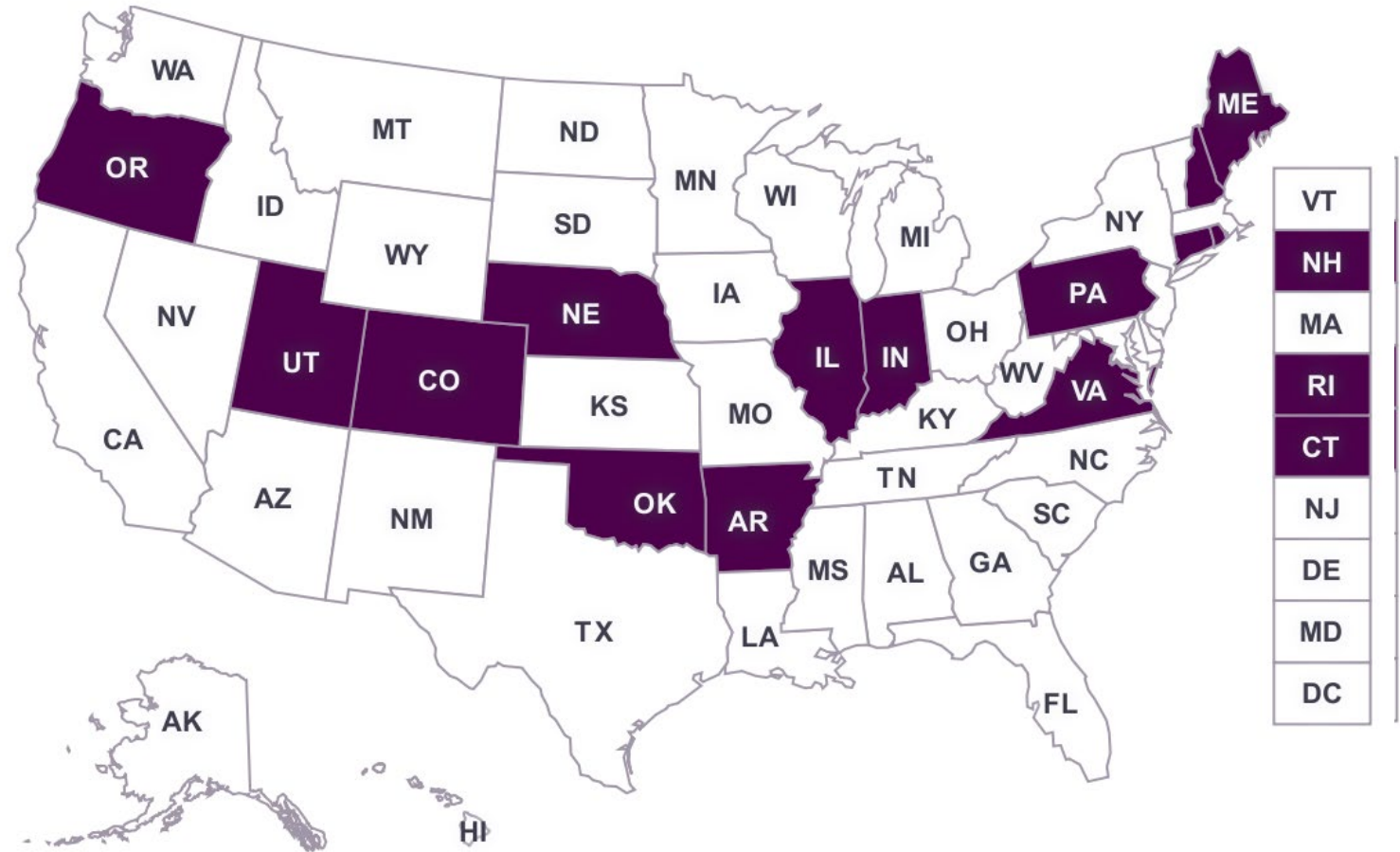


# Data-sharing and EHR

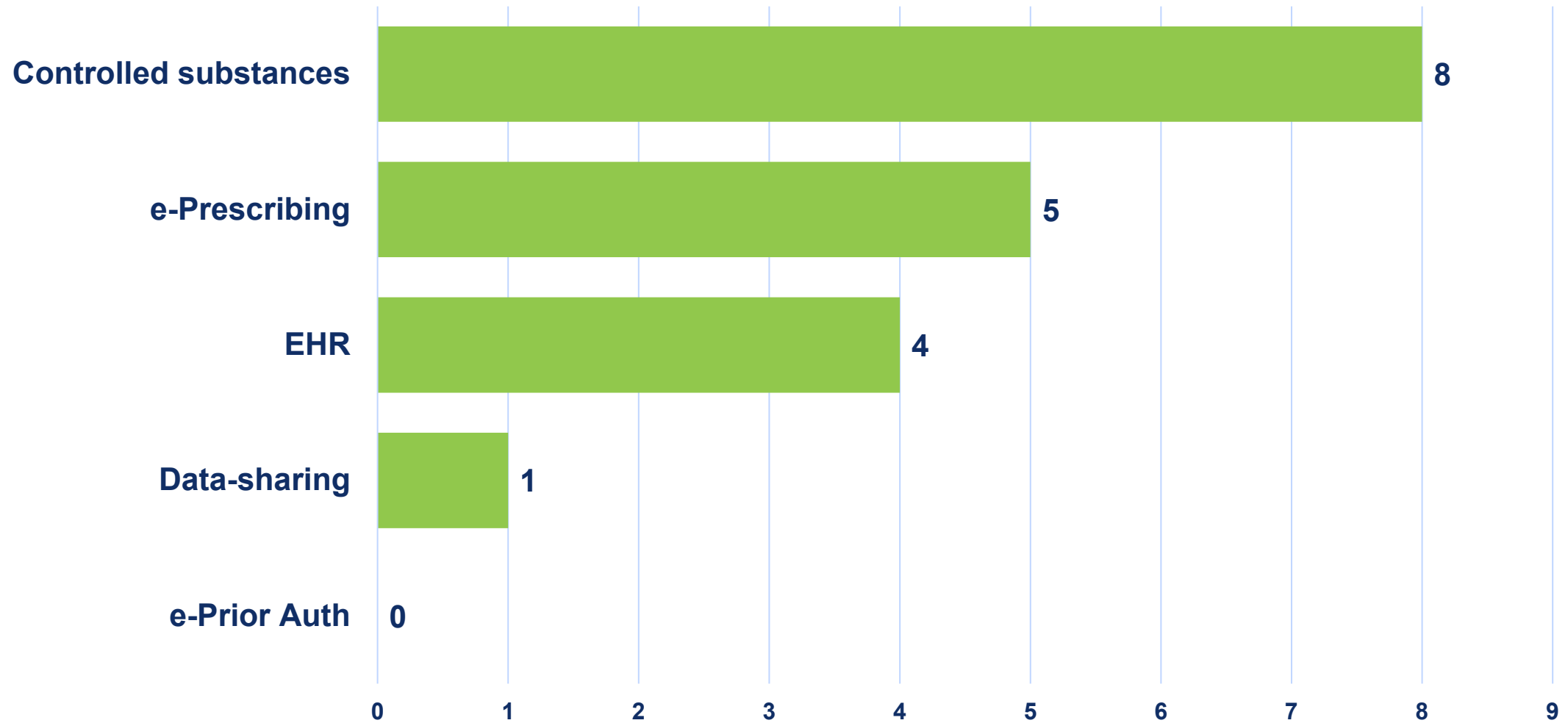


# Data-sharing and EHR

**Legislation  
enacted  
in 14 states**

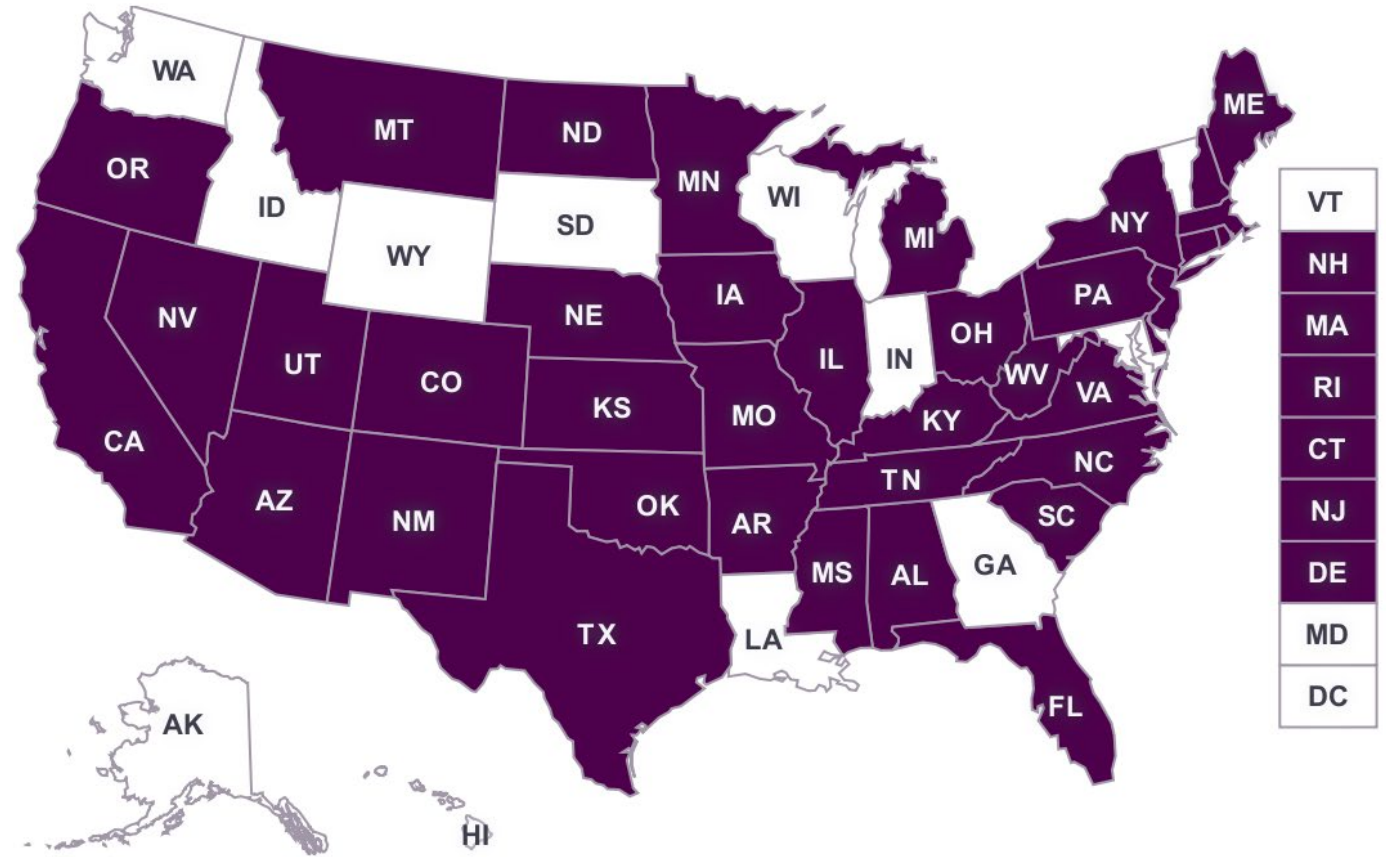


# Data-sharing and EHR



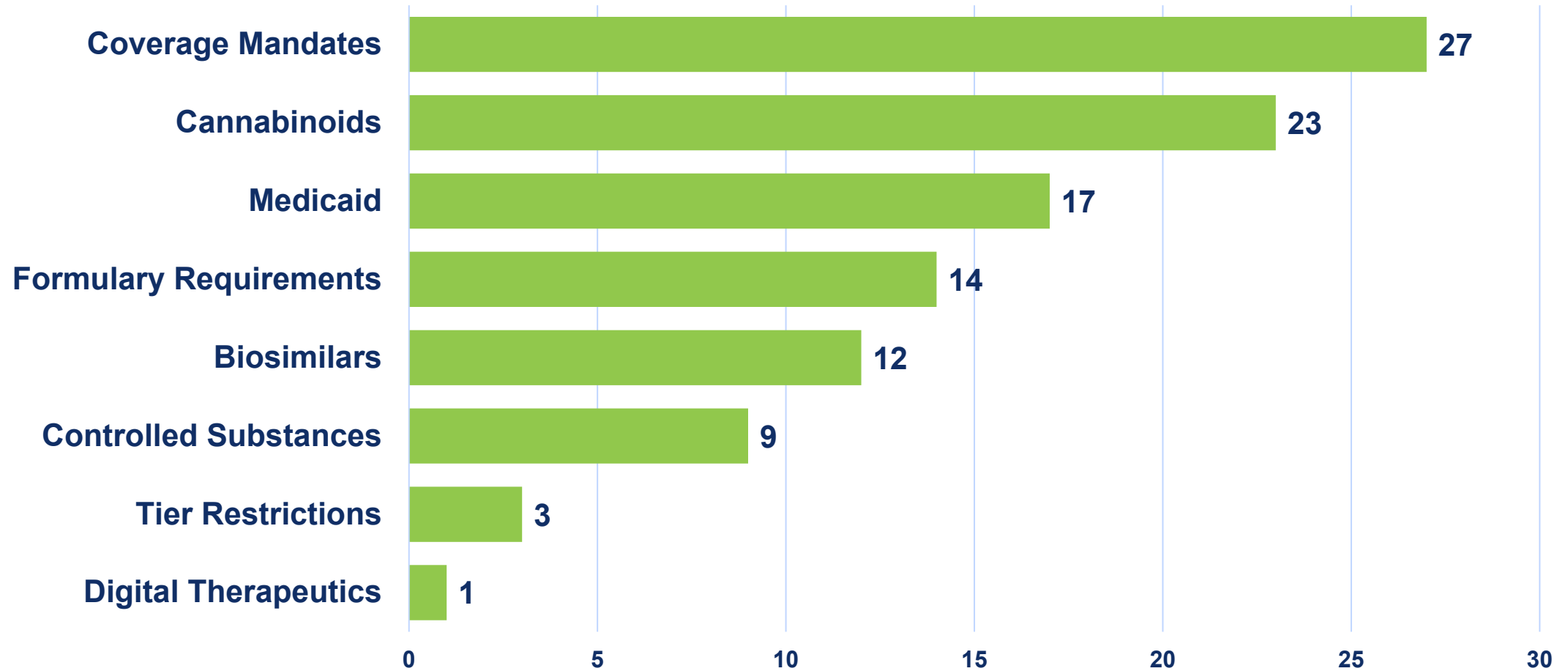
# Coverage Mandates/Tier Restrictions/ Formulary Requirements

Legislation  
introduced  
in 38 states



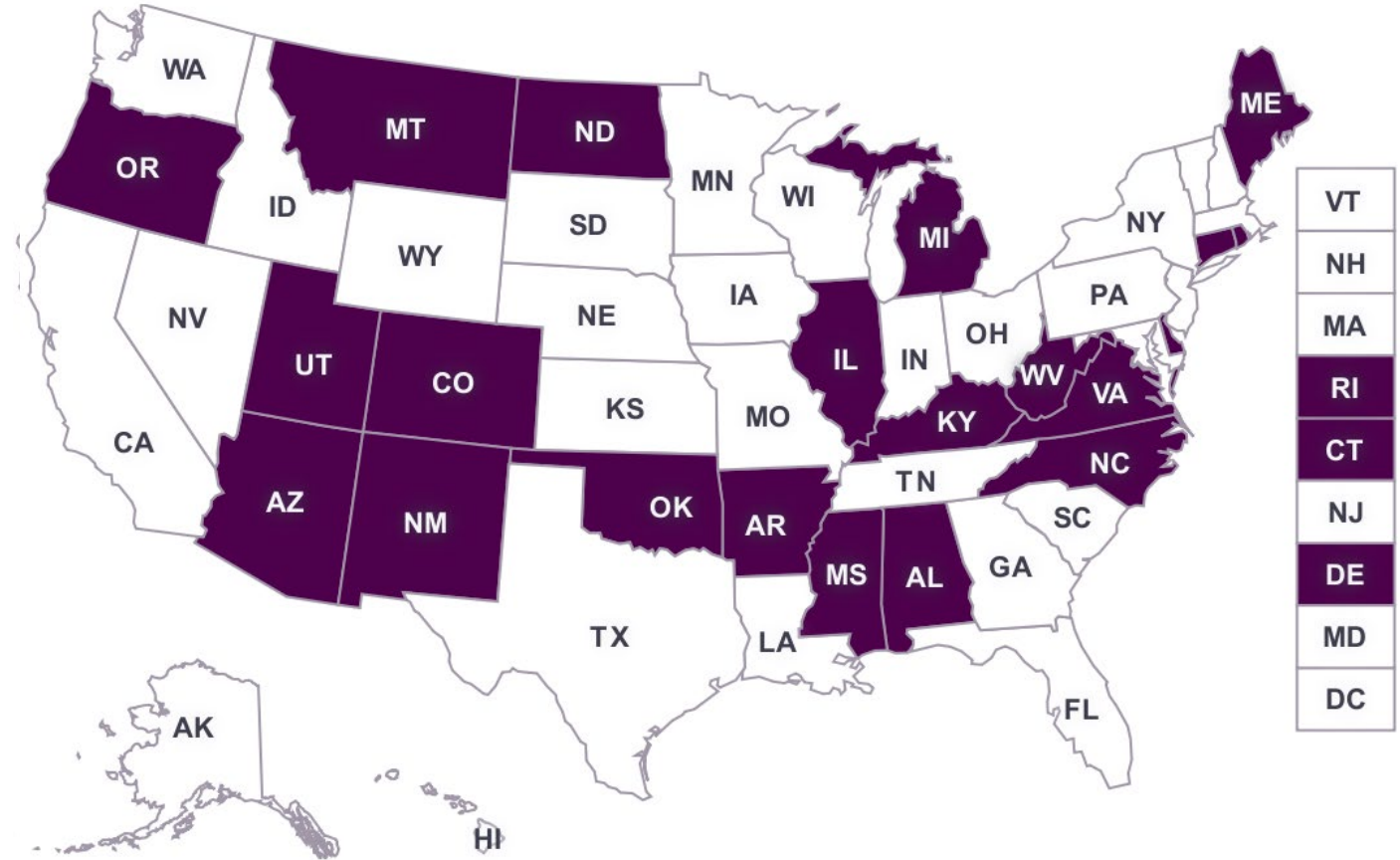


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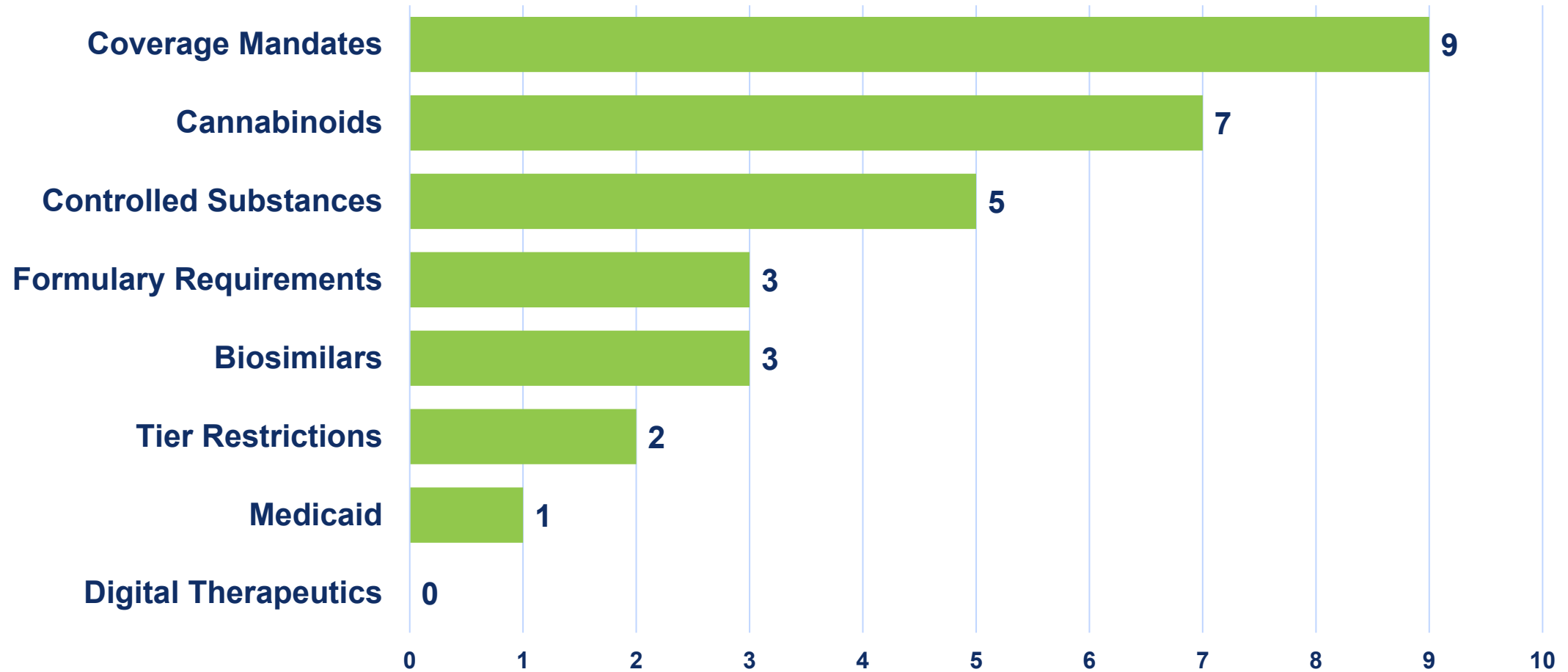


# Coverage Mandates/Tier Restrictions/ Formulary Requirements

**Legislation  
enacted  
in 21 states**

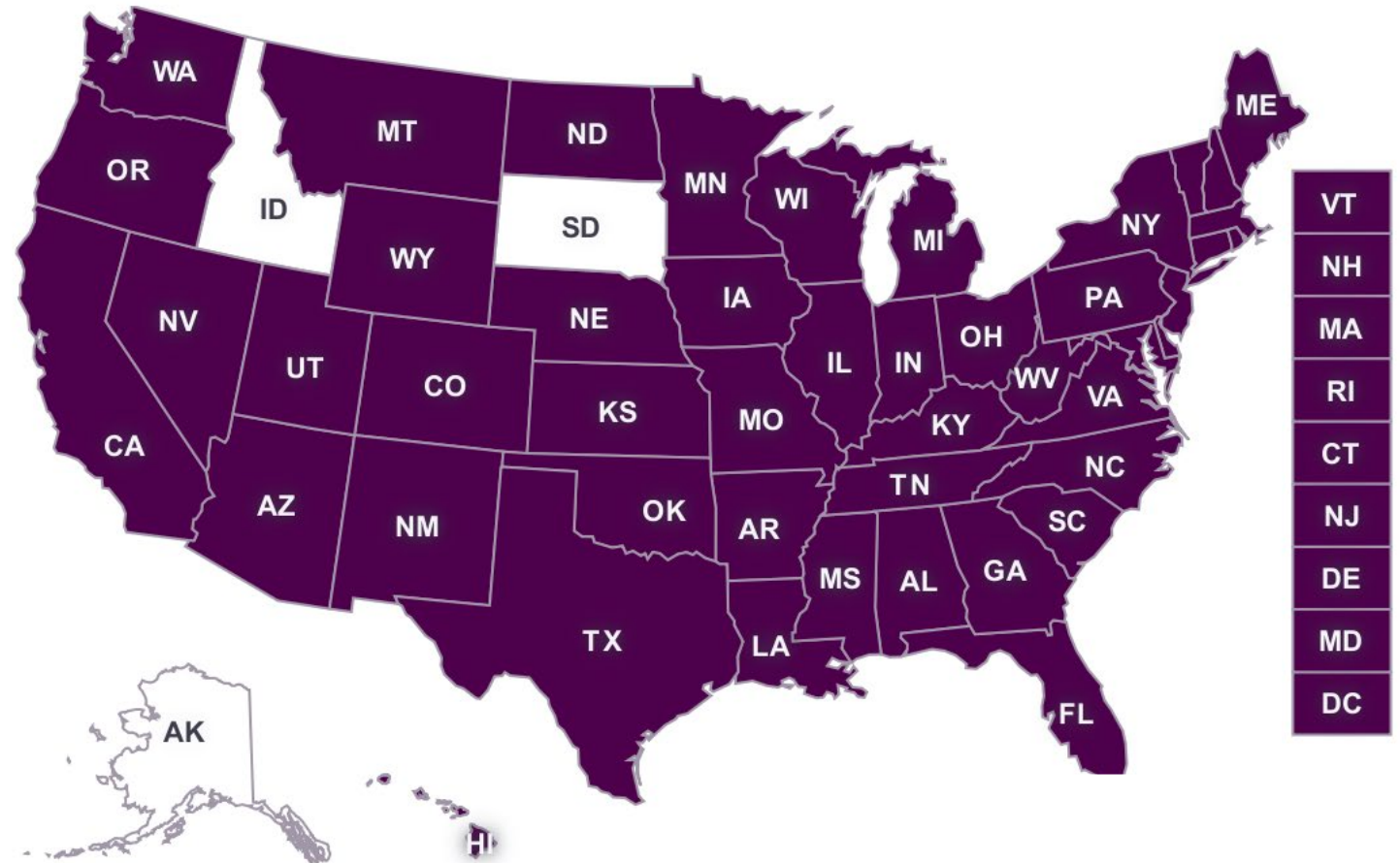


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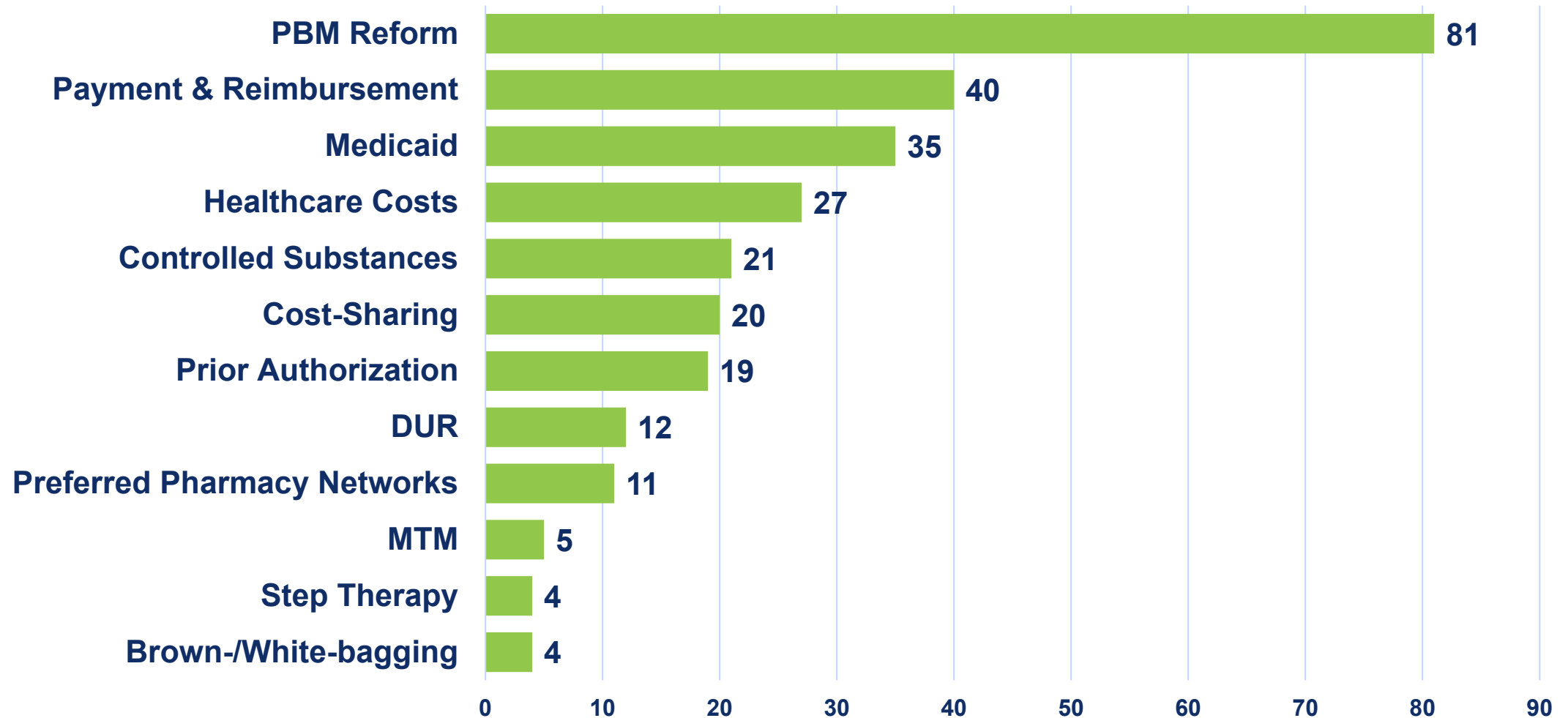


# Utilization Management Tools

**Legislation  
introduced  
in 47 states  
plus DC**

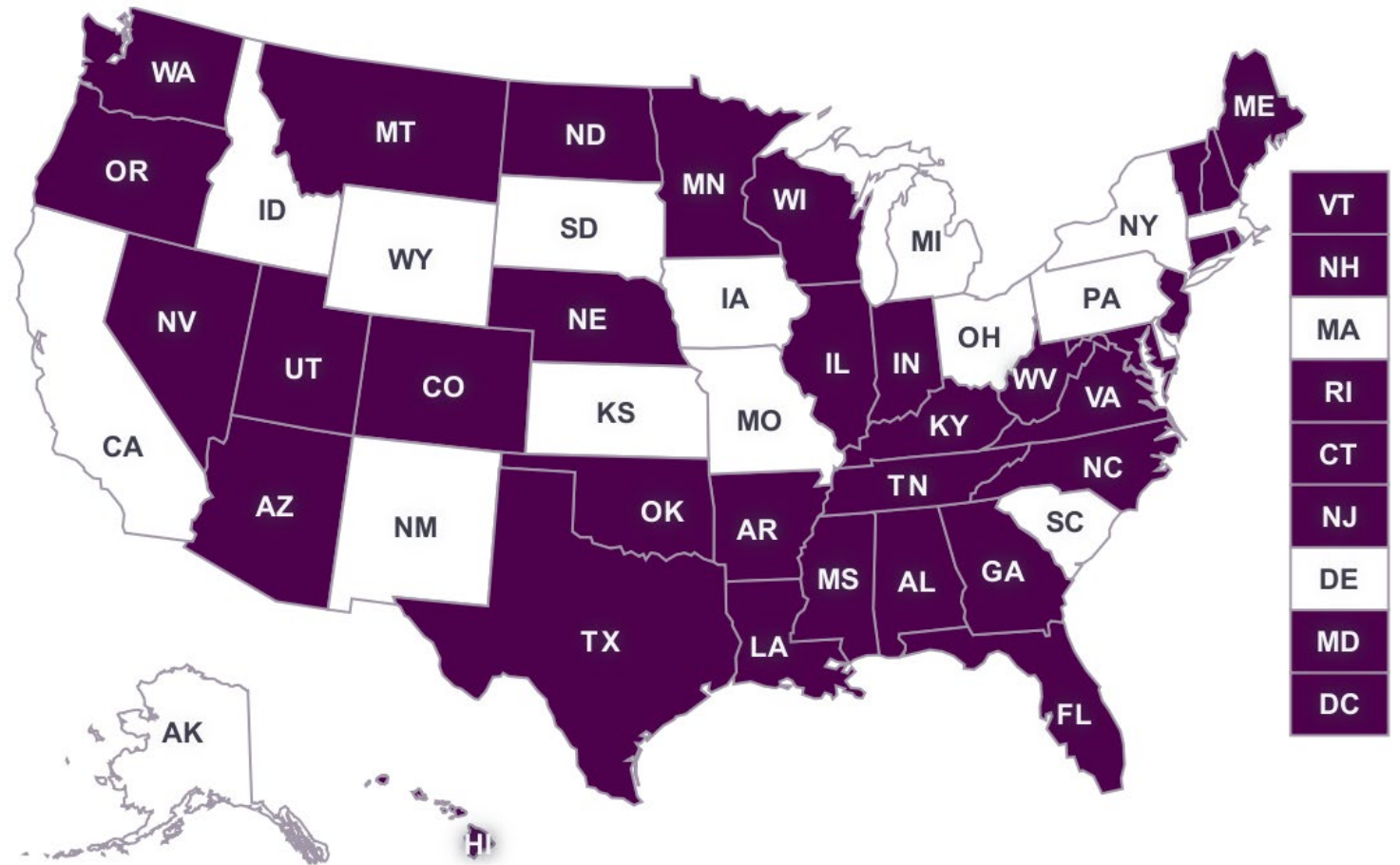


# Utilization Management Tools

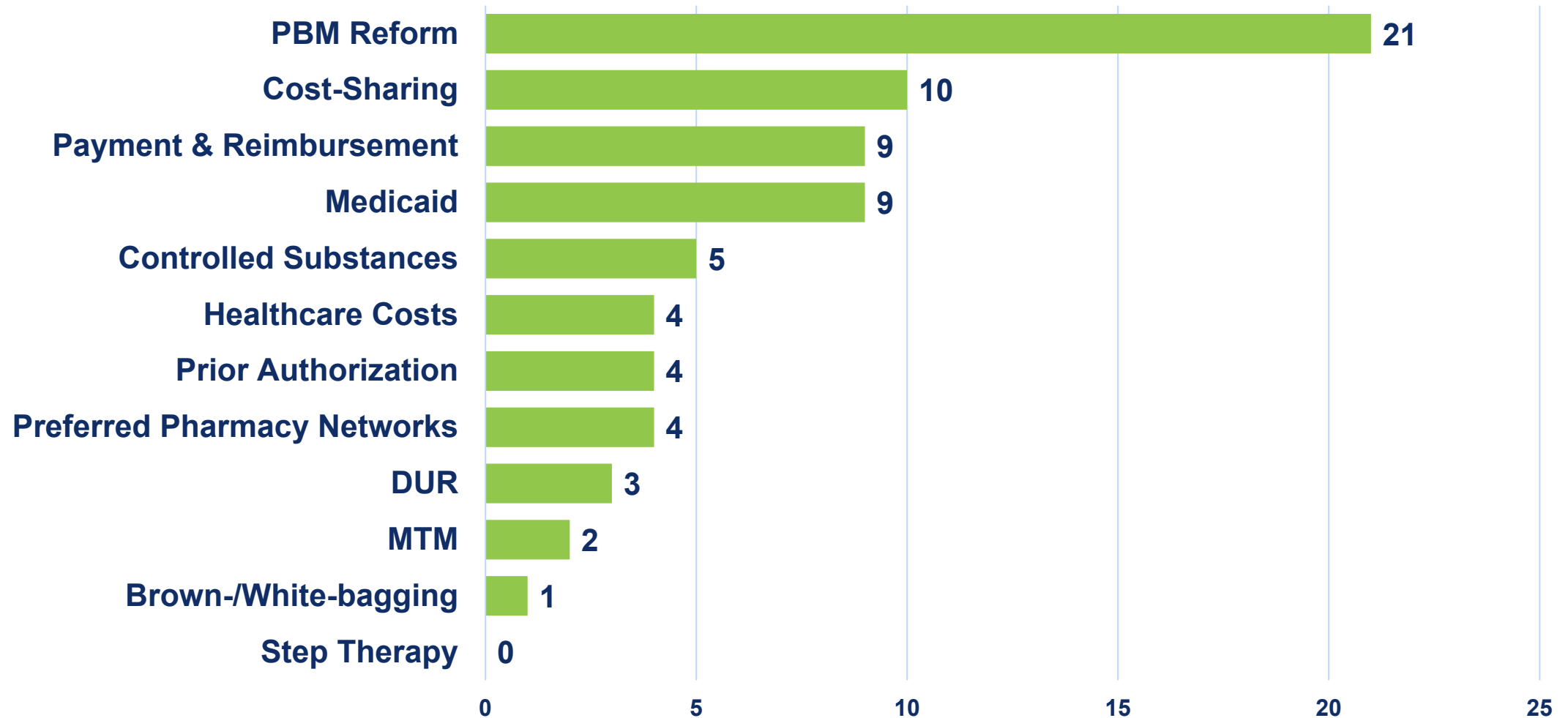


# Utilization Management Tools

**Legislation  
enacted  
in 34 states  
plus DC**

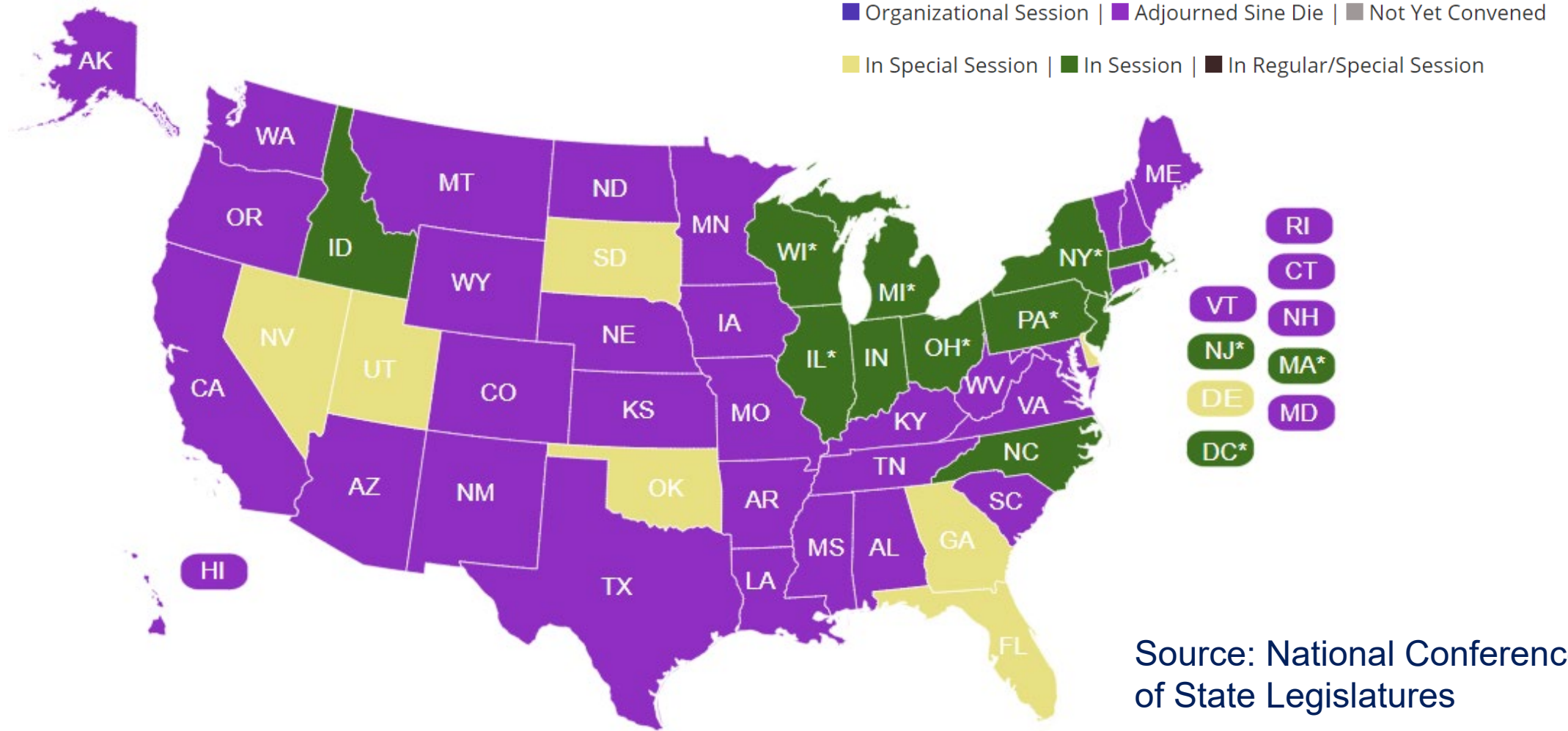


# Utilization Management Tools





# State Legislature Statuses





# Additional Information

- [amcp.org/policy-advocacy/legislative-regulatory-issues](https://amcp.org/policy-advocacy/legislative-regulatory-issues)  
PDFs of enacted legislation on our five subject areas
- [amcp.org/policy-advocacy/policy-resource-center/where-we-stand-position-statements](https://amcp.org/policy-advocacy/policy-resource-center/where-we-stand-position-statements)  
Where We Stand statements for detailed information on AMCP's policy positions
- Email [advocacy@amcp.org](mailto:advocacy@amcp.org)  
Requests for more specific information, legislative reports, questions, etc.



# Questions?