



AMCP Legislative & Regulatory Briefing

August 18, 2021

Disclaimer

Organizations may not re-use material presented at this AMCP webinar for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use this webinar material without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

Presenters



Jennifer L. Mathieu

Director, Government Relations
AMCP



Carrie Monks

Director, Regulatory Affairs
AMCP



Adam Colborn

Manager, Policy &
Government Relations
AMCP



Federal Legislation

Bipartisan Infrastructure

- H.R.3684, Infrastructure Investment and Jobs Act
- \$1.2 trillion; passed Senate 69-30
- House exploring advancing infrastructure and budget simultaneously
- Health Care Offsets
 - Sequester (\$8.7b) – extends through 2031
 - Rebate Rule (\$51b) – effective date delay to 2026
 - Vial Size (\$3b) – beginning in 2023, requires drugmakers to refund Medicare for unused medication in single-dose vials under Part B outpatient
 - COVID Relief (\$210b) – repurposes unused relief dollars

Budget Resolution/Reconciliation

- S.Con.Res.14, FY2022 Budget Reconciliation
- \$3.5 trillion, passed Senate 50-49
- Health Care Provisions
 - Medicare dental, vision, hearing benefit additions
 - Extends ACA expansion in American Rescue Plan
 - Invests in home and community-based services
 - Creates federal health program to close “Medicaid gap”
 - Reduces prescription drug costs
- House exploring advancing infrastructure and budget simultaneously
- House Budget Resolution target date – Sept. 15
- Reconciliation

The NOVEL Act

- The New Opportunity 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

CURES 2.0

- The 21st Century Cures 2.0 Act Discussion Draft
- Proposals
 - Strategies to improve use of cell and gene therapies
 - Strengthen collection of confirmatory data for accelerated approval drugs
 - Codifies the Medicare Coverage of Innovative Technologies (MCIT) rule
 - Creates the Advanced Research Projects Agency for Health (ARPA-H)
- AMCP's recommendations
 - § 303 on cell and gene therapies – include language codifying FDA's 2018 guidance on pre-approval information exchange (PIE)
 - § 309 on confirmatory studies for accelerated approval – incentivize confirmatory study completion by requiring manufacturers to pay higher rebate amounts until confirmatory trials are complete
 - § 404 on 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



Federal Regulation

Medicare Part D Rebate Rule

- Eliminates the safe harbor protections for manufacturer price concessions offered to plan sponsors or their contracted PBMs.
- The effective date had been postponed to January 1, 2023, by agreement between the Biden administration and PCMA in response to PCMA's lawsuit.
- The bipartisan infrastructure deal that passed in the Senate would further delay the effective date until January 1, 2026.

Most Favored Nation Model

- Established a mandatory, nationwide demonstration tying the price of certain Part B drugs to an international price index
- Model was slated to begin Jan. 1, 2021
 - Courts granted a preliminary injunction
- On August 10, CMS rescinded the MFN rule, effectively ending this model.

Medicaid Drug Rebate Program

- Final rule allowing manufacturers to submit multiple ‘best prices’ when a drug is subject to a value-based arrangement delayed until July 1, 2022 (6-month delay).
- To provide more time for CMS, states, and manufacturers to make the complex system changes necessary to implement the new best price and VBP program.
- Assures patient access and quality of care - particularly given the current need to devote resources to the COVID-19 public health emergency.

Medicare Coverage of Innovative Technology (MCIT)

- Establishes a coverage pathway for new, innovative medical devices approved by the FDA
 - Allows Medicare beneficiaries faster access to these breakthrough technologies
- Rule implementation delayed as part of the Biden administration's regulatory review process

Biosimilars

- On July 28, the FDA approved the first interchangeable biosimilar insulin product.
 - Because of its designation as interchangeable, this product may be substituted for the reference product at the pharmacy counter, without the intervention of the prescriber.
- All 50 states have laws allowing for pharmacy-level substitution of interchangeable biosimilars.

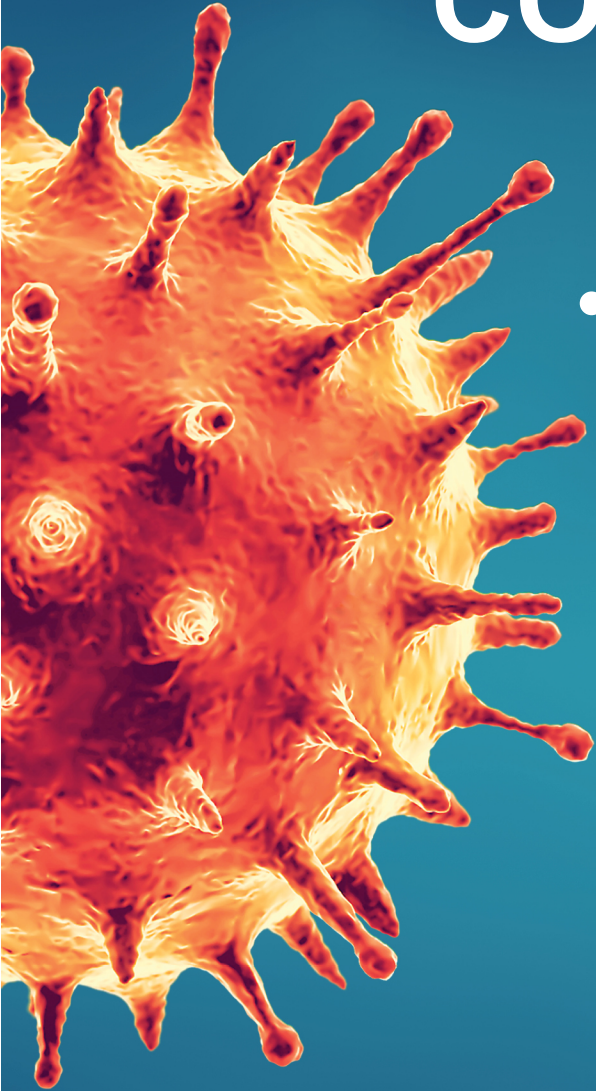
Drug Importation

- FDA Issued Final Rule on Sept. 24, 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, Florida, Maine, Vermont, and New Mexico have submitted importation plans for approval.
 - None have been approved at this point.
 - Numerous other states have introduced legislation to create importation programs.
- The Biden administration has been supportive of drug importation, but it is unclear how it will proceed on these state importation plans.

Federal/HHS Regulatory Agenda

- In July, HHS published its semi-annual regulatory agenda, listing the rules the agency intends to release, reflecting the priorities of Secretary Becerra and the Biden administration.
- Of note for AMCP:
 - Requirements for prescription drug marketing
 - DTC advertising
 - Two Medicare Part C & D policy rules
- The Spring Federal Regulatory agenda included the removal of:
 - International Price Index rule
 - Several 'program integrity' related rules

COVID Specific Rules & Regulations



- CMS has permitted pharmacists/pharmacies to:
 - Order and bill Medicare for COVID testing
 - “Order vaccine”
 - Administer vaccine
 - Preempts state laws that would effectively prohibit this



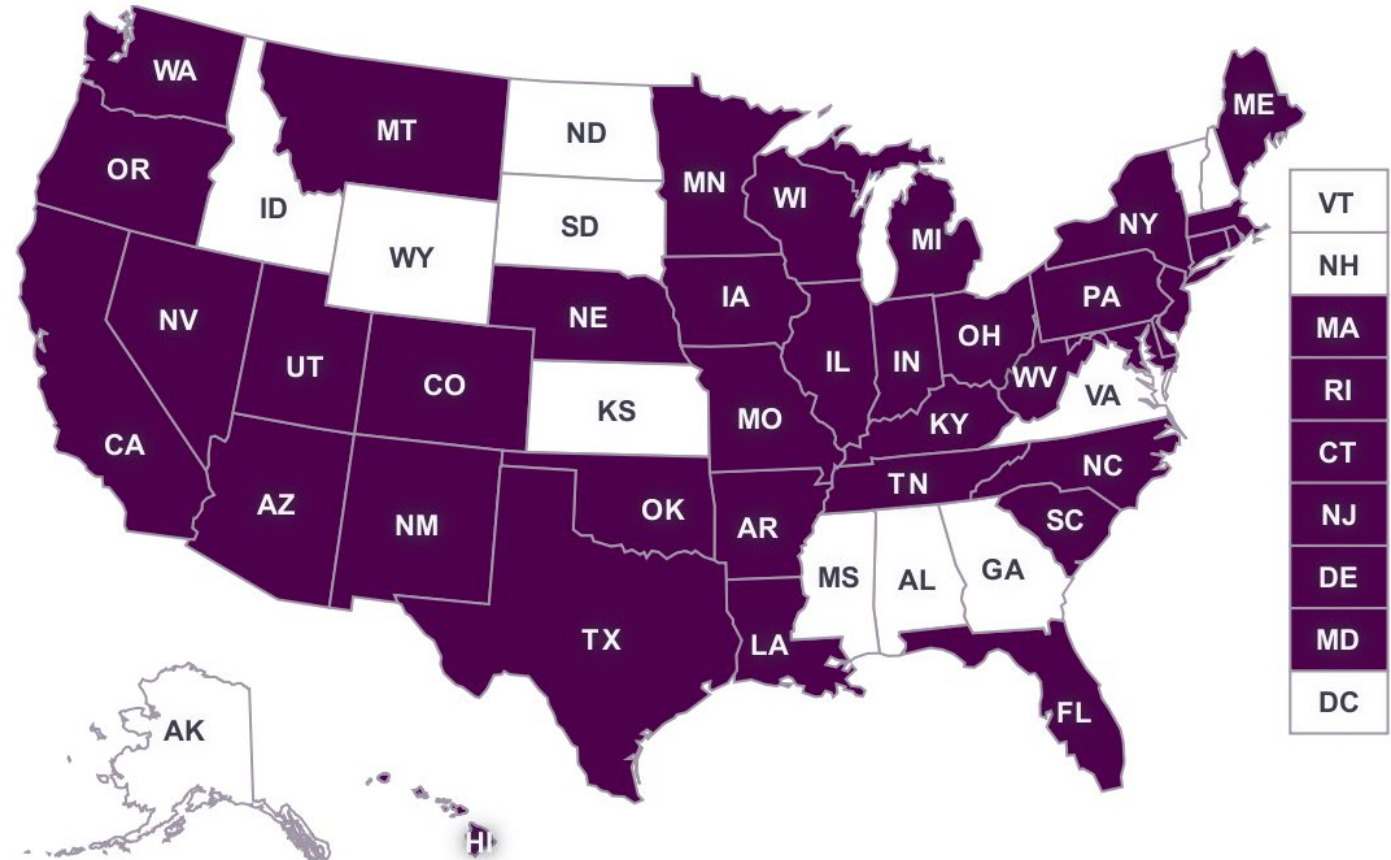
State Affairs

State Priorities

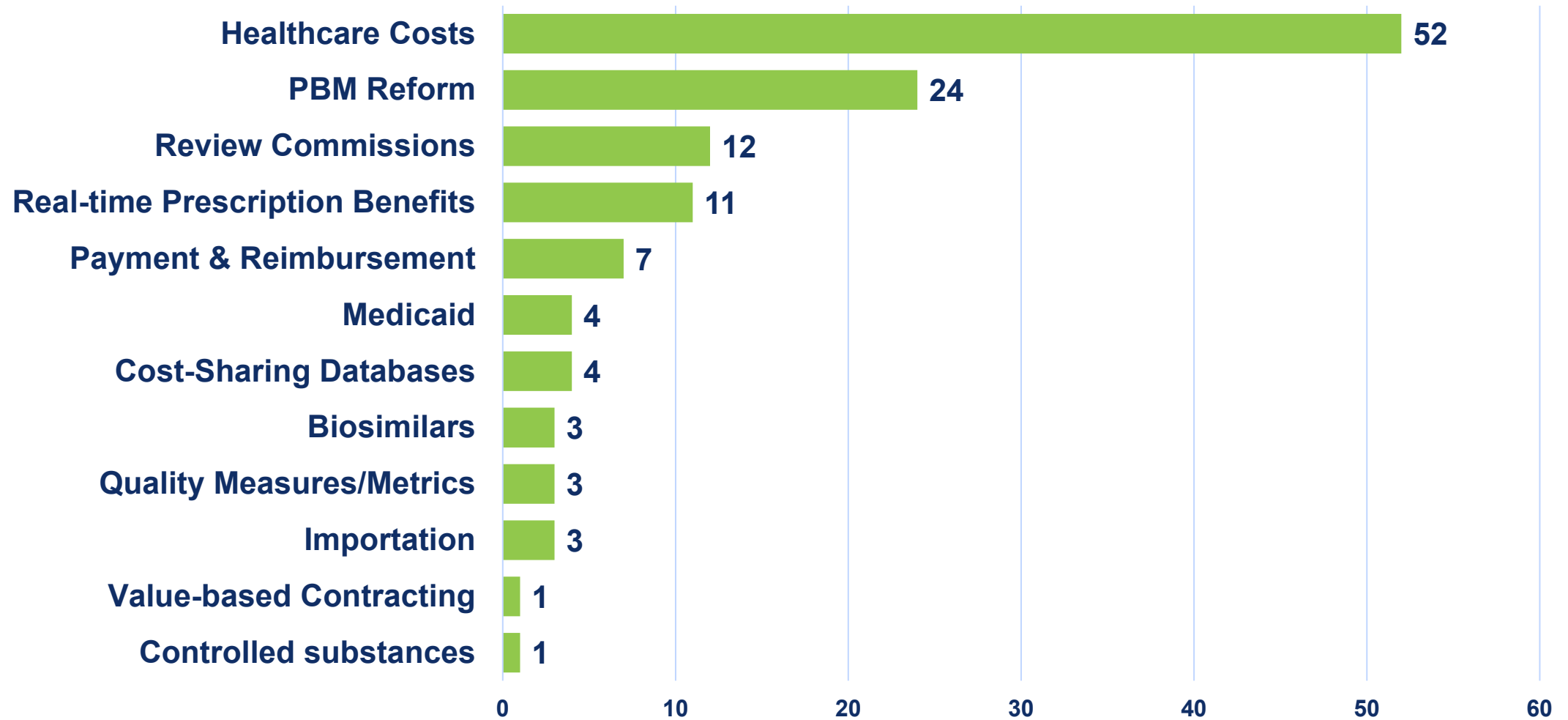
- Promote meaningful transparency on drug pricing and patient cost-sharing
- Advocate for the development of clear metrics to shift pharmaceutical payments to value-based care
- Encourage data sharing and interoperability of electronic health records
- Promote AMCP's position on formulary requirements,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

Pricing Transparency

Legislation introduced in 38 states



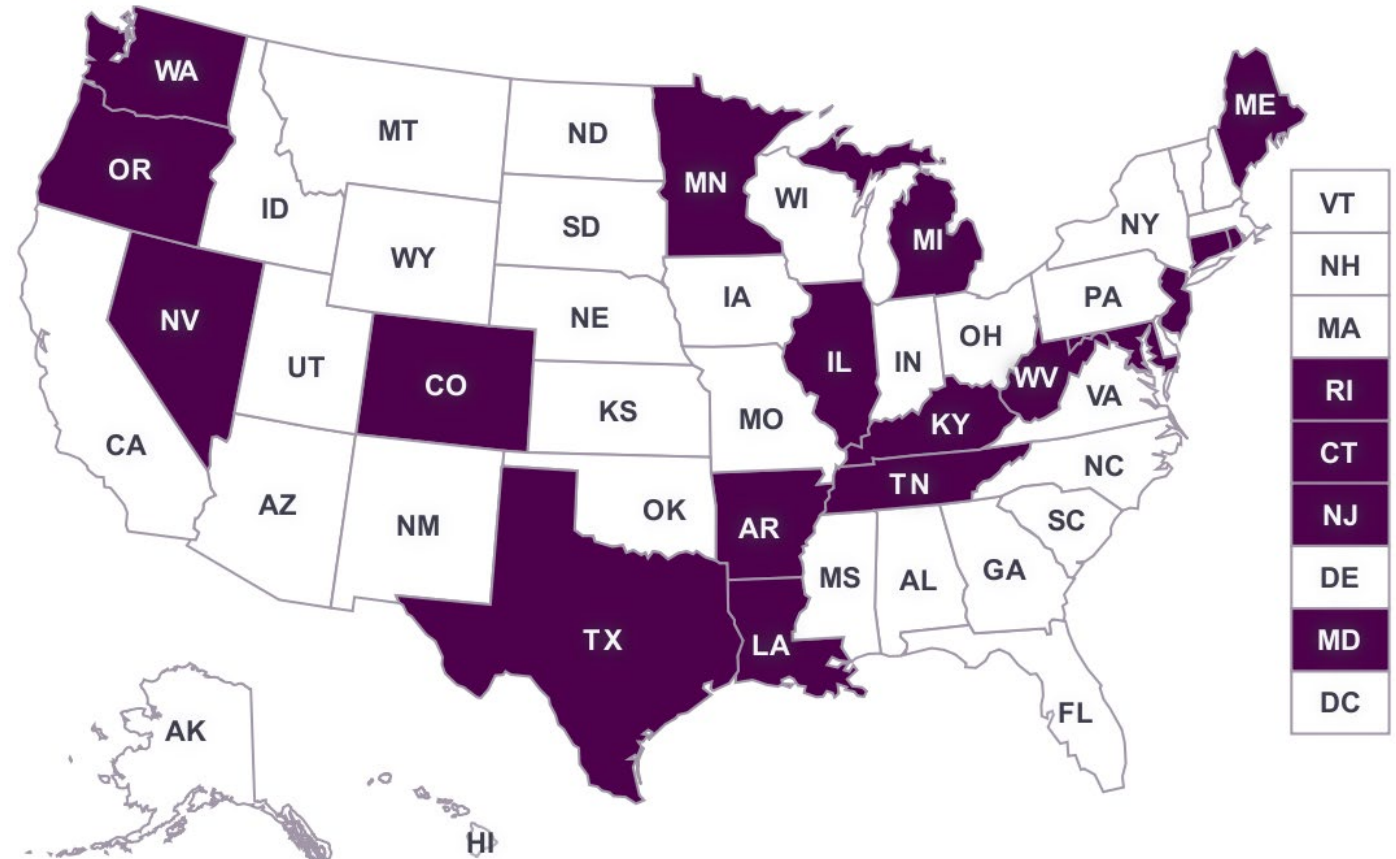
Pricing Transparency



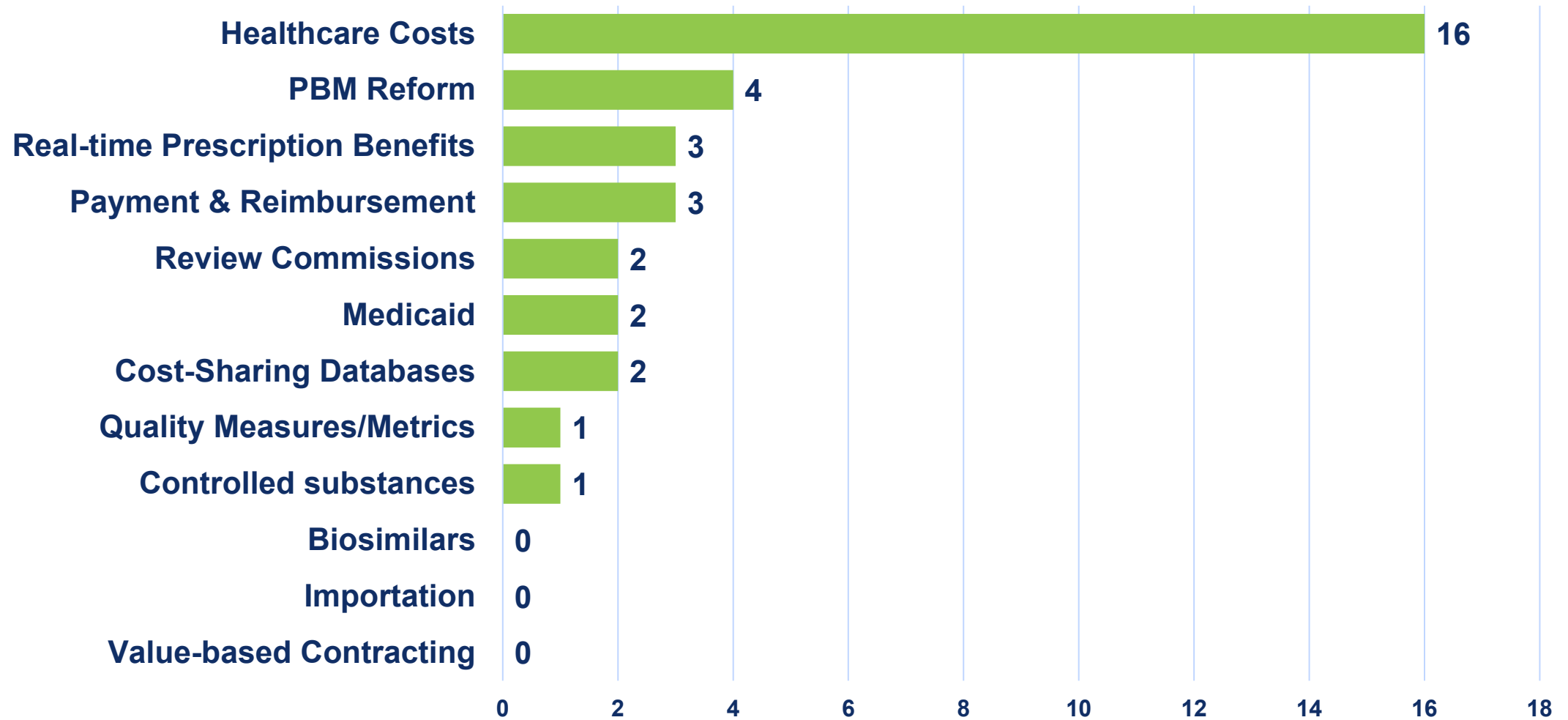
■ = Legislation enacted

Pricing Transparency

Legislation enacted in 18 states

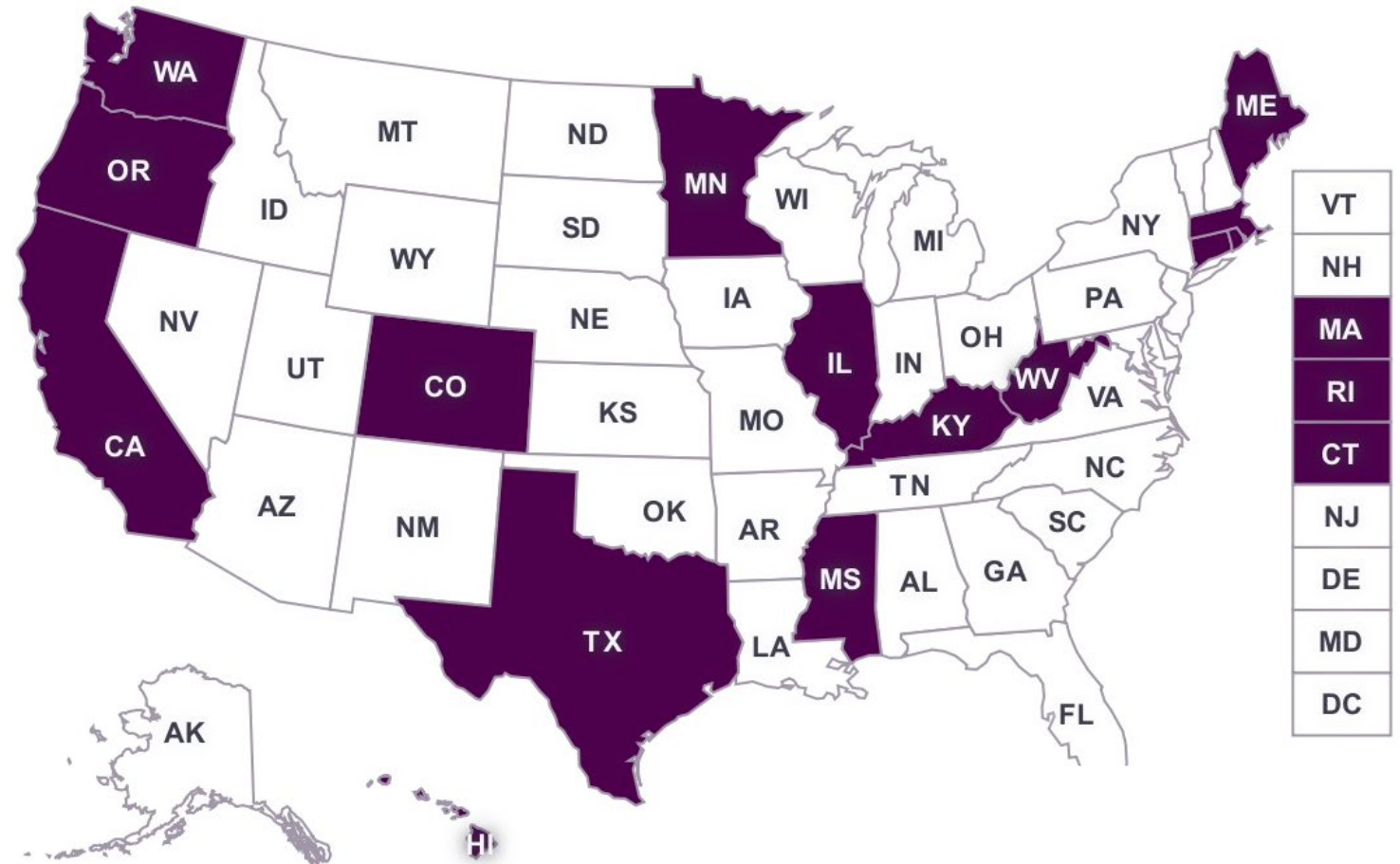


Pricing Transparency

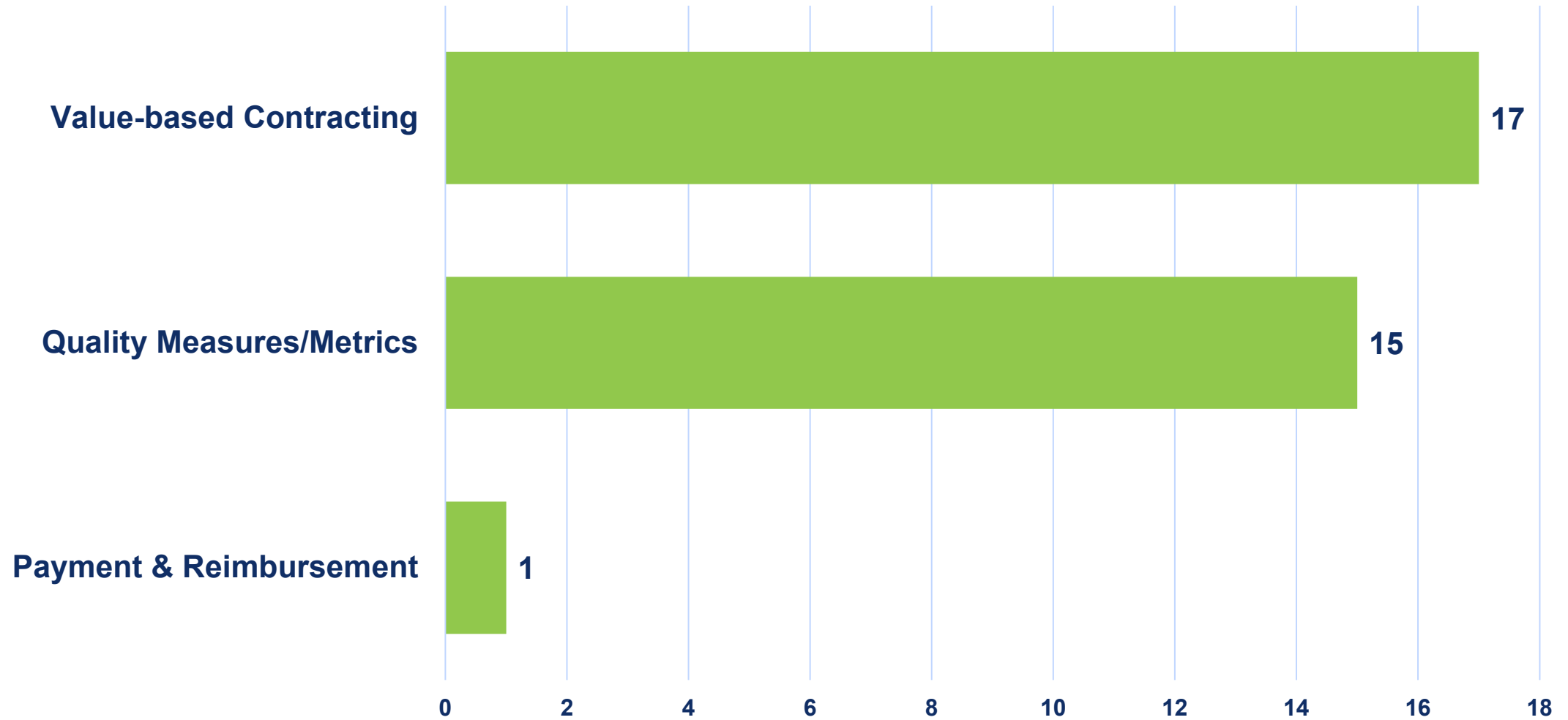


Value-based Care

Legislation introduced in 15 states

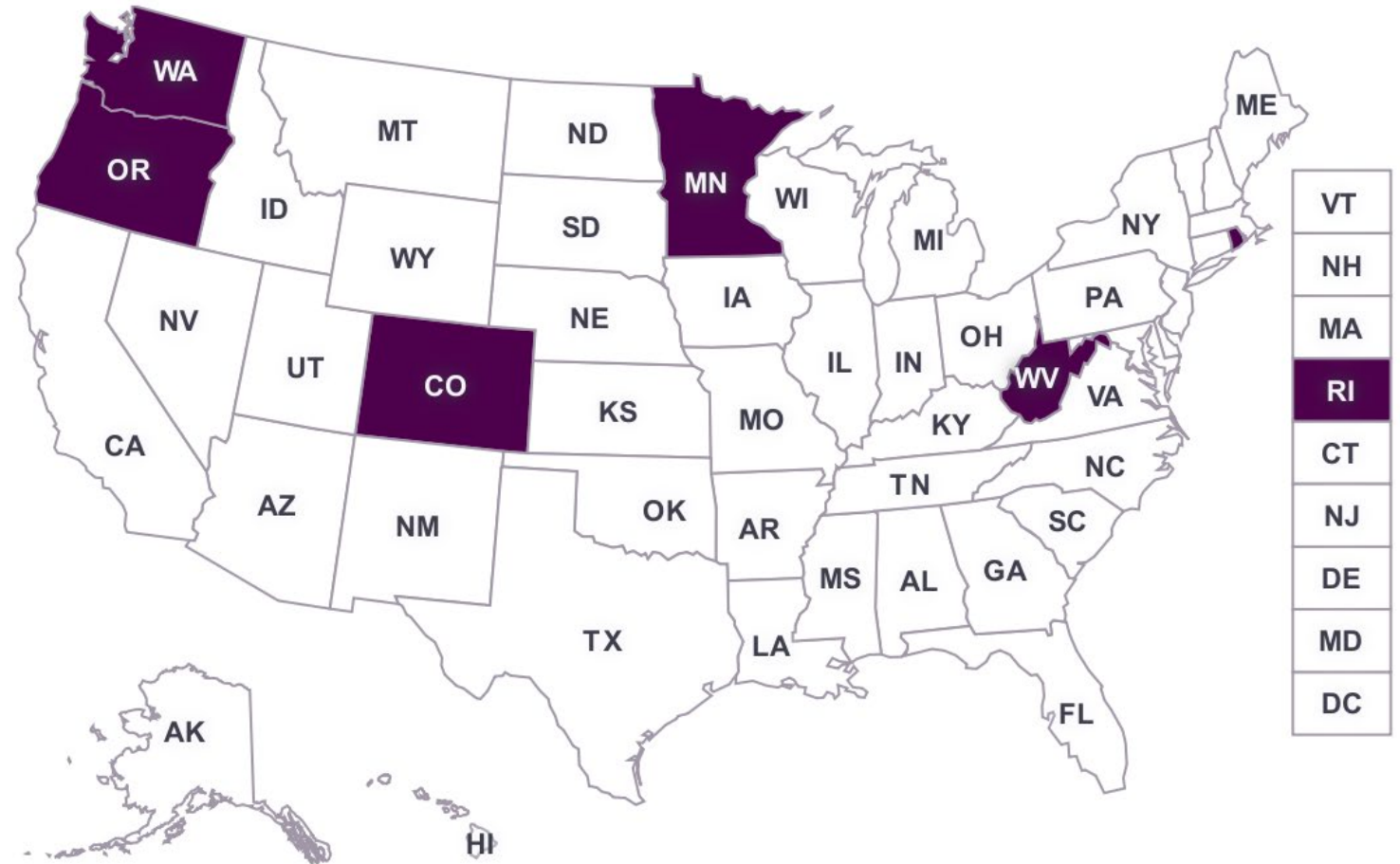


Value-based Care

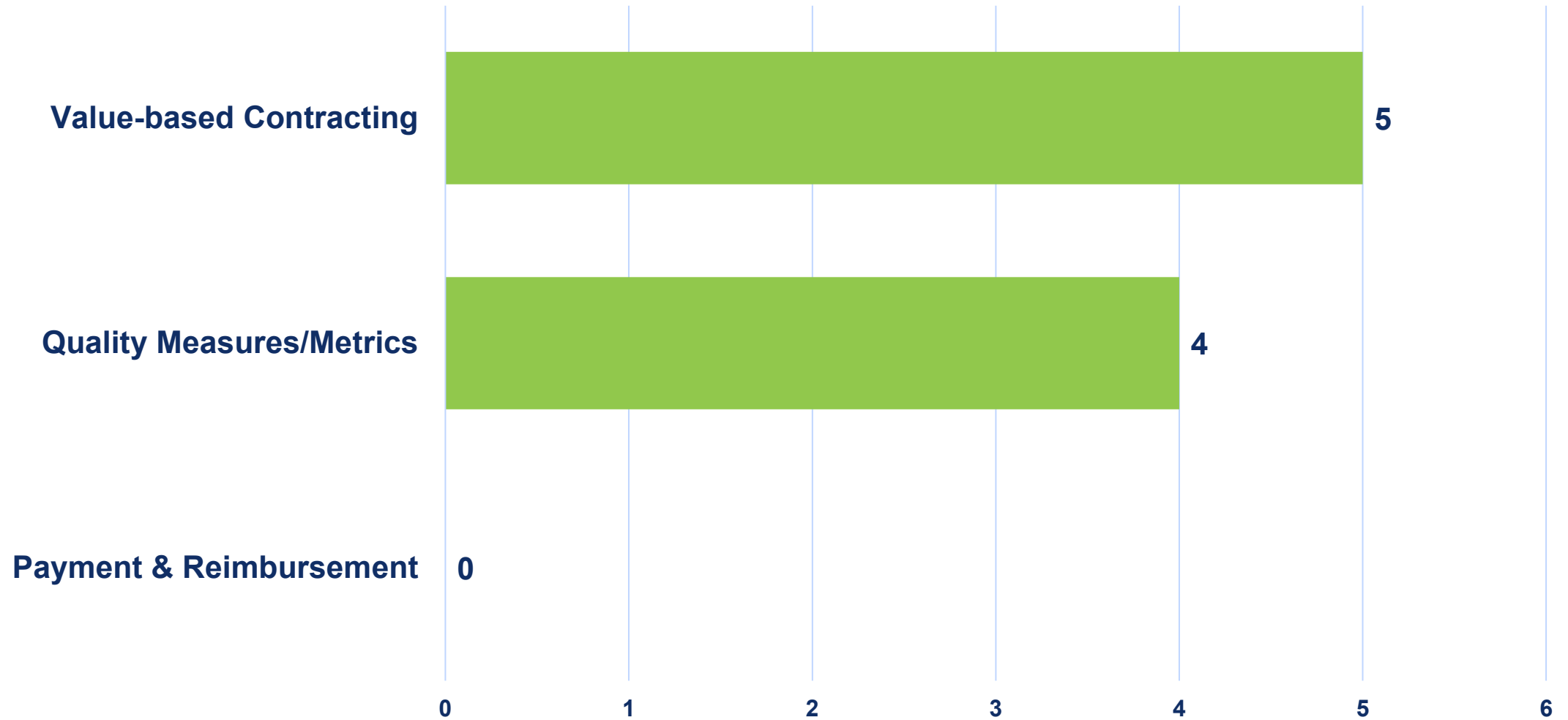


Value-based Care

Legislation enacted in 6 states



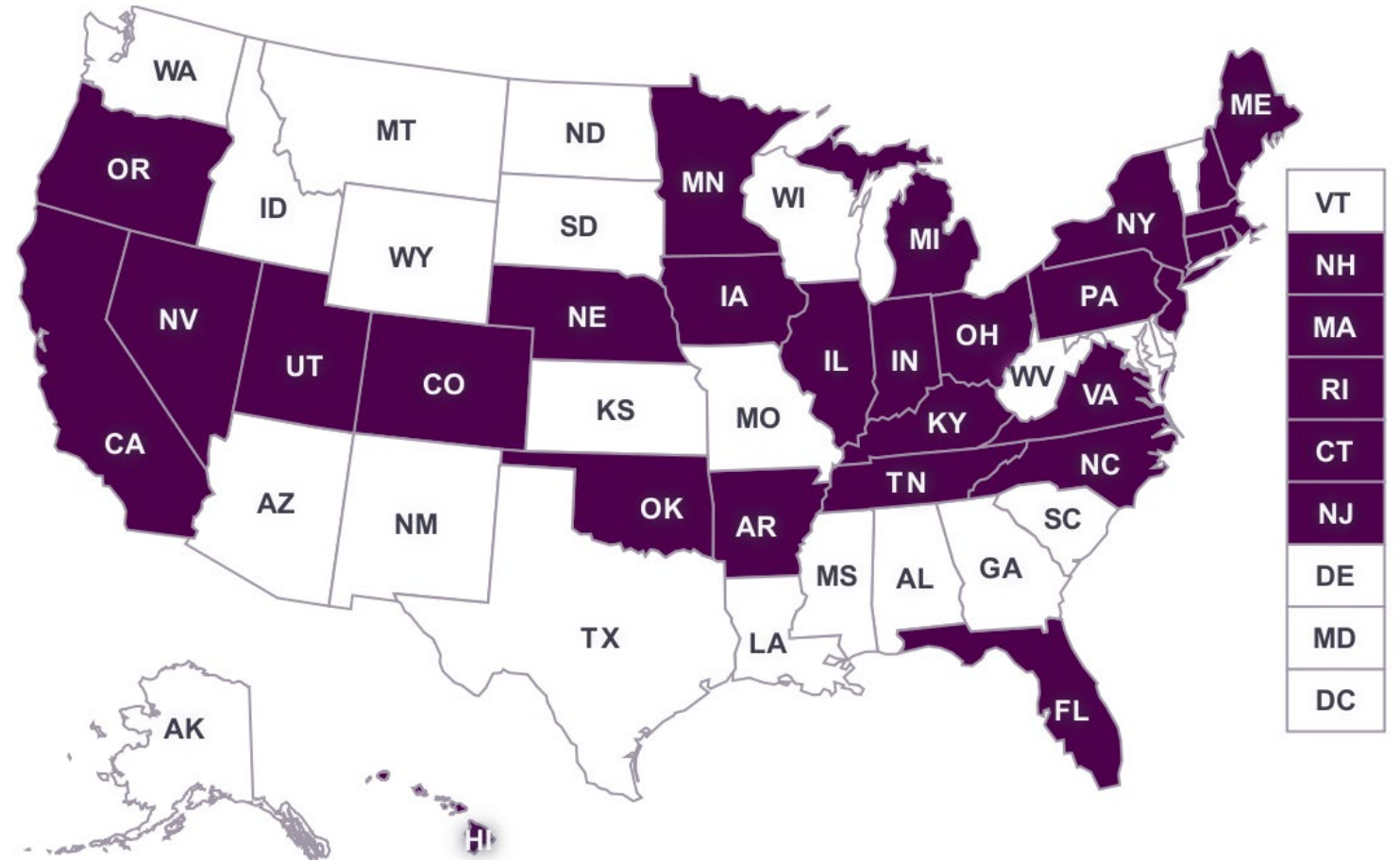
Value-based Care



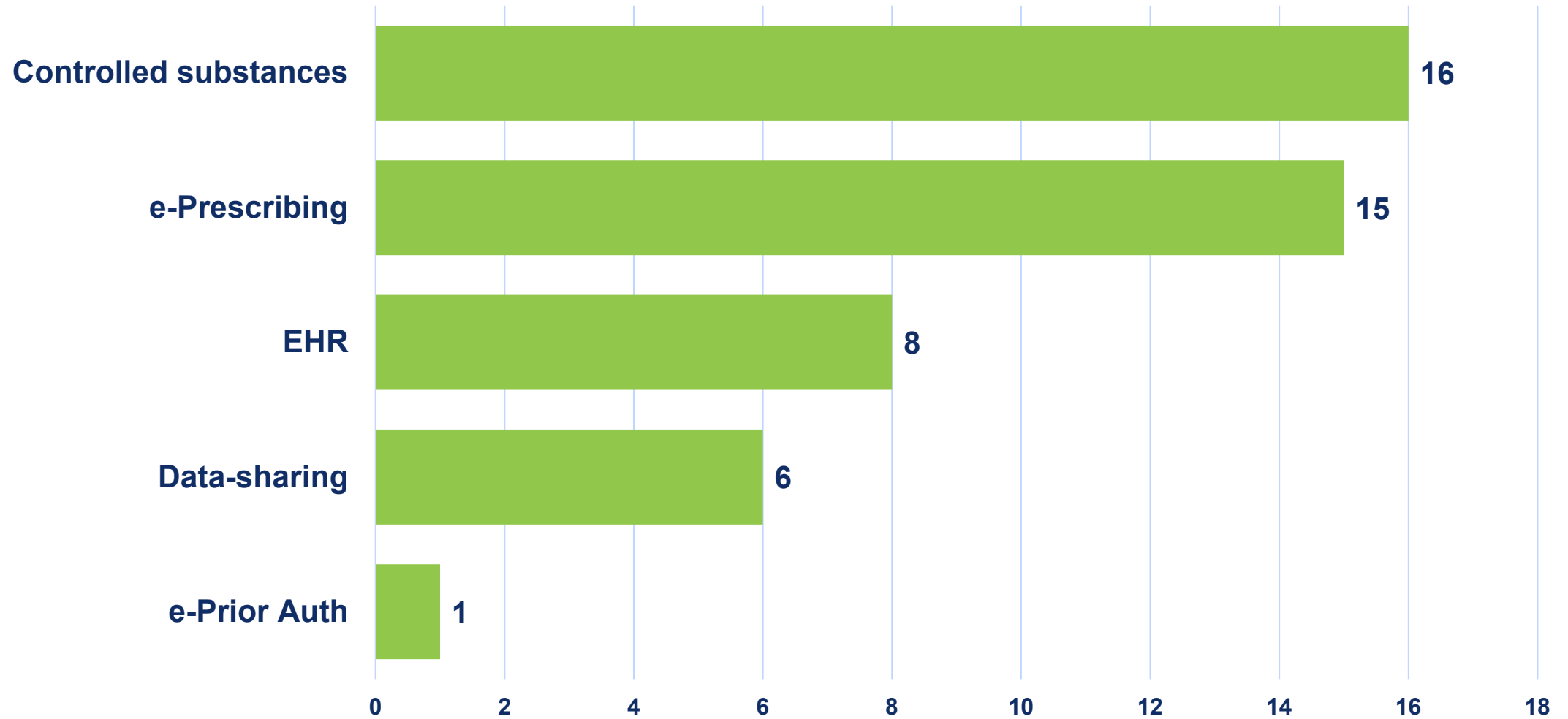
■ = Legislation introduced

Data-sharing and EHR

Legislation
introduced
in 28 states



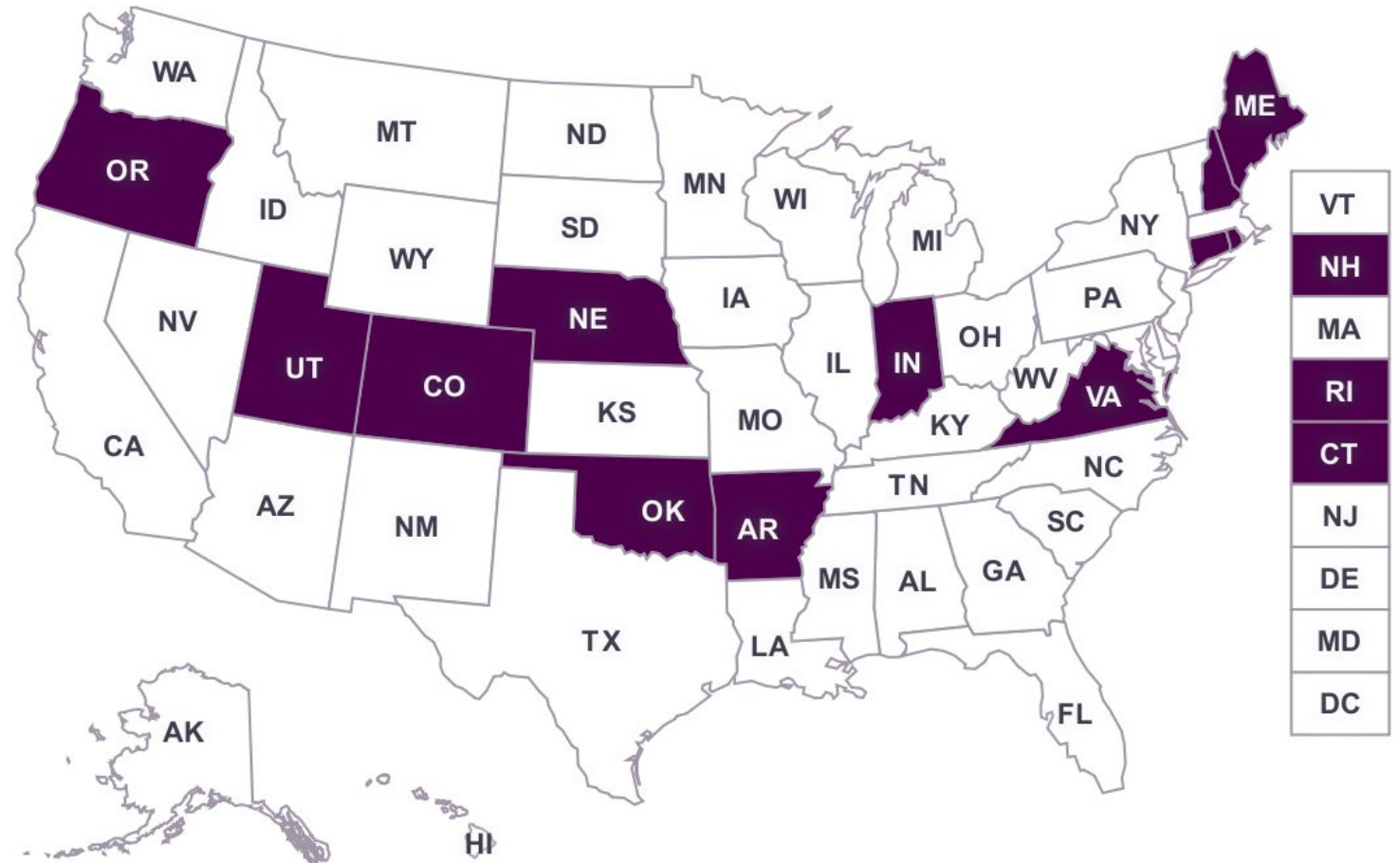
Data-sharing and EHR



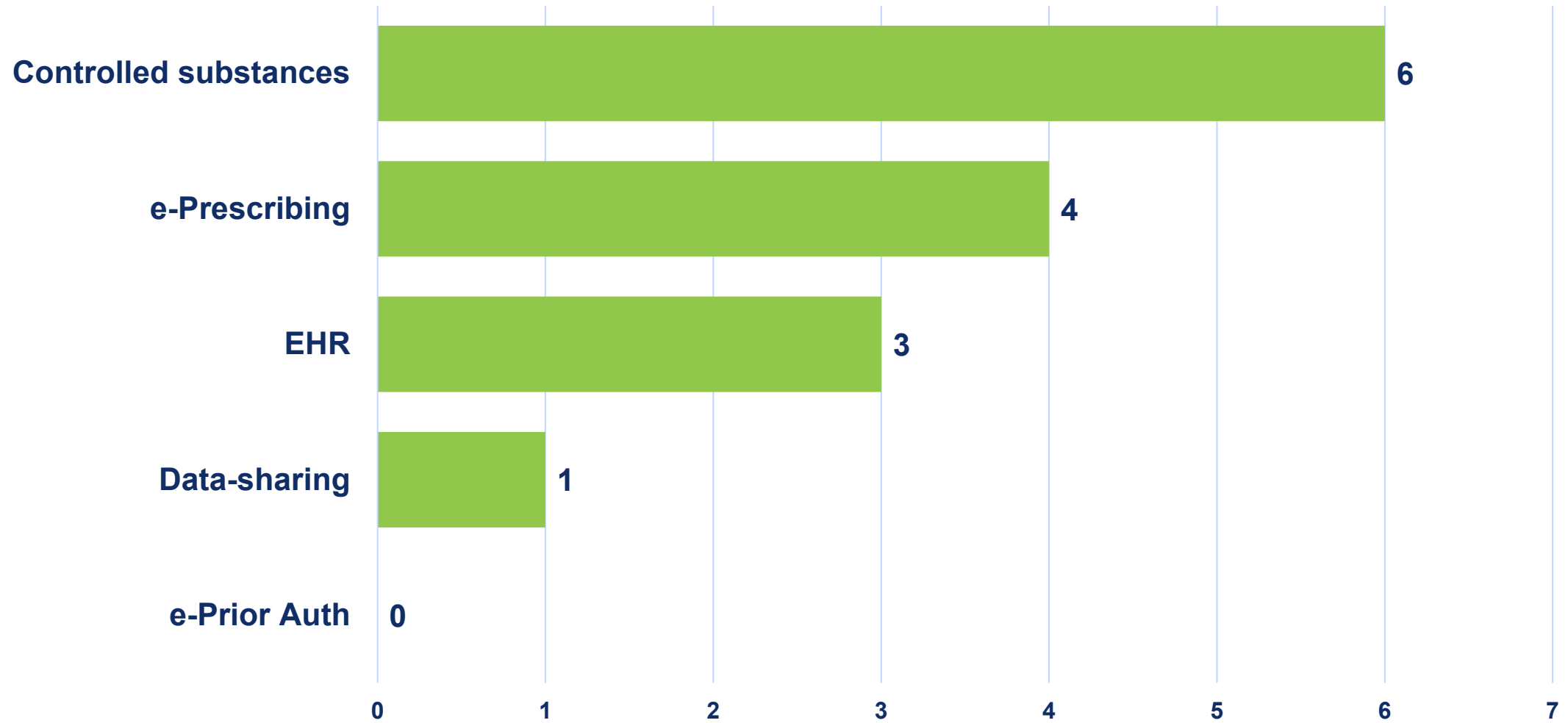
■ = Legislation enacted

Data-sharing and EHR

Legislation enacted in 12 states



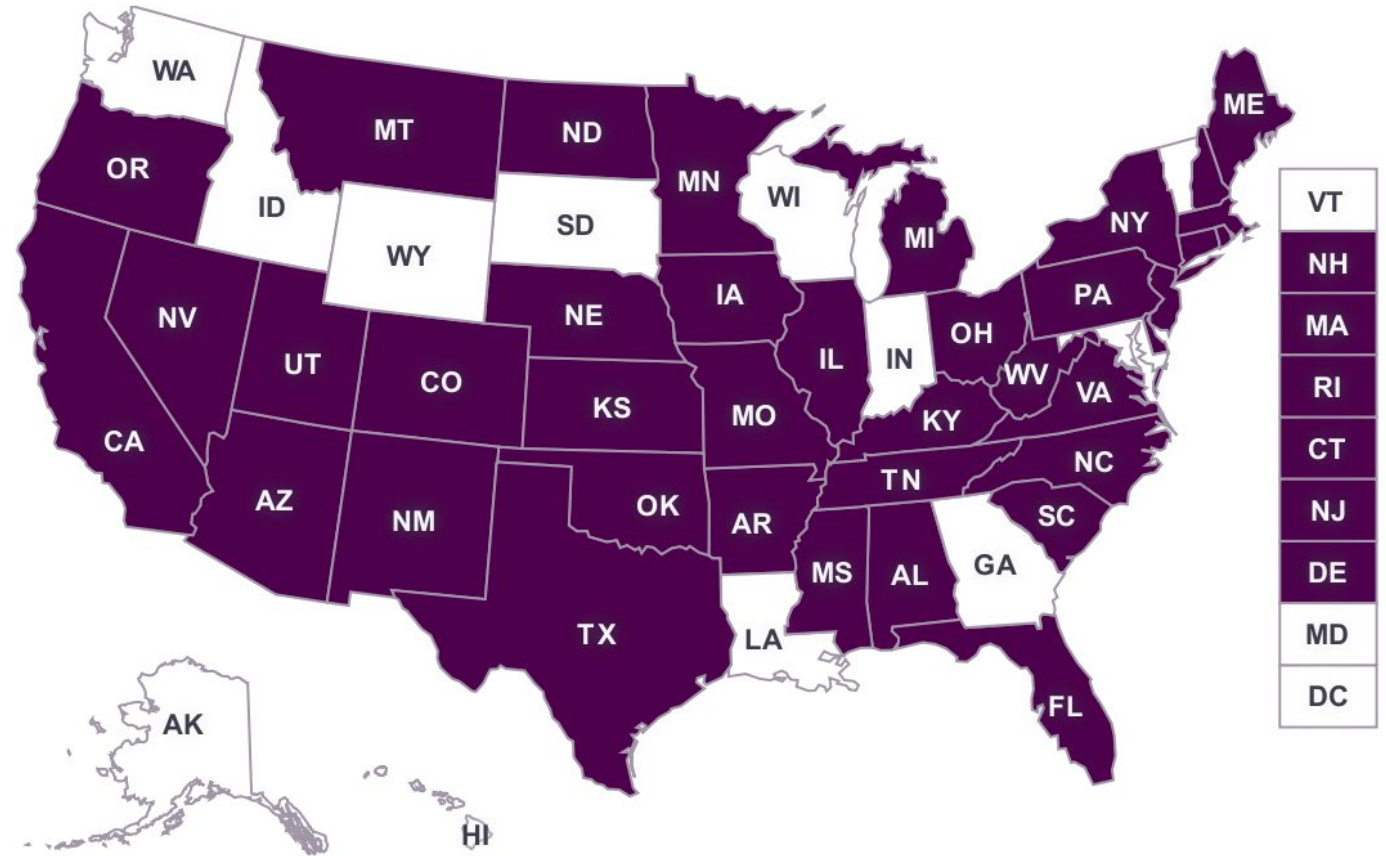
Data-sharing and EHR



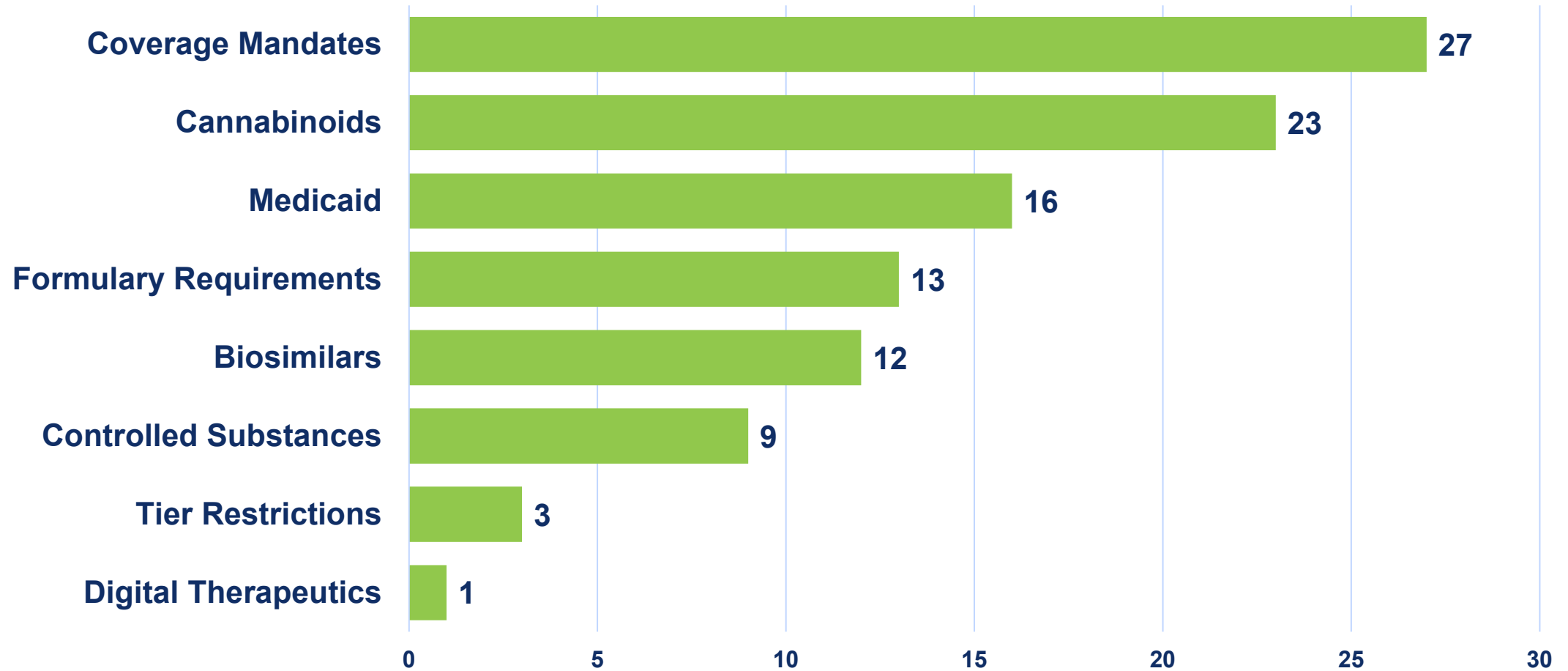
■ = Legislation introduced

Coverage Mandates/Tier Restrictions/ Formulary Requirements

Legislation
introduced
in 38 states



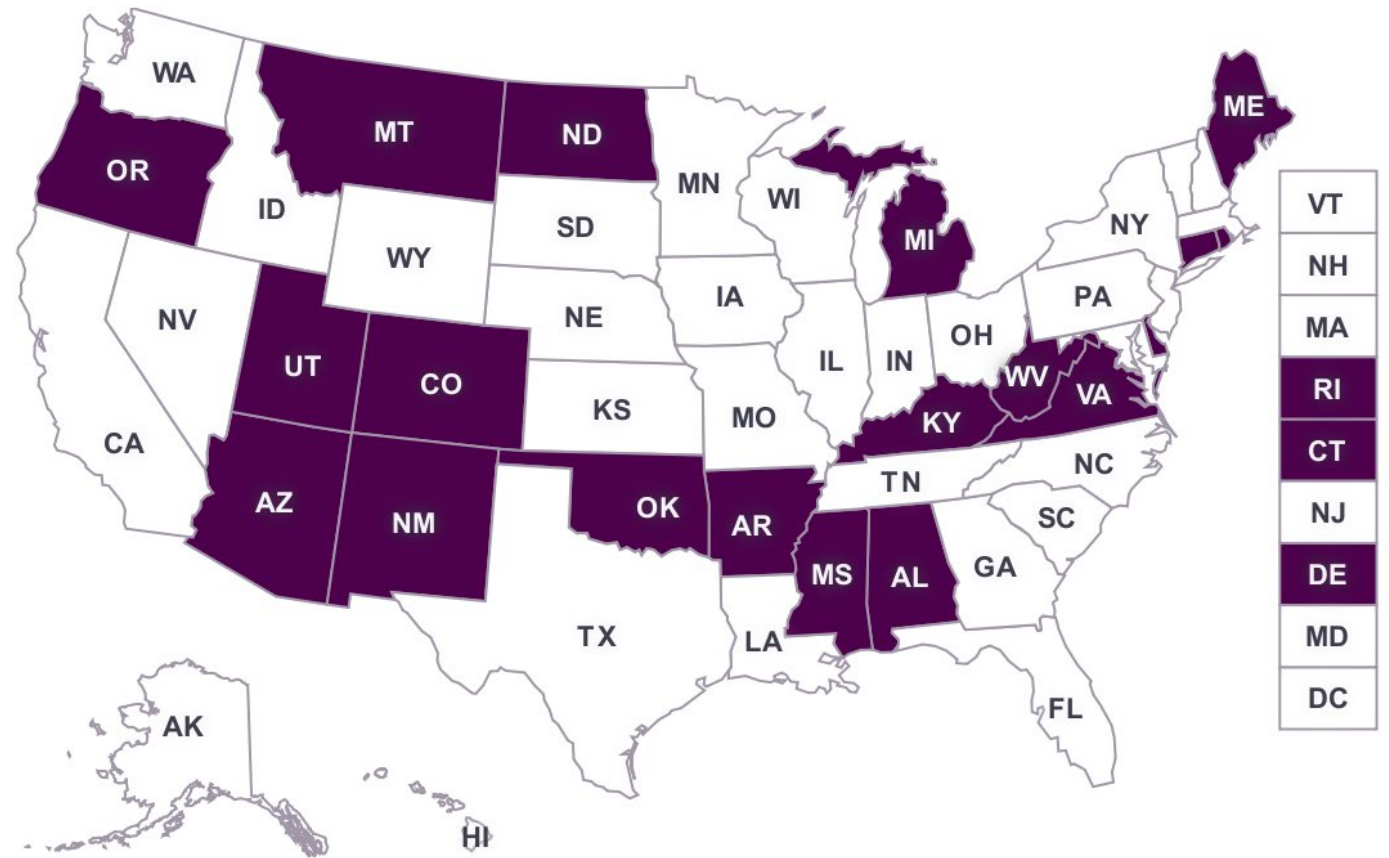
Coverage Mandates/Tier Restrictions/ Formulary Requirements



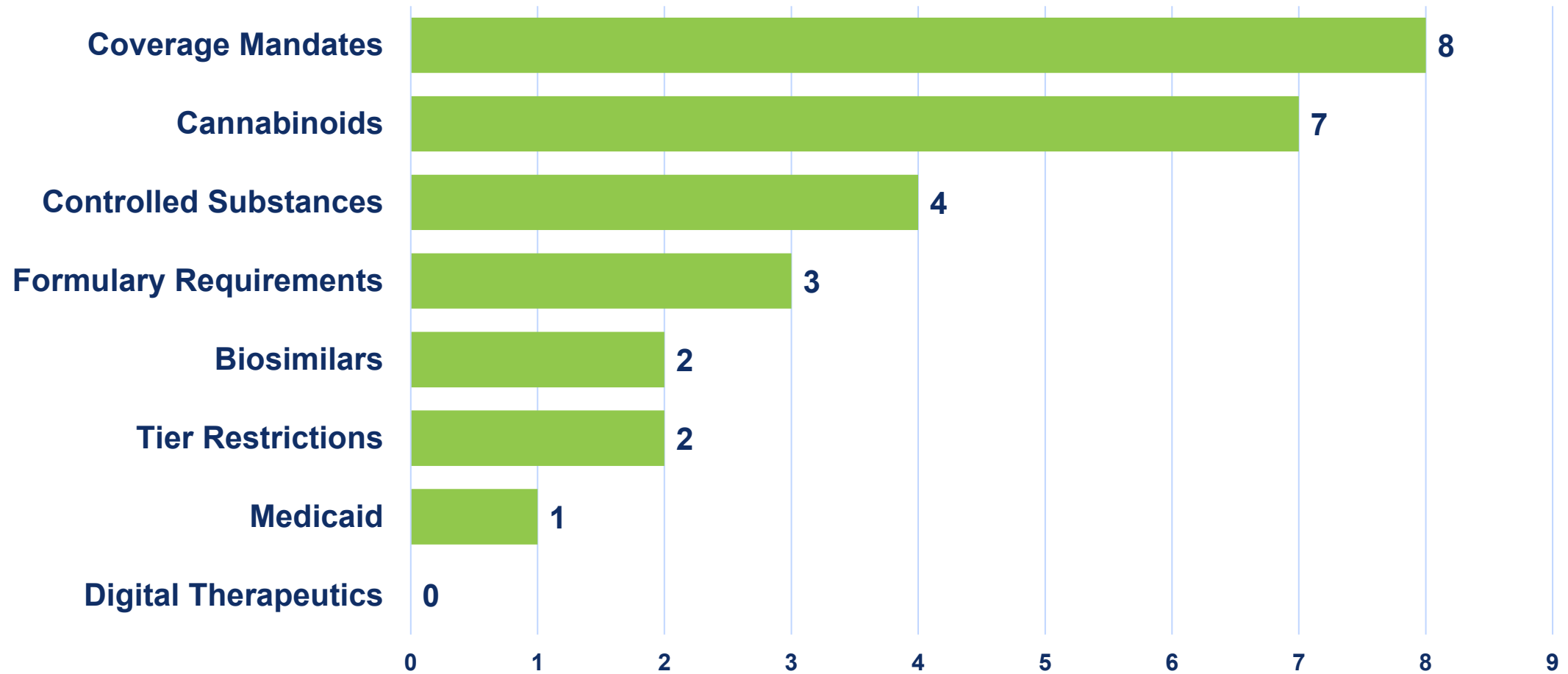
■ = Legislation enacted

Coverage Mandates/Tier Restrictions/ Formulary Requirements

Legislation
enacted
in 19 states

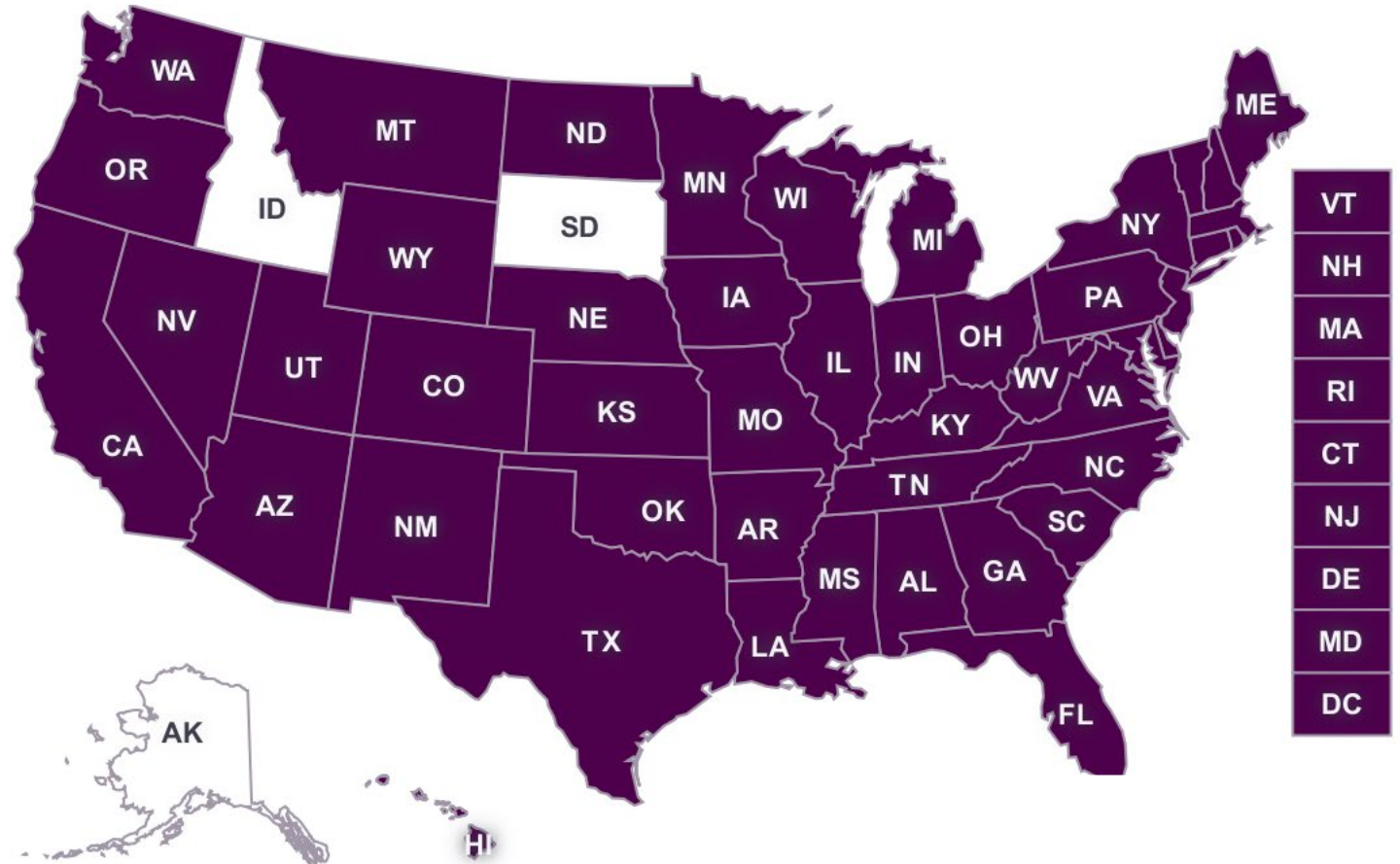


Coverage Mandates/Tier Restrictions/ Formulary Requirements

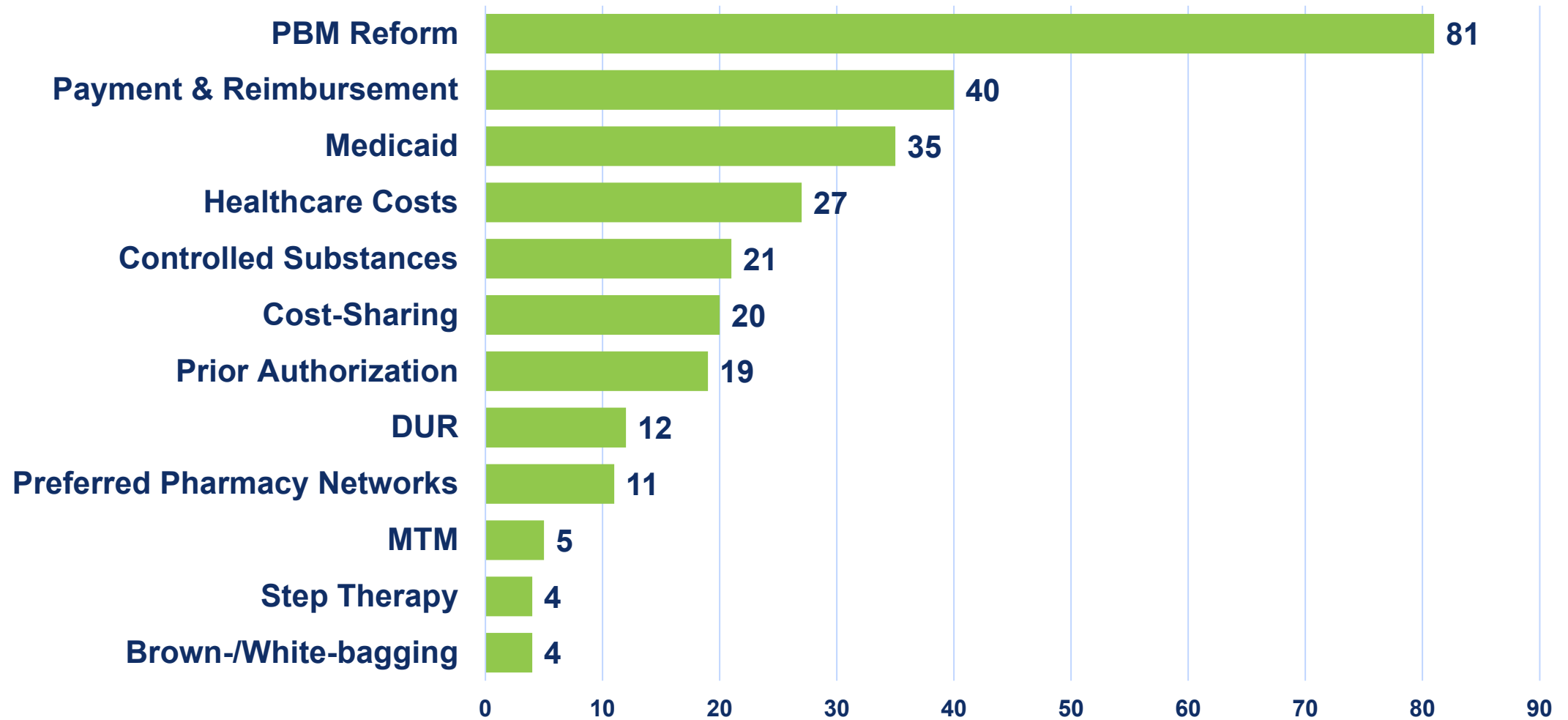


Utilization Management Tools

Legislation introduced in 47 states plus DC

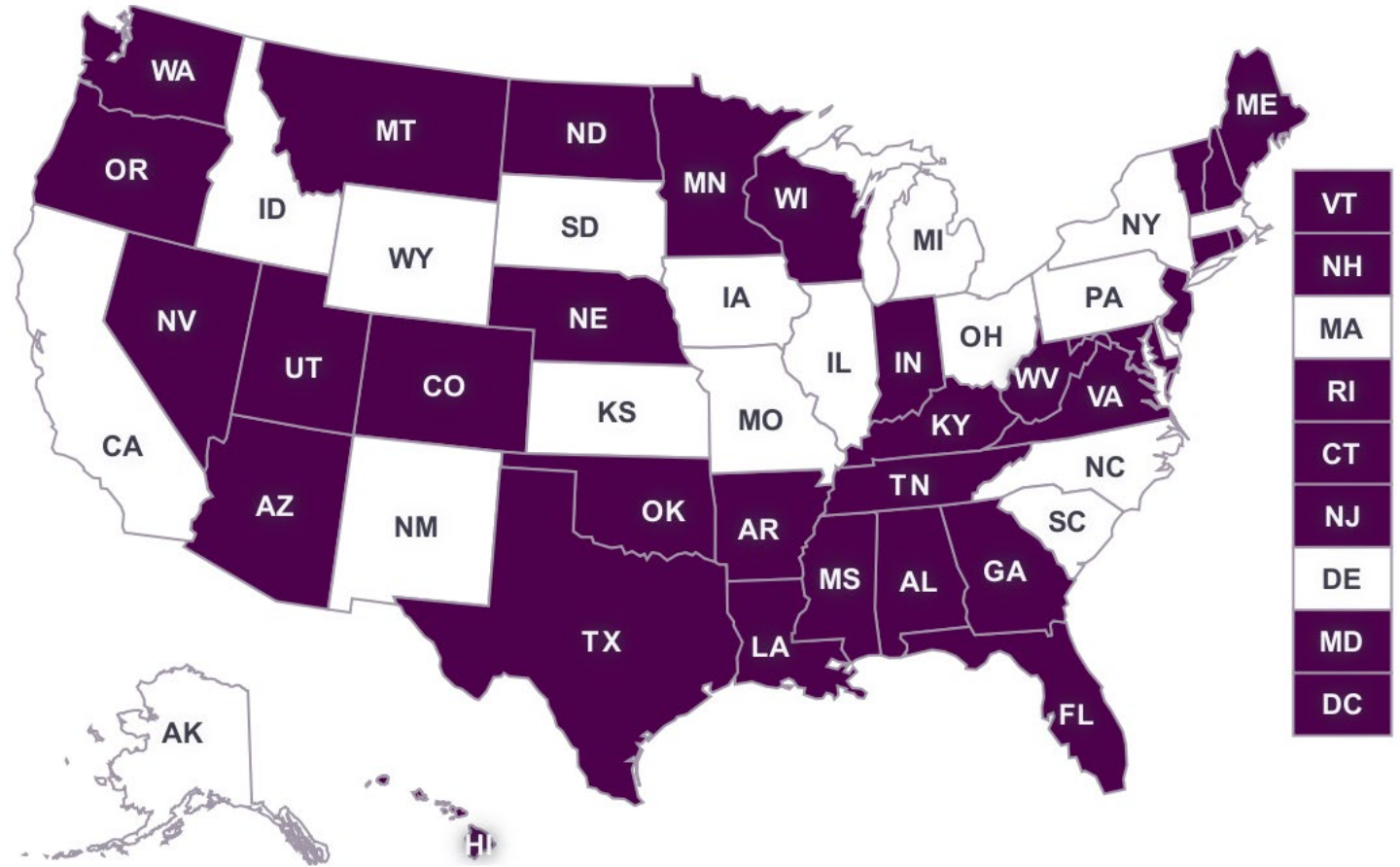


Utilization Management Tools

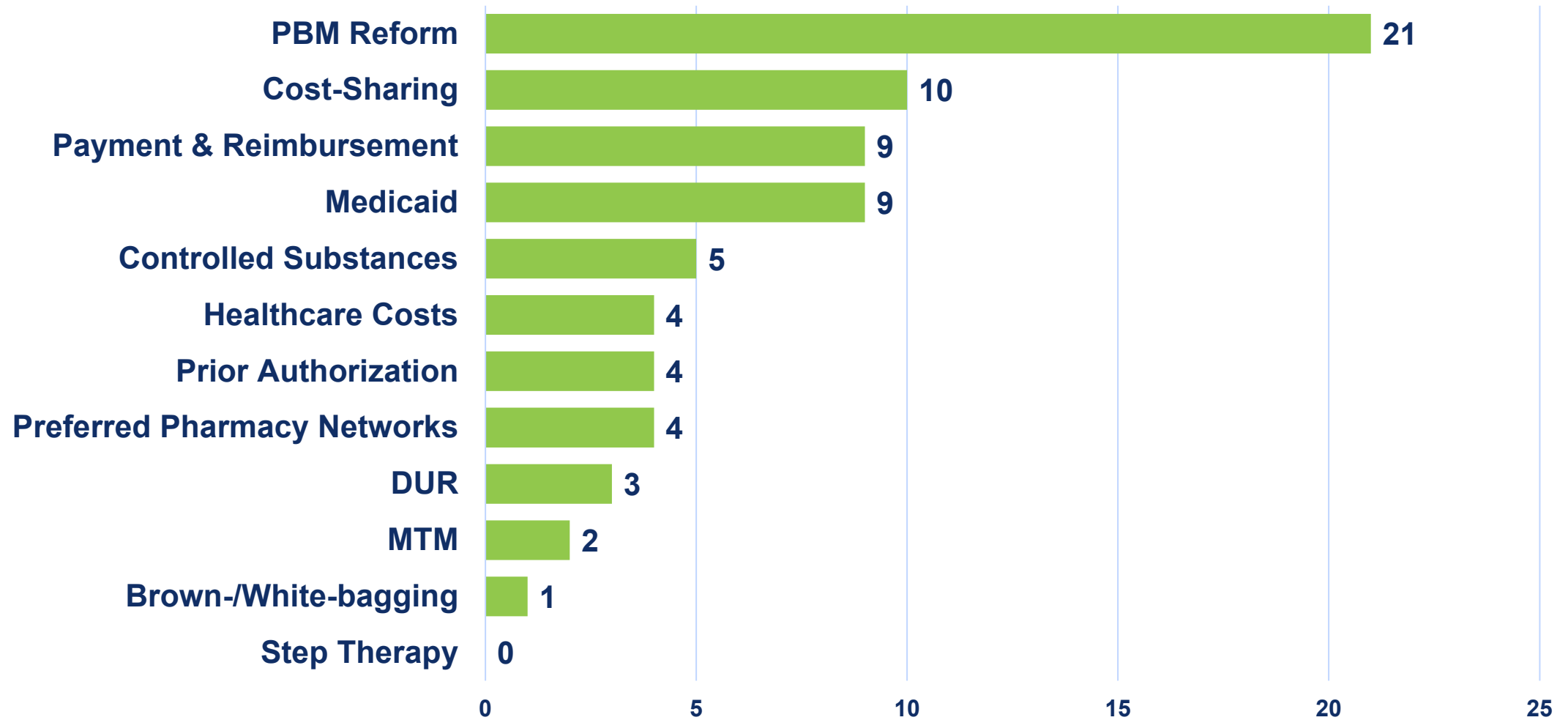


Utilization Management Tools

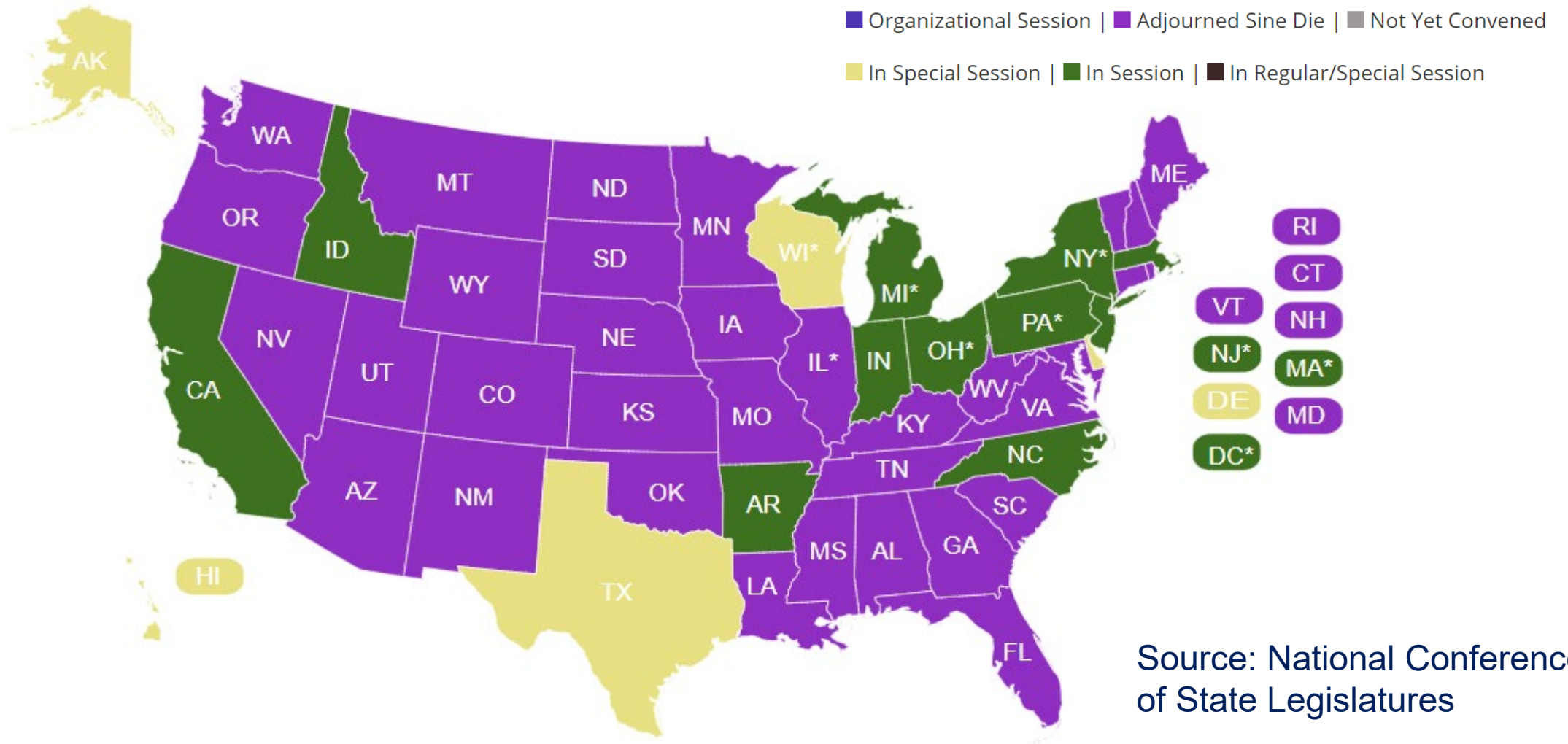
Legislation enacted in 32 states plus DC



Utilization Management Tools



State Legislature Statuses

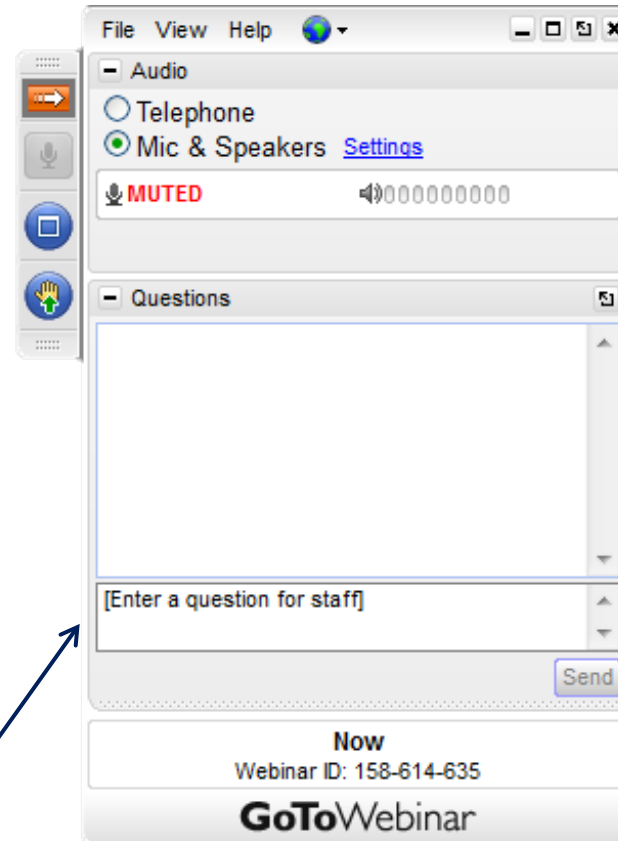


Source: National Conference of State Legislatures

Additional Information

- 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
Where We Stand statements for detailed information on AMCP's policy positions
- Email advocacy@amcp.org
Requests for more specific information, legislative reports, questions, etc.

How to Ask a Question



Type your question in the 'Questions' area

**For a list of upcoming webinars,
visit www.amcp.org/calendar**