Center for Evidence-based Policy

Evidence Synthesis Series

The Science of Good Policy

- Today's webinar will be recorded and posted on the Center for Evidence-based Policy website. Only the slides and presenter will be recorded.
- Please use the chat function to ask questions. Questions will be answered after the presentation.
- For assistance with Webex, please email plattk@ohsu.edu.

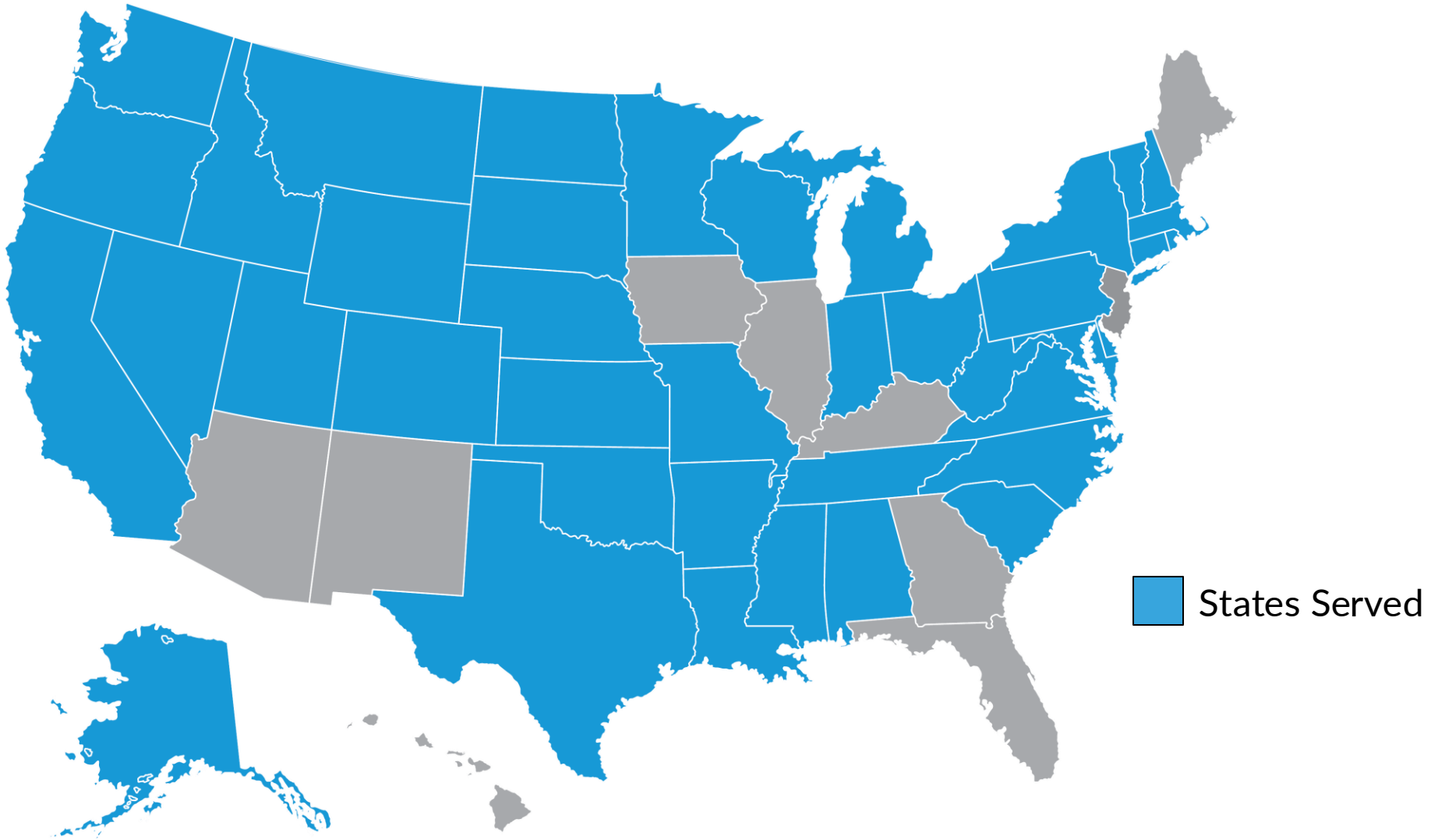
Center for Evidence-based Policy

Addressing policy challenges with evidence and collaboration

About Our Work

- Neutral and rigorous research and technical assistance services to support state policymakers
- Evidence review and synthesis
- Data analytics: administrative data integration, management, and analysis
- Policy analysis
- Technical assistance (operational and process-related)
- Trainings and workshops on evidence-based decision making

40 States Served Since 2003



About Our Organization

- Established in 2003 at Oregon Health & Science University
- Our work is driven by states, 90% in Medicaid
- We are not funded by industry or associations
- We are nonpartisan and we do not lobby
- Our work is typically proprietary

Who Are We?

Center Staff:

- Systematic reviewers
- Policy analysts
- Physicians
- Pharmacists
- Nurses
- Genetics professionals
- Epidemiologists
- Librarians
- Data scientists
- Technical editors
- Researchers

Work in 2024:

- Produced 50 evidence reports
- Researched 40 topics
- Screened over 30,000 titles and abstracts
- Reviewed in detail more than 3,000 research articles
- Graded 600 articles for quality

Today:

- Jesse Baumgartner
  Policy Analyst
- Lindsay Zetzsche
  Genetic Consultant
- Valerie King
  Director of Research
- Allison Leof
  Senior Policy Analyst
- Kelsey Platt
  Project Coordinator

Profiling State Biomarker Testing Legislation in Medicaid

Presented by

Jesse Baumgartner, MPH

Lindsay Zetzsche, MBA, MS, LCGC

Disclosure Information

- Today's presenters and the report authors do not have any conflicts of interest to disclose.

Overview

- Background
- Research Aims
- Methods
- Findings
- State Considerations
- Looking Ahead
- Questions and Discussion

Acronyms

- **ACS CAN:** American Cancer Society Cancer Action Network
- **CMS:** Centers for Medicare & Medicaid Services
- **FDA:** US Food and Drug Administration
- **LCD:** Local coverage determination
- **MAC:** Medicare administrative contractor
- **MCO:** Managed care organization
- **NCD:** National coverage determination
- **NCOIL:** National Council of Insurance Legislators
- **PLA:** proprietary laboratory analyses

Abbreviations of State Names

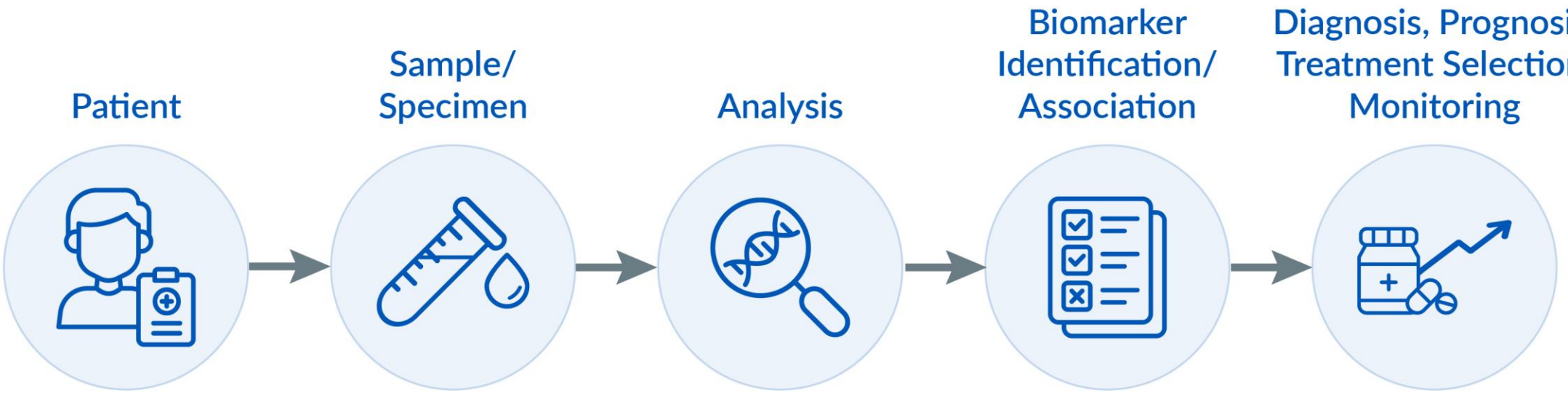
- AZ: Arizona
- AR: Arkansas
- CA: California
- CO: Colorado
- CT: Connecticut
- DE: Delaware
- FL: Florida
- GA: Georgia
- HI: Hawaii
- IA: Iowa
- IL: Illinois
- IN: Indiana
- KY: Kentucky
- LA: Louisiana
- MA: Massachusetts
- MD: Maryland
- ME: Maine
- MN: Minnesota
- MO: Missouri
- NE: Nebraska
- NH: New Hampshire
- NJ: New Jersey
- NM: New Mexico
- NY: New York
- NV: Nevada
- NC: North Carolina
- OH: Ohio
- OK: Oklahoma
- OR: Oregon
- PA: Pennsylvania
- RI: Rhode Island
- SD: South Dakota
- TN: Tennessee
- TX: Texas
- VT: Vermont
- WA: Washington
- WV: West Virginia

Background: Topic Nomination

- This topic was nominated by Medicaid Evidence-based Decisions (MED) project participants
- MED is a collaborative of 22 state Medicaid programs
- State-driven governance and research agenda
- Researchers at the Center for Evidence-based Policy developed and carried out the project, based on state feedback

Background *(1 of 3)*

- Biomarker testing supports precision medicine by using defined associations to provide critical information that guides patient care



Background *(2 of 3)*

- There is nationwide focus on access and insurance coverage for these tests
- Since 2021, more than 20 states have passed laws requiring insurance plans to cover biomarker testing; more than a dozen additional states have recently proposed bills
- These laws have notable advocacy support, led by the American Cancer Society's Cancer Action Network (ACS CAN)

Sources. *Access to Biomarker Testing* *(ACS CAN, 2025);* *The State of State Biomarker Testing Insurance Coverage Laws* *(2024).*

Background *(3 of 3)*

- Initial focus on cancer, but most laws now cover all conditions
- Most laws and proposed bills apply to state Medicaid programs, Medicaid MCOs, and state-regulated commercial plans
- NCOIL finalized model legislation in 2023 for states to use
- The details of biomarker testing laws may vary across states, and it is uncertain how different laws may expand the coverage universe and financial costs of state Medicaid agencies
- Agencies are now implementing coverage under these laws

Sources. *NCOIL Biomarker Testing Insurance Coverage Model Act (2023); The State of State Biomarker Testing Insurance Coverage Laws (2024).*

Typical Law Structure

- Passed and proposed laws often align with NCOIL model legislation:

COVERED SERVICE

Biomarker testing for diagnosis, treatment, management, or ongoing monitoring of condition to guide treatment

COVERAGE STANDARD

When test provides clinical utility, as demonstrated by medical and scientific evidence categories

EVIDENCE CATEGORIES

- FDA designations
- Medicare coverage determinations
- Clinical practice guidelines

ADDITIONAL

- Screening test exclusion
- Application to Medicaid MCOs
- Accessible exceptions/ appeals process

Source. *NCOIL Biomarker Testing Insurance Coverage Model Act* *(2023).*

Aim of Research

- With most biomarker testing laws applying to state Medicaid programs, and active or proposed legislation in more than 70% of states, this report explored:
  - The structures and provisions of different state laws
  - The potential impact on Medicaid coverage responsibilities and financial costs
  - Considerations for agencies as they evaluate pending legislation and implement biomarker testing coverage policies after laws are passed

Methods

- Review and analysis of biomarker testing laws and proposed bills in all 50 states and District of Columbia **through March 19**
- Interviews with:
  - State Medicaid agencies
  - Subject matter experts (insurance policy, clinical, legal, research)
- Full review of policy and academic literature

Findings

50-State and District of Columbia Scan: Characteristics of Laws and Bills *(through March 19, 2025)*

21 States Passed Laws and 14 Proposed Them (as of March 19, 2025)

- Effective dates for passed laws range from 2022 to 2026

Year effective	States with **passed** legislation
2022	IL AZ
2023	AR GA NV
2024	CA CT FL IN KY NM OK RI TX
2025	CO IA LA MD MN NY
2026	PA

States with **proposed** legislation

HI ME MA MO NE NH NJ
OH OR SD TN VT WA WV

*Notes. Current as of March 19, 2025. States in **blue** have passed laws; states in **gray** have only proposed bills. Somes states with passed laws (e.g., Connecticut, Nevada) have newly proposed bills to expand the scope.*

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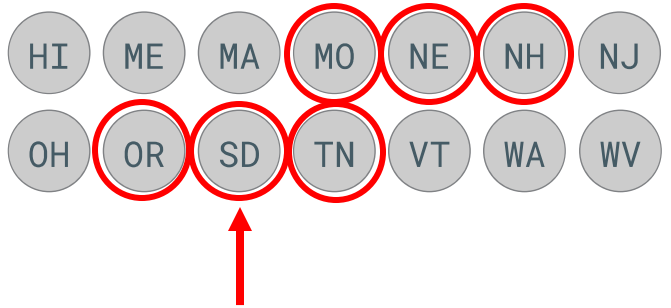

States with proposed bills for the first time in 2025 legislative session

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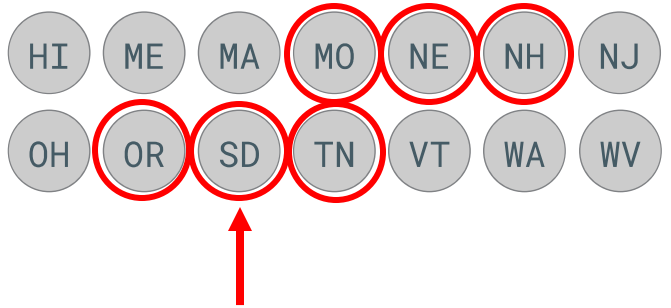

States with proposed bills for the first time in 2025 legislative session

+ DE and NC bills proposed during the last 2 months

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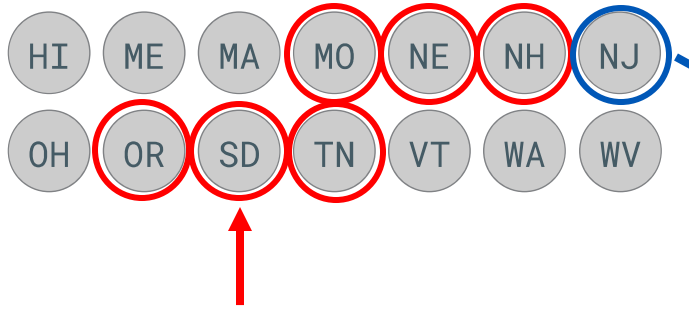

NJ bill became law in April

States with proposed bills for the first time in 2025 legislative session

+ DE and NC bills proposed during the last 7 weeks

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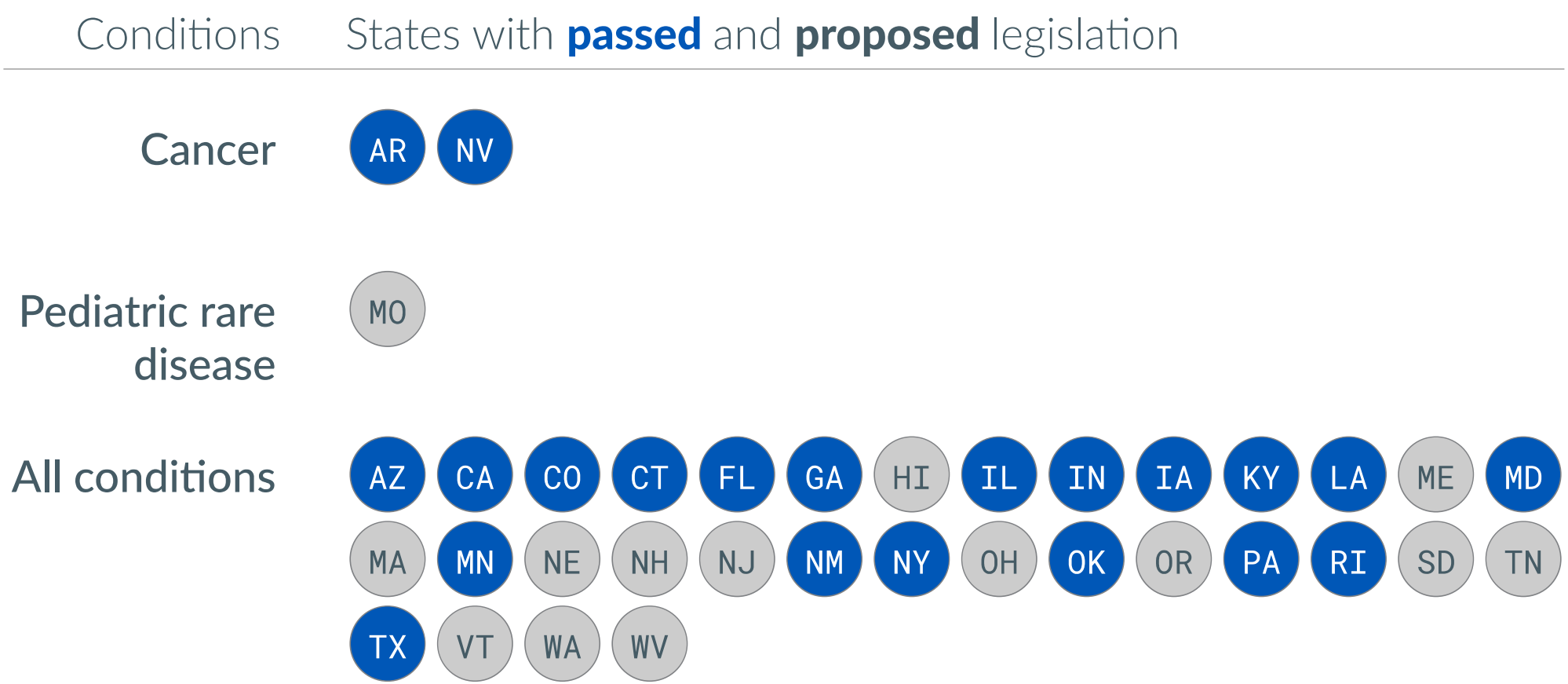
Most Passed and Proposed Laws Apply to Both Medicaid and State-Regulated Commercial Insurance Plans

Coverage groups	States with **passed** and **proposed** legislation
Medicaid	CT
State-regulated commercial plans	AR CO LA RI SD
Both	AZ CA FL GA HI IL IN IA KY ME MD MA MN MO NE NV NH NJ NM NY OH OK OR PA TN TX VT WA WV

*Notes. Current as of March 19, 2025. States in **blue** have passed laws; states in **gray** have only proposed bills. State-regulated commercial plans typically include state employee plans. Florida law only applies to Medicaid and state employee plans.*

Most Laws Apply to All Health Conditions



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The Concepts, Standards, and Language Used to Create Coverage Requirements Can Vary by State

Purposes of diagnosis, treatment, management, monitoring

Supported or demonstrated by medical and scientific evidence

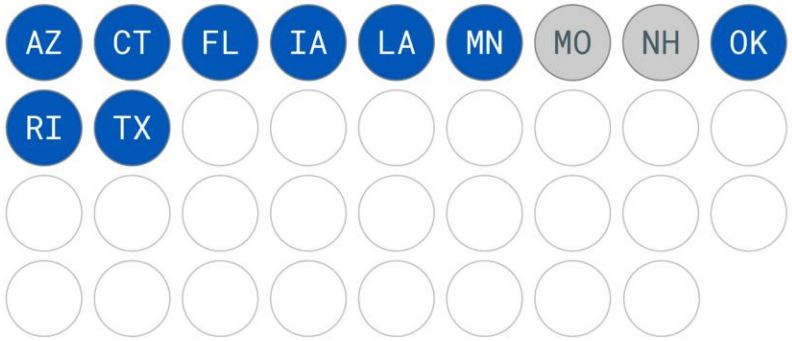
*Notes. Current as of March 19, 2025. States in **blue** have passed laws; states in **gray** have only proposed bills.*

The Concepts, Standards, and Language Used to Create Coverage Requirements Can Vary by State

Purposes of diagnosis, treatment, management, monitoring

Supported or demonstrated by medical and scientific evidence

Clinical utility



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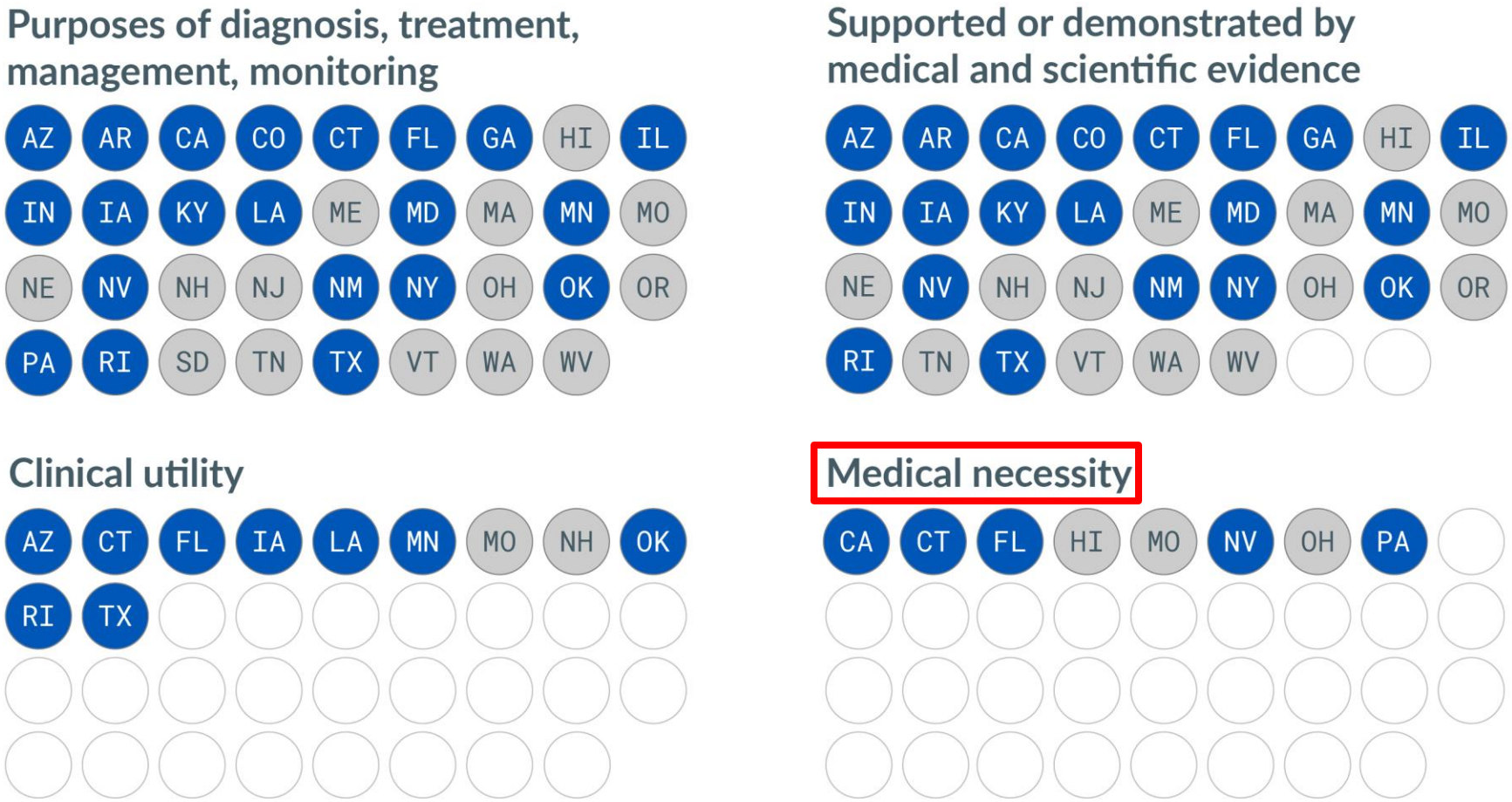

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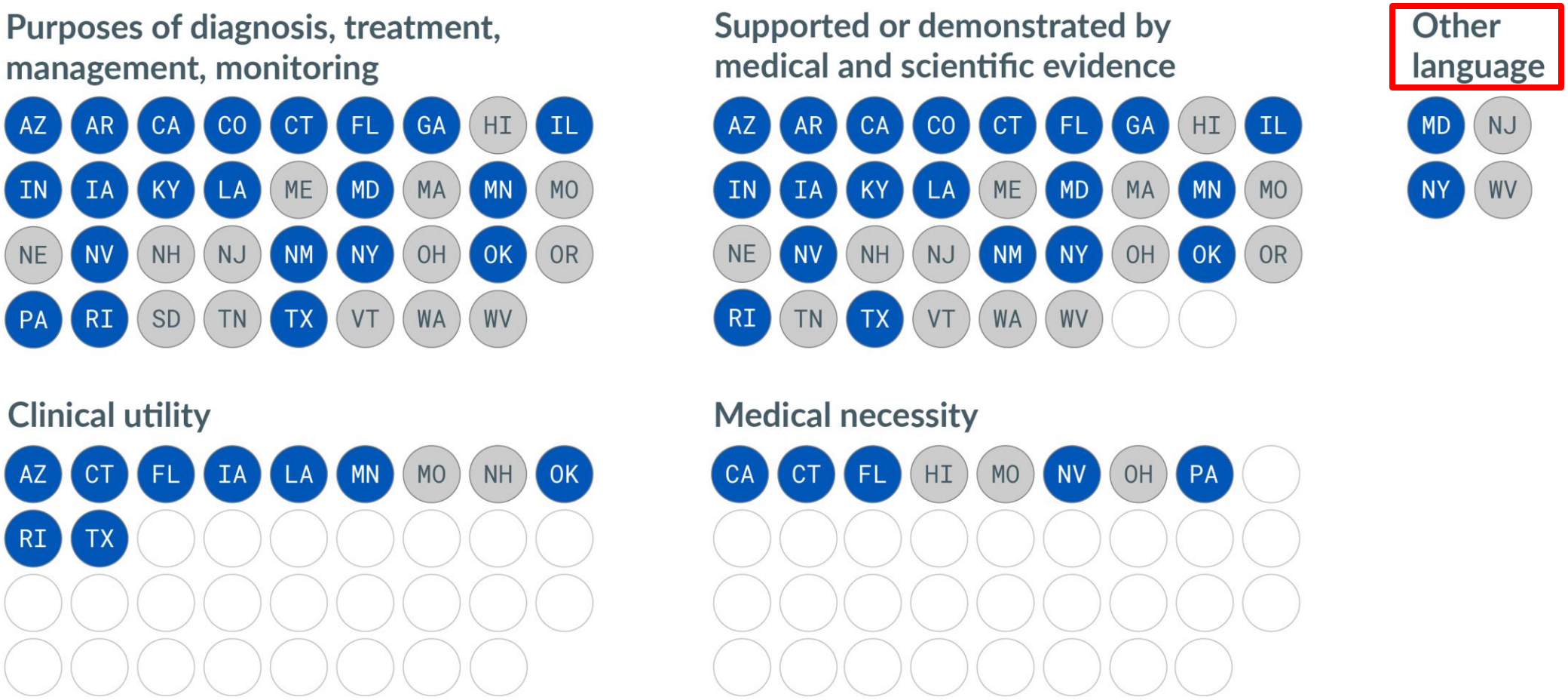

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Examples of Biomarker Testing Law Core Coverage Requirements

ONLY EVIDENCE CATEGORIES (KY)

"When the test is supported by medical and scientific evidence, *including but not limited to*: …"

MEDICAL NECESSITY, CLINICAL UTILITY (CT)

"The commissioner shall ensure that such coverage **is medically necessary pursuant to section 17b-259b of the general statutes** and, to assist in such determination of medical necessity, shall analyze relevant information … **including medical and scientific evidence** supporting such test **when the test provides clinical utility** as demonstrated by …"

CLINICAL UTILITY (IA)

"When the biomarker testing has **demonstrated clinical utility**, including but not limited to any of the following …"

ALTERNATIVE LANGUAGE DESCRIBING COVERAGE STANDARD (NJ)

"When the **efficacy and appropriateness of biomarker precision medical testing** for the diagnosis, treatment, appropriate management, or guiding treatment decisions for a subscriber's disease or condition **is recognized by** …"

Source. Final laws for Connecticut, Iowa, Kentucky, New Jersey.

Evidence Categories Typically Listed in Laws

- Coverage mandates typically tied to support from "medical and scientific" evidence sources
- Pennsylvania is the only state with a passed law not mentioning evidence
- Main evidence categories found in bills:

FDA Related	Medicare Related	Other
• Indications for FDA-approved or -cleared tests • Indicated tests for drugs approved by FDA • Warnings and precautions on FDA-approved drug labels*	• CMS National Coverage Determinations (NCDs) • Medicare Administrative Contractor (MAC) Local Coverage Determinations (LCDs)	• Nationally recognized clinical practice guidelines • Consensus statements* • Peer-reviewed literature* • Other (e.g., National Academy of Medicine standards)*

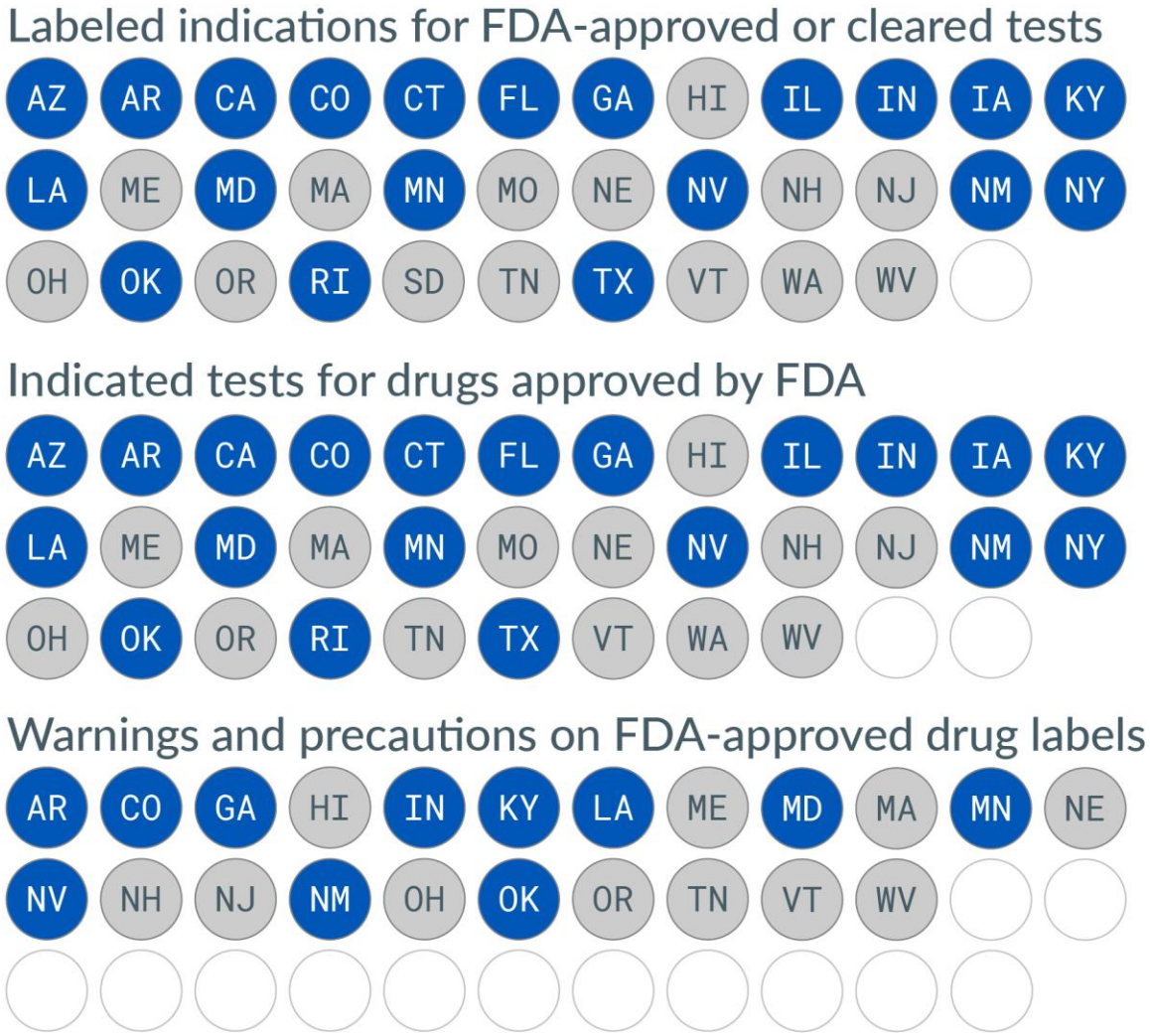
**Not included in NCOIL Biomarker Testing Insurance Coverage Model Act.*

Most Laws Include FDA-Approved or Cleared Tests and Indicated Tests Within the Evidence Categories

Of 21 states with laws **passed**:

- 95% (20 states) have labeled indications for FDA-approved or FDA-cleared tests
- 95% (20 states) have indicated tests for drugs approved by the FDA
- 52% (11 states) have warnings and precautions on FDA-approved drug labels

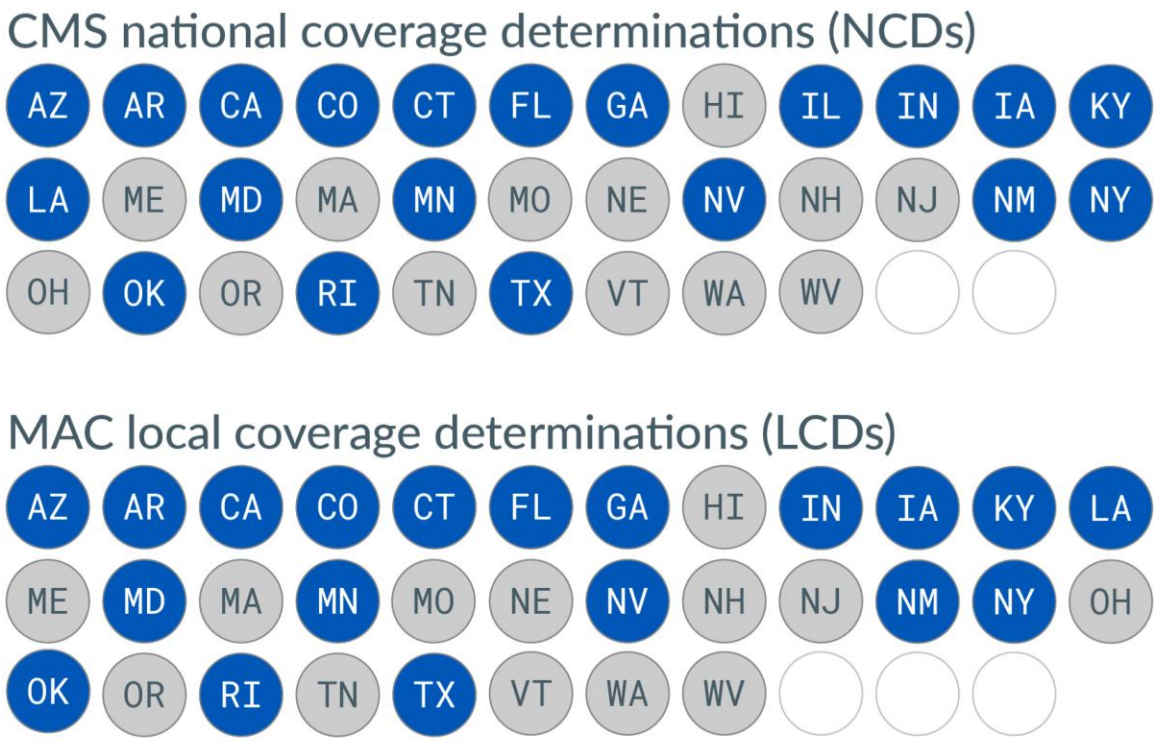
*Notes. Current as of March 19, 2025. States in **blue** have passed laws; states in **gray** have only proposed bills.*



Almost All Laws Include Medicare National and Local Coverage Determinations Within the Evidence Categories

Of 21 states with laws **passed**:

- 95% (20 states) include CMS NCDs
- 90% (19 states) include Medicare administrative contractor (MAC) LCDs
  - Illinois and Pennsylvania are the only states with passed bills that do not include LCDs (Pennsylvania has no evidence criteria)
  - California specifies that LCDs must be from MAC covering California



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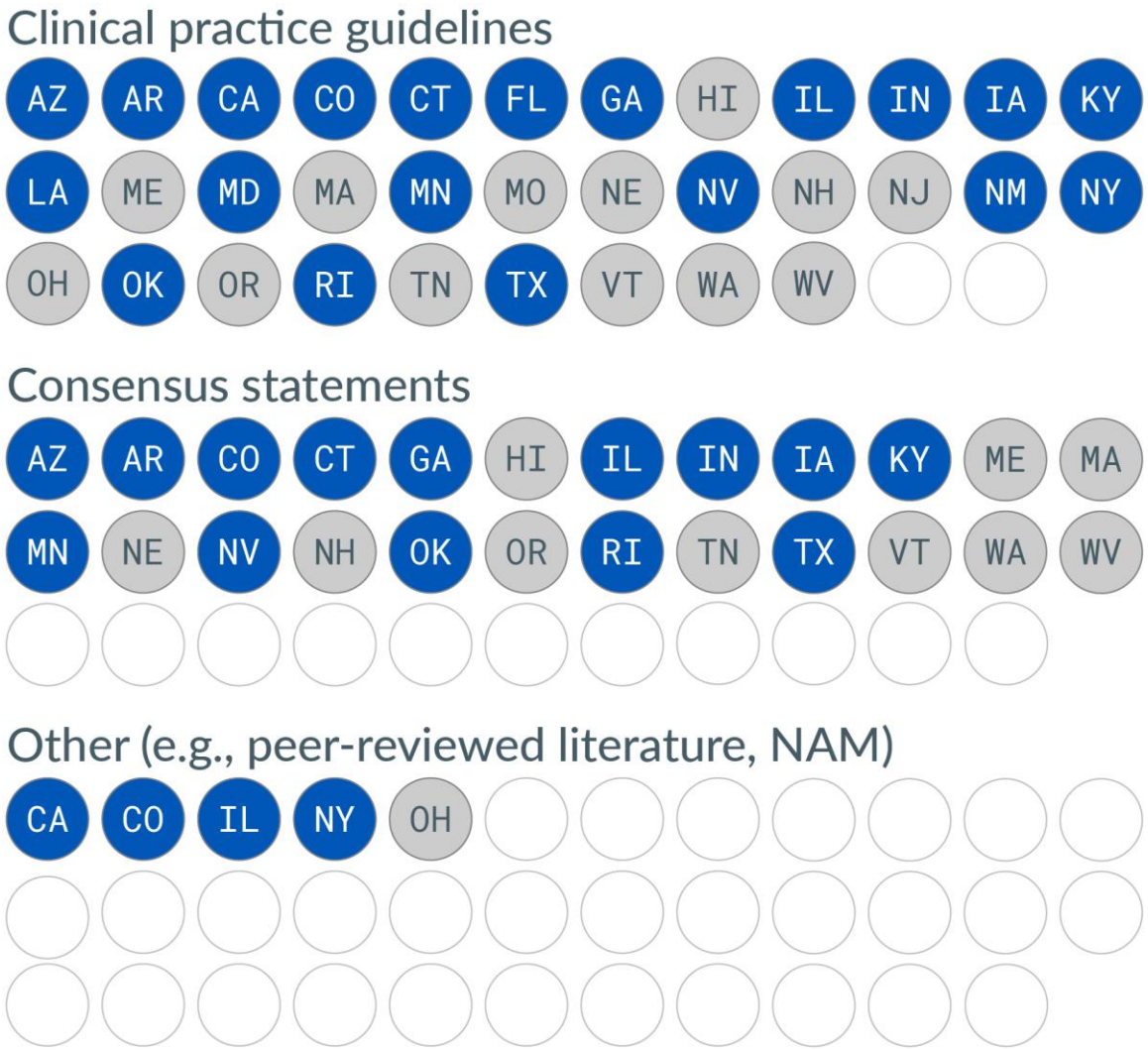
Most Laws Include Clinical Practice Guidelines Within the Evidence Categories, While Fewer Include Consensus Statements

Of 21 states with laws **passed**:

- 95% (20 states) include clinical practice guidelines (typically "nationally recognized")
- 67% (14 states) include consensus statements
- 19% (4 states) include other categories, such as:
  - Peer-reviewed literature
  - National Academy of Medicine (NAM) standards



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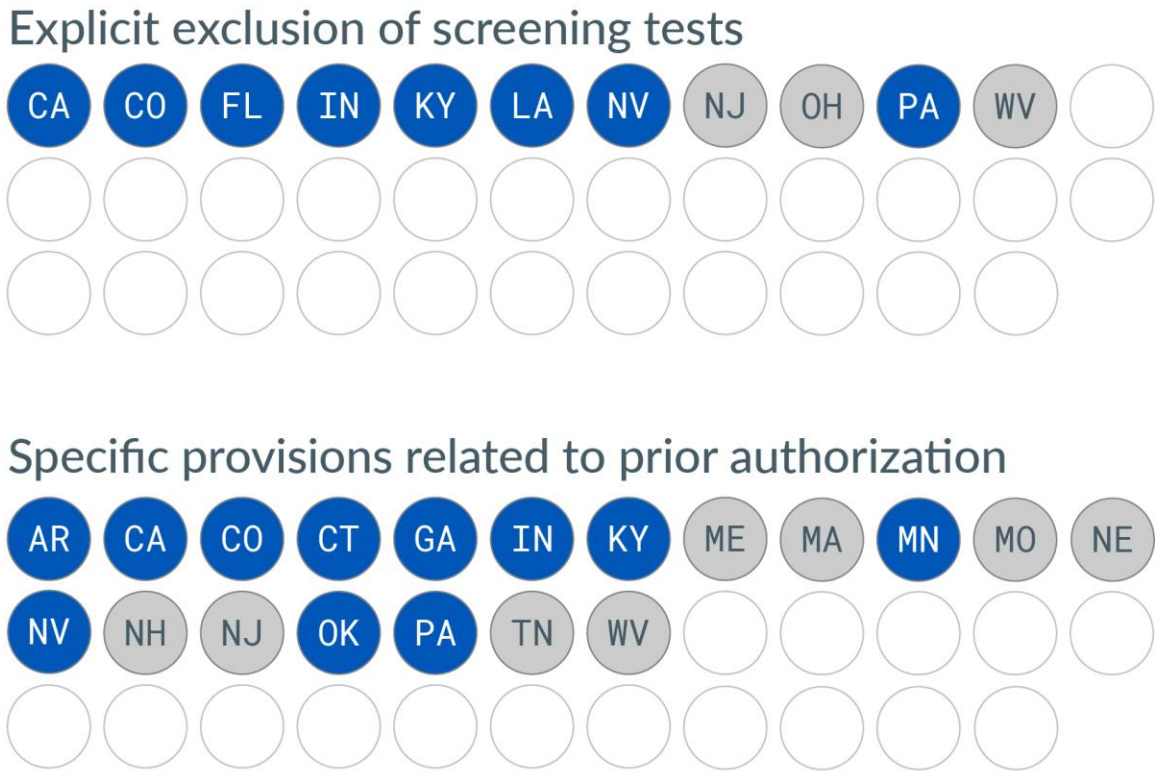
Most Laws Do Not Explicitly Exclude Screening Tests, While Around Half Mention Prior Authorization

Of 21 states with laws **passed**:

- 38% (8 states) include a provision that explicitly excludes screening purposes from the coverage requirement
- 52% (11 states) include provisions specific to prior authorization
  - Response time standards
  - Preserving the right of Medicaid or private plans to use utilization management
  - Applying state prior authorization laws to biomarker test coverage



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Law Interpretation May Depend on Concepts Included

"SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE"

- Many laws and bills predicate coverage only on this
- Questions around the weight held by single evidence categories (e.g., FDA clearance)
- Not aligned with NCOIL model bill

CLINICAL UTILITY

- In NCOIL model bill
- Additional standard may provide more coverage discretion
- May still create different coverage determination processes and standards

MEDICAL NECESSITY

- More states including this term and concept in their coverage laws and bills
- Some states tying coverage directly to Medicaid medical necessity statute and process (e.g., CA, CT)

ALTERNATIVE LANGUAGE

- e.g., "efficacy and appropriateness" of testing (NJ)
- Different language around coverage standards may align more closely with agency's existing test evaluation process

Considerations Around Evidence Categories and Standards

FDA CATEGORIES

- FDA clearance or approval process does not review clinical utility
- Drug label "warnings and precautions" may not provide clear clinical direction; not in NCOIL bill, still in new bills

MEDICARE COVERAGE DETERMINATIONS

- Medicare population differences
- LCD ambiguities and conflicts
- Single LCD contractor with large footprint

CONSENSUS STATEMENTS

- Concerns about conflicts of interest, evidence standards, transparency
- Removed from NCOIL model in 2023 but still in many new bills

OTHER CATEGORIES

- Clinical practice guidelines can conflict, lag new clinical standards
- Broad definition of peer-reviewed literature

Additional Legislation Elements and Provisions of Note

DEFINITION OF "BIOMARKER" AND "BIOMARKER TESTING"

- Extremely broad
- Often extends beyond genetic/molecular tests
- Examples included in definitions may impact coverage decisions

PRESENCE OF SCREENING EXCLUSION PROVISION

- Added to NCOIL model legislation in Fall 2023, but many laws and bills still lack this provision
- Potential large coverage implications if included in mandate

STATE COST REPORTING

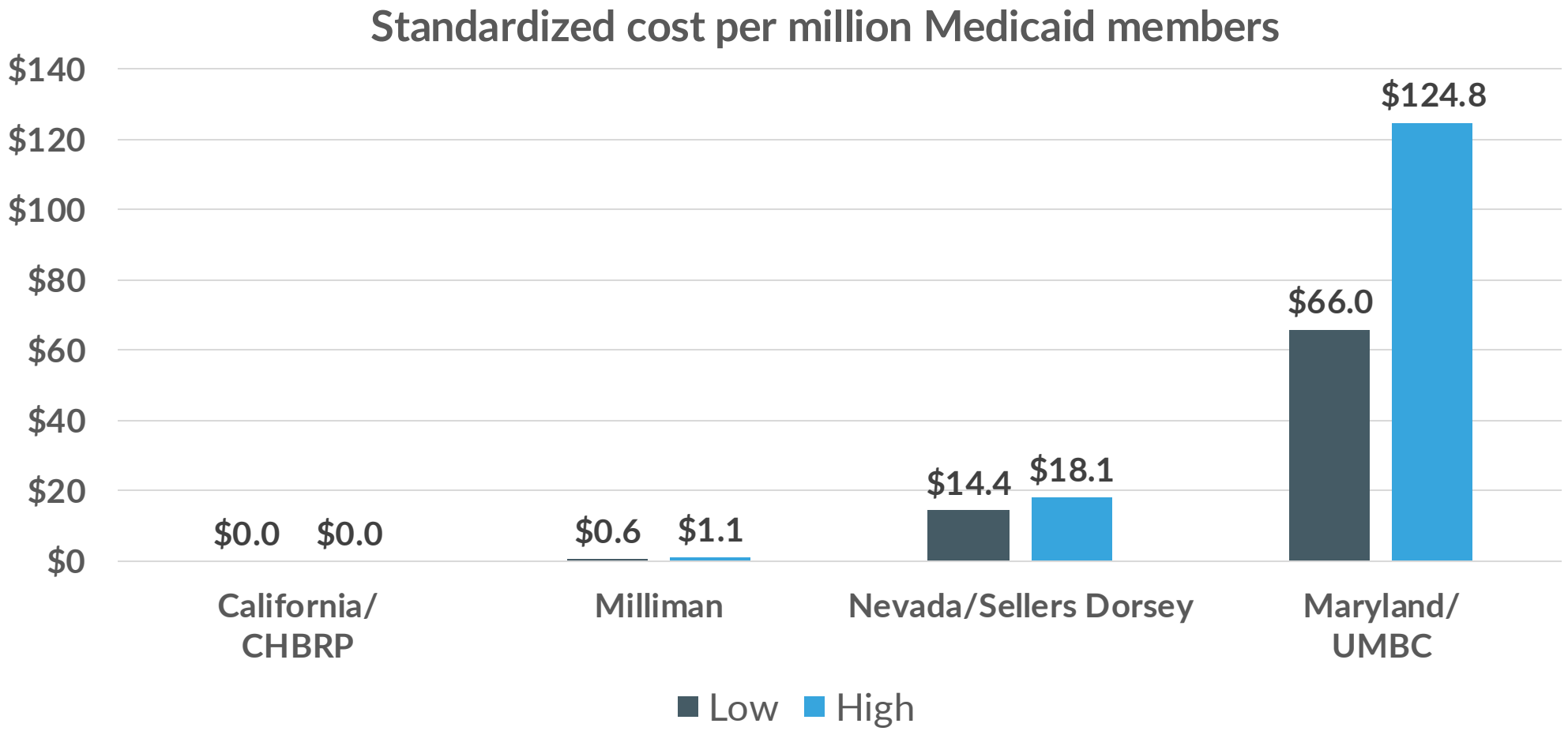
- Among passed laws, few require reporting on costs after implementation
- Only MD and NV had released notable impact estimate reports after law

Potential Financial Impact of Biomarker Testing Legislation

Summary

- Most states that have passed or introduced biomarker testing legislation also include some type of fiscal analysis
- Fiscal note details are inconsistent
- Many fiscal notes estimated minimal financial impact on states and Medicaid
- Other state legislative analyses included more notable Medicaid cost increase estimates

Cost Increase Estimates Among 4 Highlighted Fiscal Analyses Vary Widely



Note. Maryland estimates are for fiscal year 2030. Dollar amounts are in millions.
Sources. Fiscal analyses from California, Maryland, Milliman, Nevada.
Abbreviations. CHBRP: California Health Benefits Review Program; UMBC: University of Maryland, Baltimore County.

Fiscal Estimate Considerations

UTILIZATION RATE OF BIOMARKER TESTING

Examples ranging from 19.2 per 1,000 enrollees, to 45% uptake among all chronic conditions

AVERAGE COST PER BIOMARKER TEST

Examples ranging from $79 to $1,700 per test

COVERAGE MANDATE INTERPRETATION AND DEGREE OF EXPANSION

Examples ranging from narrow interpretation (no change) to broad test universe expansion including screening tests and minimal efficacy standards

Impact of Expanded Coverage Example: Biomarker Testing for Non-Small Cell Lung Cancer

If biomarker testing laws shift coverage mandates to reimburse more complex biomarker tests, the test cost can shift higher; in the case of non-small cell lung cancer (NSCLC), by around $3,000

EVIDENCE-BASED NATIONAL CLINICAL GUIDELINES

National Comprehensive Cancer Network (NCCN) recommends the following biomarker testing for non-metastatic (stage 1–stage 3a) NSCLC:

- *EGFR* mutations ($325)
- *ALK* mutations ($85)
- PD-L1 IHC ($108)

Total: $518

MEDICARE LOCAL COVERAGE DETERMINATION (LCD)

Several large multiplex genetic panels are covered by LCD "MolDX: Next-Generation Sequencing for Solid Tumors" for stage 3 and 4 cancers:

- Genetic panels with CPT codes 81445, 81449, 81457, 81458, 81459 **($598–$2,990)**
- Molecular pathology unlisted CPT code 81479
- Genetic panels with PLA codes 0244U, 0250U, 0329U, 0334U, 0379U, 0391U **($2,920–$3,600)**

FDA COMPANION DIAGNOSTIC DEVICE

Does not specify stage of cancer when test can be used; includes tests that are individual biomarkers and those that are large multiplex genetic panels. Examples include:

- Cobas EGFR Mutation Test by Roche ($325)
- PD-L1 IHC pharmDx by Dako ($108)
- FoundationOne CDx **($3,500)**
- Guardant360 CDx **($5,000)**

Note. Pricing obtained from CMS Clinical Laboratory Fee Schedule and Physician Fee Schedule.

Biomarker Testing Law Considerations

Potential Medicaid Agency Involvement in Legislative Process

Assessment of Coverage and Procedural Impact

- Does the state biomarker testing coverage law or bill:
  - Address all conditions, or only cancer?
  - Exclude screening tests?
  - Reference medical necessity, clinical utility, or another concept that is a coverage standard beyond just support from any evidence criteria categories?
  - Include provisions that impact prior authorization or other utilization management processes?

Assessment of Fiscal Impact

UTILIZATION RATE OF BIOMARKER TESTING

AVERAGE COST PER BIOMARKER TEST

COVERAGE MANDATE INTERPRETATION AND DEGREE OF EXPANSION

ADDITIONAL COST = [Future Test Utilization x Predicted Average Biomarker Test Cost]
MINUS (–)
[Current Test Utilization x Current Average Biomarker Test Cost]

Implementing Coverage Policies Under Legislation

UPDATED POLICY DOCUMENTATION (MCO PARTNERS)

CODING AND OPERATIONAL CONSIDERATIONS

DEVELOPING TEST REVIEW PROCESSES AND FRAMEWORKS TO FIT LEGISLATION

ACCESS TO GENETIC REVIEW EXPERTISE

Looking Ahead

Additional Context

KEY DRIVERS AND GOALS OF LEGISLATION

INFLUENCE FROM MULTIPLE STAKEHOLDERS

POTENTIAL LITIGATION

SIMILAR PHARMACO-GENOMIC TESTING BILLS EMERGING

Questions and Discussion

Thank you!

Questions?

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Building an Integrated System of Care for Children with Special Health Care Needs: A Policy and Data Review

Thursday, September 18
11:00am (Pacific Time)

We'd love to hear from you!

Learn More

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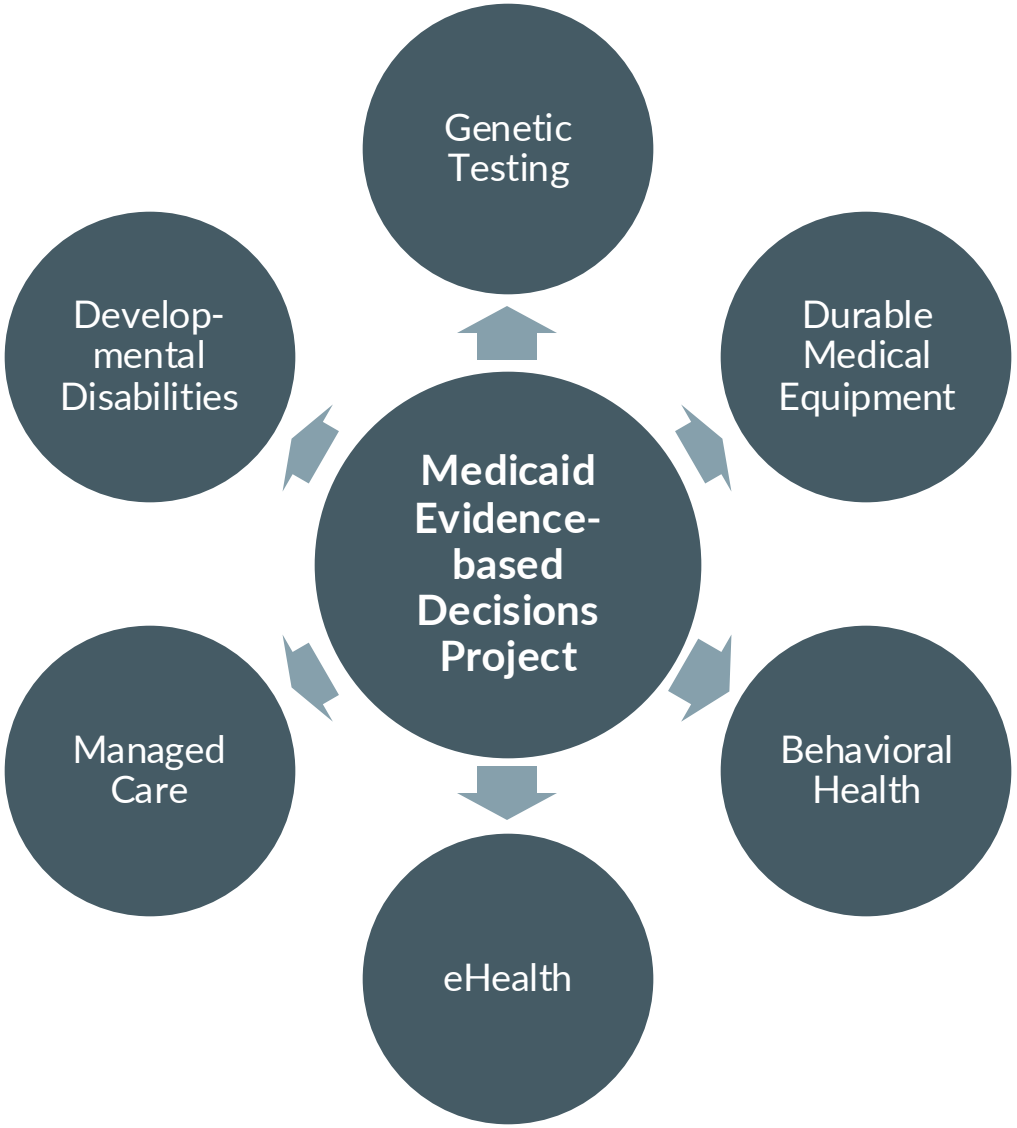
CENTER FOR
EVIDENCE-BASED POLICY

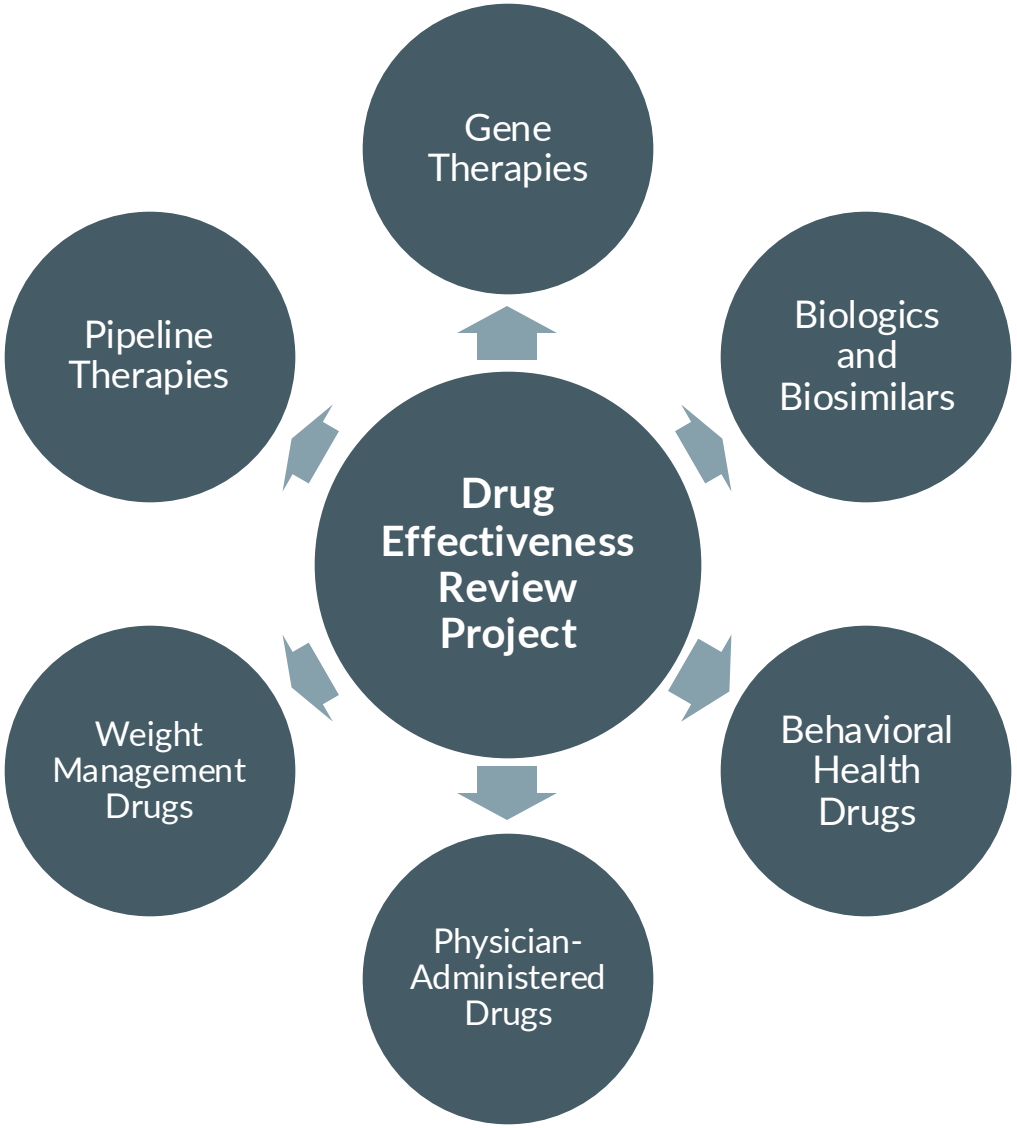
Ongoing Work at the Center for Evidence-based Policy *(1 of 4)*

- Medical, dental, and behavioral health: Medicaid Evidence-based Decisions Project (MED) – 22 states
- Pharmacy: Drug Effectiveness Review Project (DERP) – 14 states
- Technical assistance to individual states – 7 states in 2024

Ongoing Work at the Center for Evidence-based Policy *(2 of 4)*



Ongoing Work at the Center for Evidence-based Policy *(3 of 4)*



Ongoing Work at the Center for Evidence-based Policy *(4 of 4)*