AVALON HEALTHCARE SOLUTIONS

UNDERSTANDING BIOMARKER LEGISLATION TO DELIVER THE RIGHT TEST FOR THE RIGHT CARE AT THE RIGHT COST

November 14, 2023

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WELCOME & INTRODUCTIONS

Michele Norton - Senior Vice President, Product Marketing, Avalon

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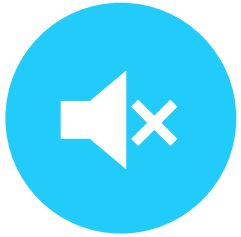
Before We Start

This meeting is being recorded.



We will be **MUTING** everyone except the presenter to make sure the audio is clean and clear.

Q&A will be done by using the **“Questions” feature**.

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Agenda

OVERVIEW & INTRODUCTIONS

Michele Norton - Senior Vice President, Product Marketing, Avalon

WHAT'S THE LATEST FROM WASHINGTON, DC

Julie Barnes - Principal, Maverick Health Policy

BIOMARKER LEGISLATION: CURRENT STATE, DRIVERS & IMPACT

Alex Sommer - Vice President, State Government Affairs, Avalon

Lindsey Abraham - Vice President, Government Programs, Avalon

PRECISION BRINGS CLARITY

Sarah Bretz - Product Manager, Avalon

Q&A

Michele Norton, SVP, Product Marketing, Avalon

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WHAT'S THE LATEST FROM WASHINGTON, DC

Julie Barnes - Principal, Maverick Health Policy

Maverick Health Policy

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Federal Policy Update

FDA'S LAB-DEVELOPED TESTS (LDTS) PROPOSED RULE (SEPT. 29, 2023)

- Classifies *in vitro* diagnostics as medical devices even when the manufacturer is a laboratory
- Four year phase-in of new oversight requirements, some grandfathering of older tests
- Includes an RFI on academic medical centers and potential carveout
- **Comments due on December 4, 2023**
- ACLA, AdvaMed, and others oppose rule – FDA's authority is questionable, doesn't have the resources necessary, Congress should pass the VALID Act

The *Chevron* doctrine may be overturned by SCOTUS soon – elimination of deferential framework for courts reviewing agency interpretations of statutes would dramatically impact FDA rules

SUPREME COURT OF THE UNITED STATES

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FDA Launches Pilot Program to Help Reduce Risks Associated with Using Laboratory Developed Tests to Identify Cancer Biomarkers

Pilot Geared Toward Sponsors of Certain Oncology Drug Products Used with Certain In Vitro Diagnostic Tests to Identify Patients for Certain Cancer Treatments

June 20, 2023

- Companion Diagnostic Tests analyze human samples for biomarkers to help match patients to specific treatments.
- The FDA is asking drug manufacturers for performance information about lab tests that are used to enroll patients into the clinical trials that support drug approval.
- The FDA will post minimum performance characteristics recommended for similar tests.
- Labs may use this information to guide their development of LDTs to identify specific biomarkers used for selecting cancer treatment.

BIOMARKER CURRENT STATE, DRIVERS & IMPACT

Alex Sommer - Vice President, State Government Affairs, Avalon

Lindsey Abraham - Vice President, Government Programs, Avalon

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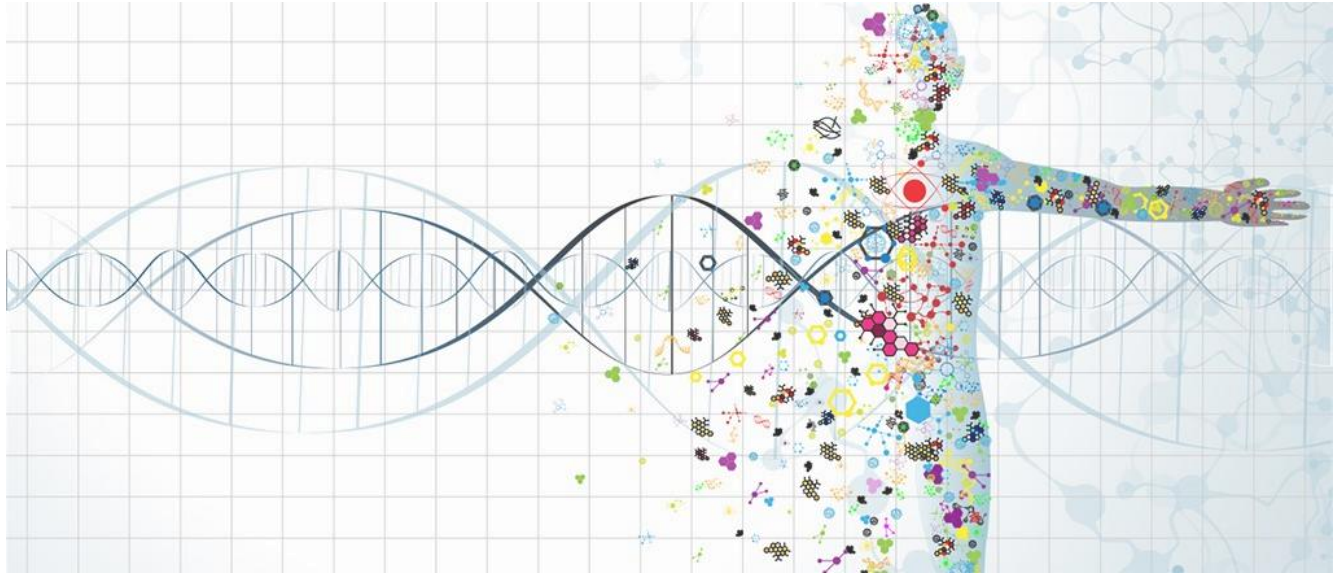
The Promise of Precision Health

TAILORING MEDICAL TREATMENT TO THE INDIVIDUAL CHARACTERISTICS OF EACH PATIENT

- Personalized treatment plans
- Targeted therapies for better outcomes
- Reduced side effects and improved patient experiences



Transformation from the 2003 Human Genome Project to the current state explosion of genetic testing and genomic data analysis, molecular diagnostics, and targeted therapies

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Biomarker Legislation

A POST-DIAGNOSIS COVERAGE MANDATE

Health insurers, nonprofit health service plans, and health maintenance organizations issuing, amending, delivering, or renewing a health insurance contract on or after [DATE] shall include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to:

1) *labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) of the United States government or indicated tests for an FDA-approved drug;*

2) *Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; OR*

3) *Nationally recognized clinical practice guidelines*

Biomarker Legislation

DEFINING KEY TERMS

What is "biomarker testing"?

"The analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal Food and Drug Administration."

And what are "nationally recognized clinical practice guidelines"?

"Evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care."*

* Biomarker Testing Insurance Coverage Model Act, National Conference of Insurance Legislators, adopted July 2023, *available at* https://ncoil.org/wp-content/uploads/2023/07/NCOIL-Biomarker-Model-Final-July-2023.pdf

Current Biomarker Status

WHAT WE ARE SEEING

Scope Contingencies?

- Medical and scientific evidentiary support

Sources for Medical and Scientific Support?

Included in the bills are often a non-exclusive list of sources for medical and scientific evidentiary support

- Labeled indications for FDA-approved tests
- Indicated tests for FDA-approved drugs
- NCDs (CMS)
- LCDs (MACs)
- Nationally recognized clinical practice guidelines*
- Consensus statements*
- Warnings and precautions on FDA approved drug labels

Current Biomarker Status

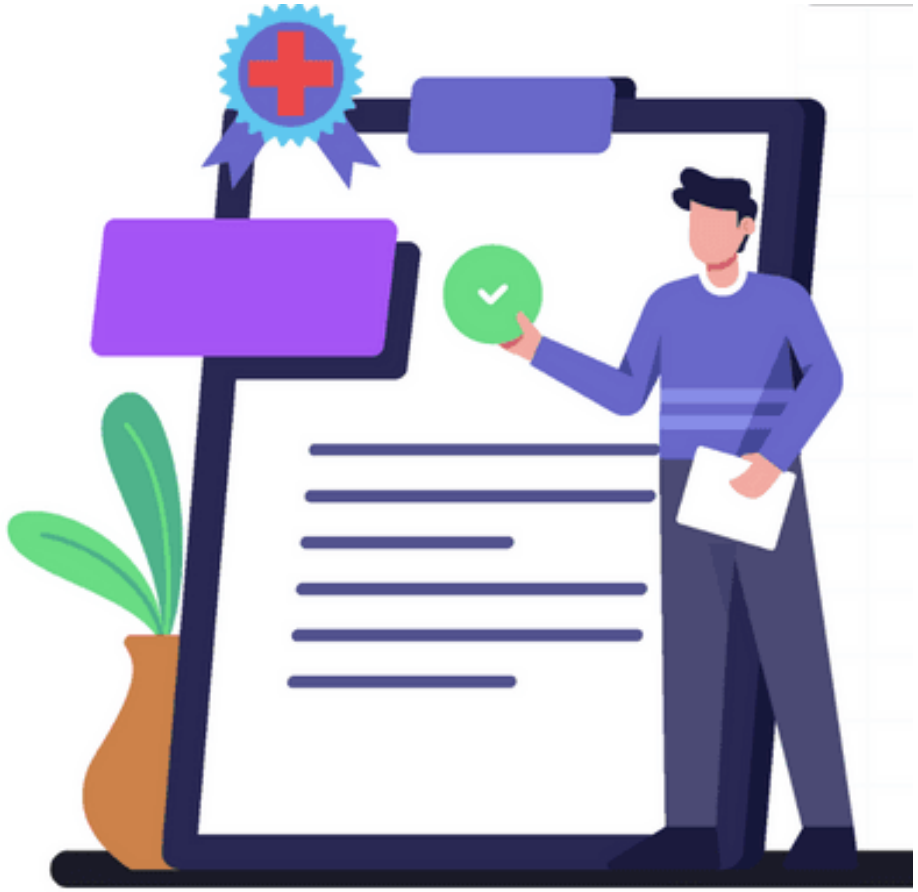
WHAT WE ARE SEEING

Prior Authorization Requirements?

- PA is generally permissible.
- Some bills include TAT for non-urgent and urgent requests.
- Other bills state that plans must comply with relevant PA standards.

Exception/Appeal Process?

- Broad requirement
- Requires a clear, convenient, readily accessible appeals process.



Current Biomarker Status

POLL QUESTION

How many states have already enacted a Biomarker Bill?

a) 12

b) 14

c) 18

d) 24

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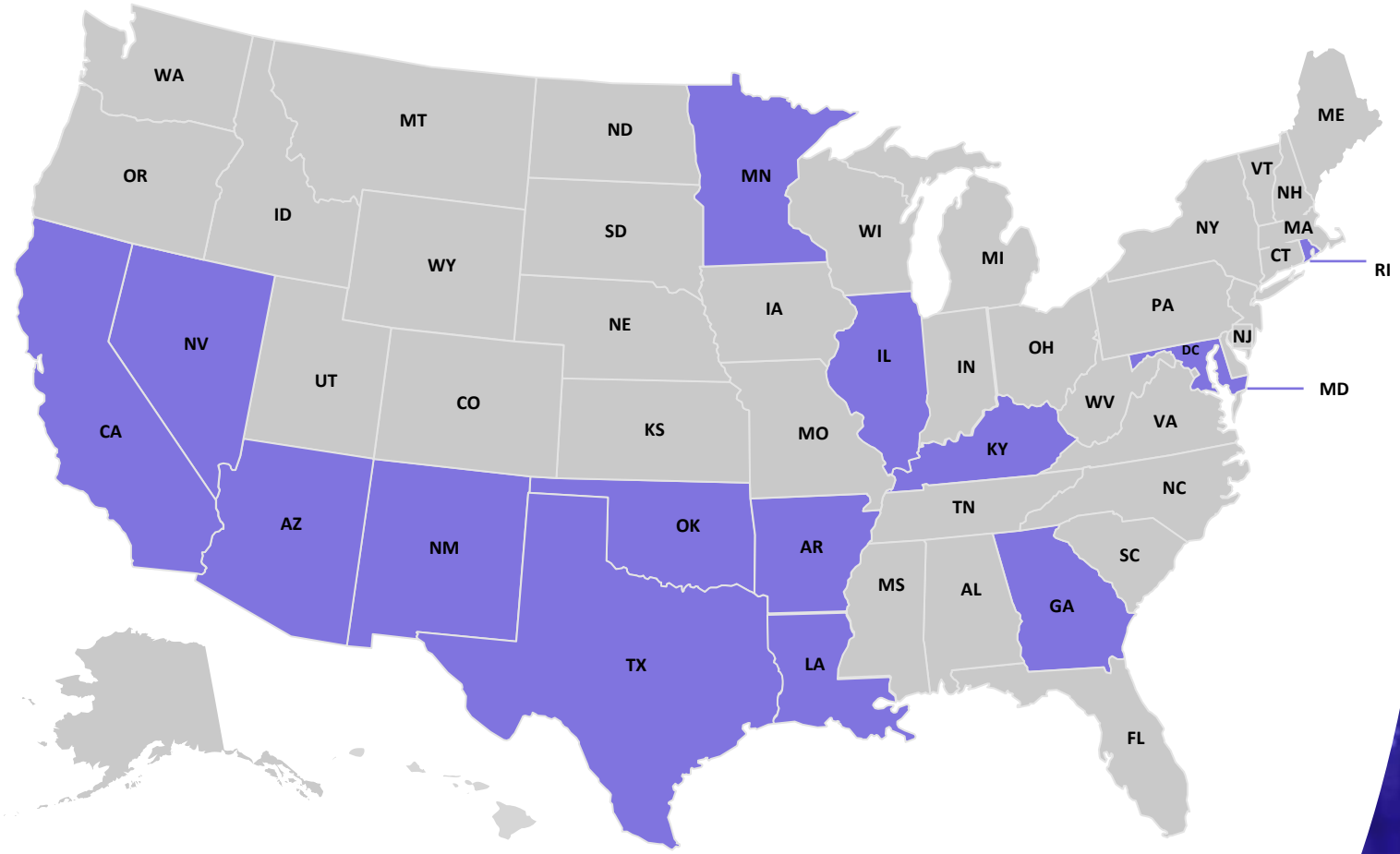
Current Biomarker Status

CURRENT STATE

- 14 states have enacted some version of a Biomarker Law.
  - Arizona, Arkansas, California, Georgia, Illinois, Kentucky, Louisiana, Maryland, Minnesota, Nevada, New Mexico, Oklahoma, Rhode Island, and Texas



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Current Biomarker Status

POLL QUESTION

What is your opinion based on your current knowledge of Biomarker Bills and your experience?

a) These bills are well-needed and timely

b) These bills are problematic due to poor writing/execution

c) These bills were well-intentioned but led to bad results

d) I'm unsure about these bills and need more information

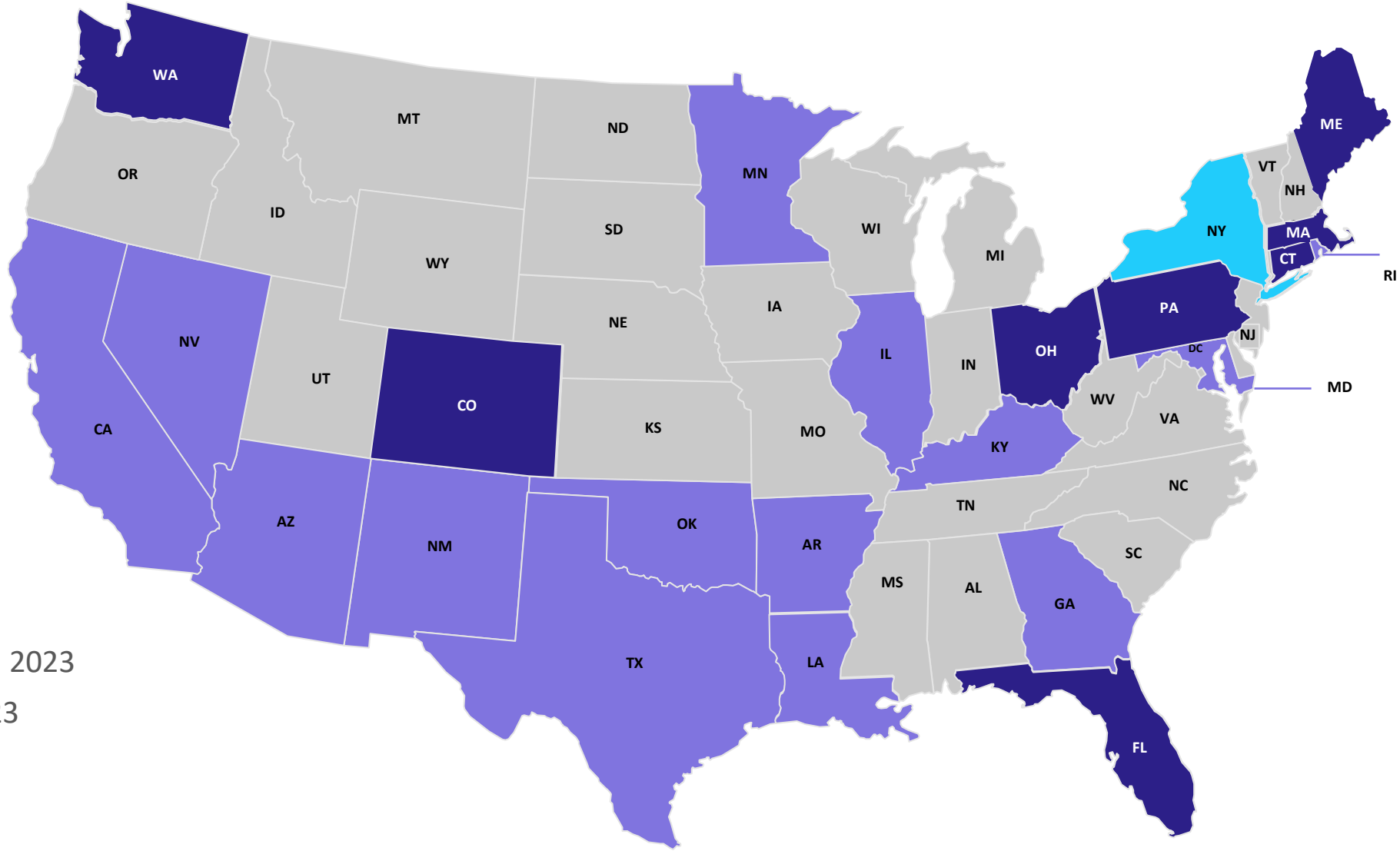
Current Biomarker Status

PROS AND CONS

PROS	CONS
• More attention and awareness to biomarker tests • Motivate plans to consider new tests and innovation • Intended to improve access • Remove disparities in HealthCare	• Broad and Ambiguous • Potential for inappropriate usage or adverse outcomes, especially in low-risk patients • Cost is not sustainable and may cause an increase in premiums • Confusion and inconsistency in Implementation

What's Coming – More State Legislation

BIOMARKER LEGISLATION ALREADY IN OR COMING SOON TO A STATE NEAR YOU



- Enacted
- Introduced in 2023
- Passed in 2023

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What's Next and How Do Health Plans Prepare?

If your state has not yet enacted a biomarker law, pay close attention to what is proposed – while the bills tend to be similar, the impact of the mandate hinges on seemingly minor details. Definitions, as always, matter.

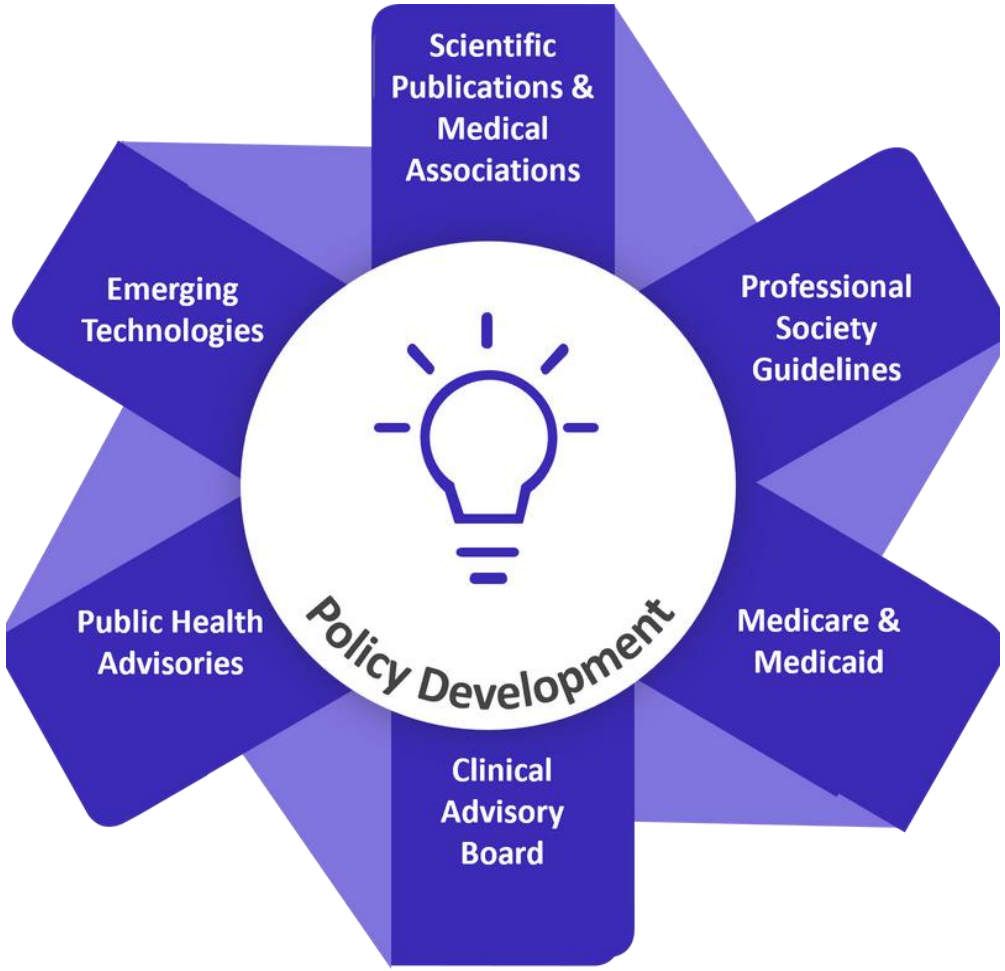
Review existing coverage criteria and medical policies, considering the process by which they were adopted and the clinical and scientific sources supporting them.

Evaluate plan documents for evidence of biomarker testing coverage.

Assess your plan's appeals process and whether it is (a) appropriately applied to the coverage mandated by the biomarker law in your state and (b) sufficiently convenient.

Watch the early adopter states for insight to how these laws will be enforced.

Avalon's Solution to Biomarker Requirements



Avalon's **dedicated full-time scientists** support and maintain approximately 130 outpatient laboratory policies

All Policies are researched, written, and maintained in-house by **a dedicated science team, including PhDs**

Demonstrated conditions of coverage

Each policy has **robust scientific rigor,** typically **using ~ 50 references**

Annual updates are **reviewed and approved** by Avalon's independent **Clinical Advisory Board**

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PRECISION BRINGS CLARITY

Sarah Bretz – Product Manager, Avalon

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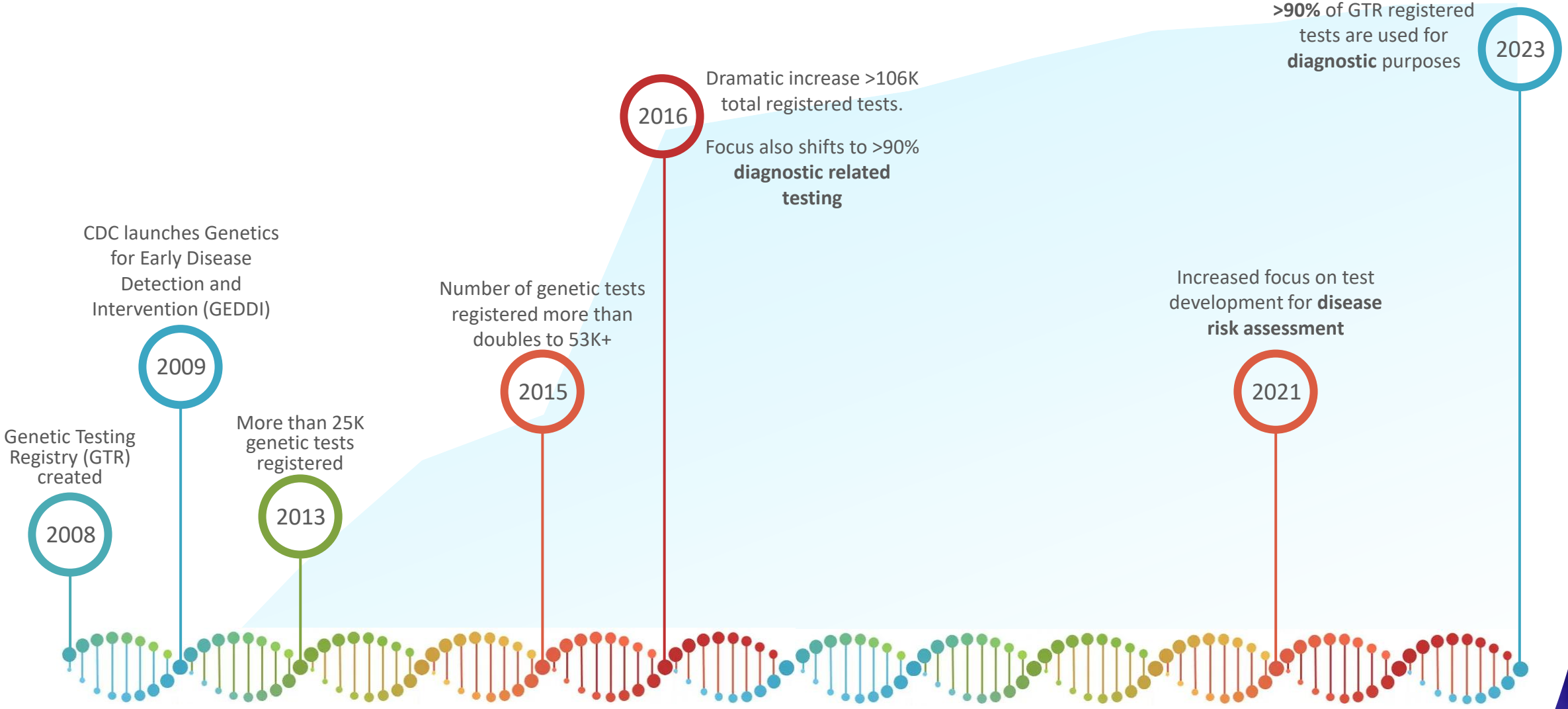
Genetic Testing Growth



NIH. (2023, Oct) *NIH Genetic Testing Registry (GTR).* http://www.ncbi.nlm.nih.gov/gtr/

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Biomarker Legislation Language

ROOM FOR INTERPRETATION

- Ambiguous language = Broader coverage
- Broader coverage ≠ Quality care
- Increased premiums to offset cost increases impacts everyone.
- Inconsistent interpretation and implementation of coverage rules.

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Coverage Considerations

THE RIGHT TEST, FOR THE RIGHT CARE

- Timely access to guideline-recommended biomarker testing can lead to better health outcomes
- A study in 2020 evaluated total cost of care for non-small cell lung cancer patients
  - Patients who underwent broad panel biomarker testing experienced ~$8,500 PMPM reduced cost of care due to optimal treatment[1]
  - Commercial payers experienced $127,000+ less cost for sequential testing[2]

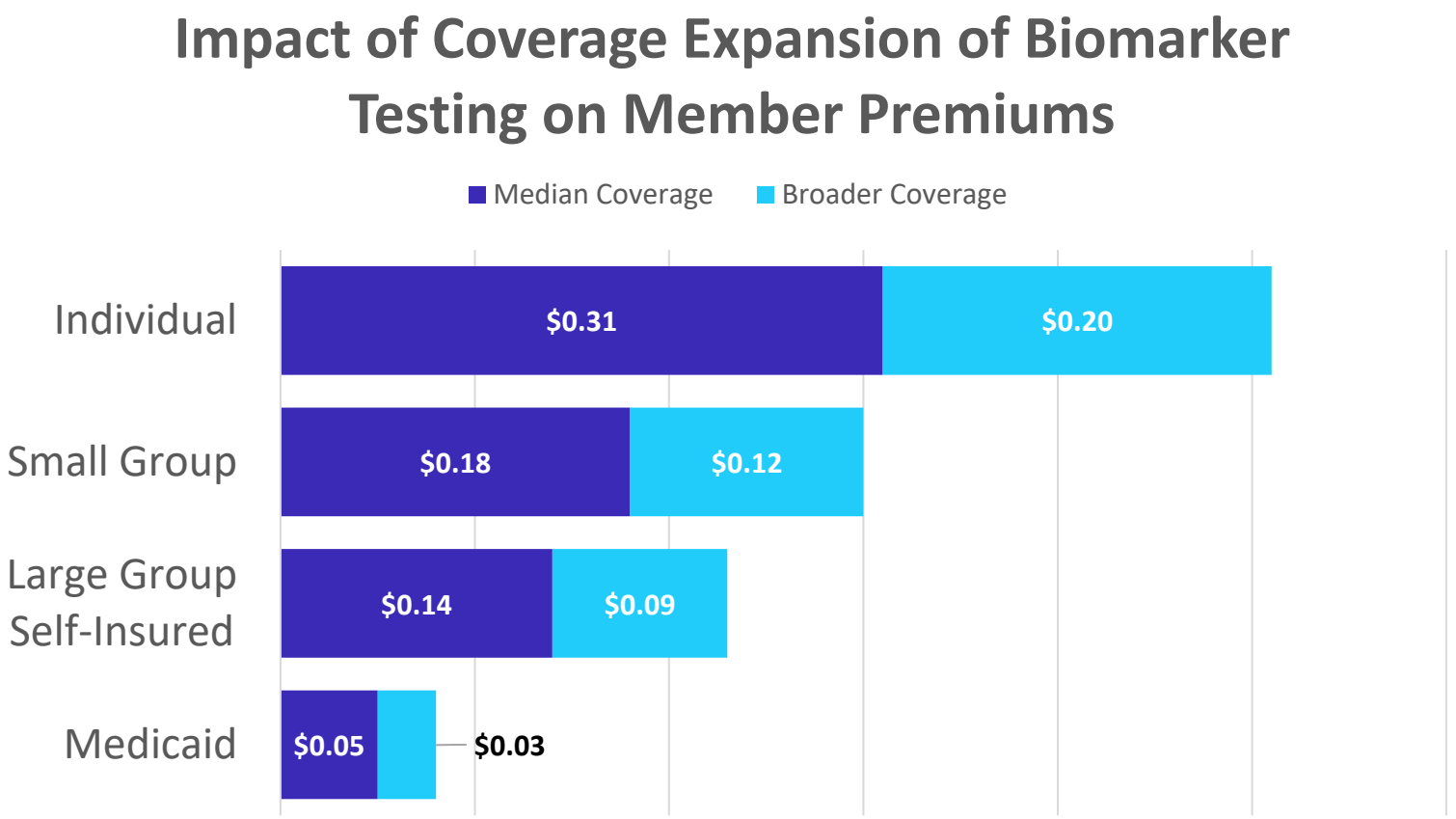
- How do you choose the right genetic test among 175,000+ options?
  - 40,000+ tests under 81479

1. Brito RA, Cullum B, Hastings K, et al. Total cost of lung cancer care associated with broad panel versus narrow panel sequencing. Journal of Clinical Oncology 2020; 38, no. 15_suppl; 7077. https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.7077
2. Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non-Small Cell Lunch Cancer https://doi.org/10.1016/j.jval.2018.04.1372

Cost Considerations

THE RIGHT TEST, FOR THE RIGHT CARE, *AT THE RIGHT COST*

- Based on Milliman's administrative claims data, **the expansion of biomarker testing coverage would increase commercial premiums $0.14 - $0.51 PMPM.**[1]
- Guideline-recommended biomarker testing can lead to reduced costs.
  - Avoids cascade testing



1. Milliman. (2023, Oct) *The landscape of biomarker testing coverage in the United States.* https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-US

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Other Considerations

- Consider input from multiple sources
- Consult with experts
  - Review of clinical guidelines, consensus statements, and study evidence
- Frequent review of existing policies
  - *Things change rapidly*

> *"Two heads are better than one, not because either is infallible, but because they are unlikely to go wrong in the same direction."*
> -C.S. Lewis

Science Is Our True North

- Comprehensive Lab Policy Library
- Independent Clinical Advisory Board
- Quarterly Lab Policy Review & Development
- New Test Evaluation Process

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Application of Policy

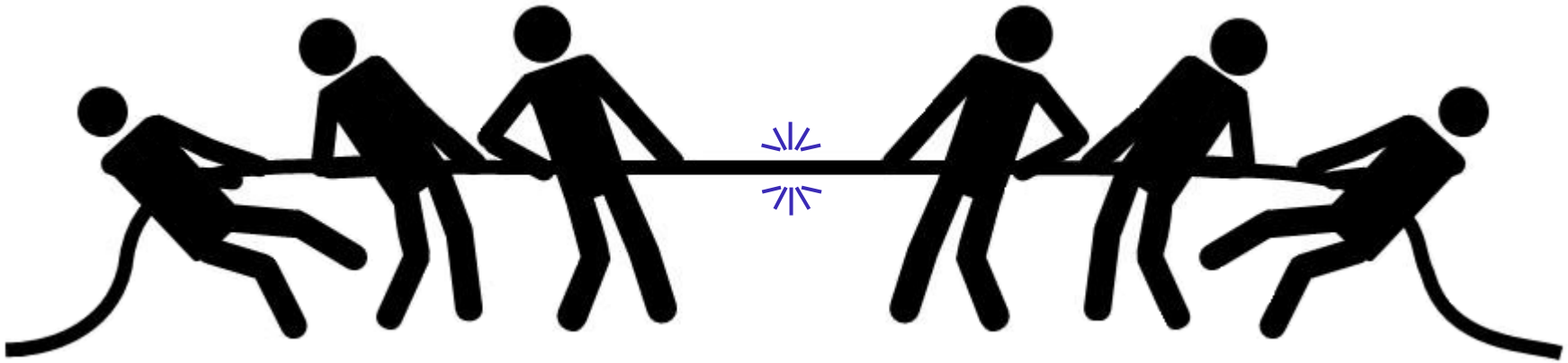
RIGHT POLICY, RIGHT TEST

- Discrete test identification
- Test-specific genetic lab policies
- Test assessment process
  - Clinical Utility
  - Clinical Validity
  - Analytical Validity
- Consideration of other qualifying criteria (i.e., Society guidelines, FDA approval, NCD/LCD coverage rules, independent third-party test evaluations)

Containing Costs

- Plans are mandated to cover tests
- Investigational/experimental tests not covered
- Prior authorization requirements
- Burden of appeals

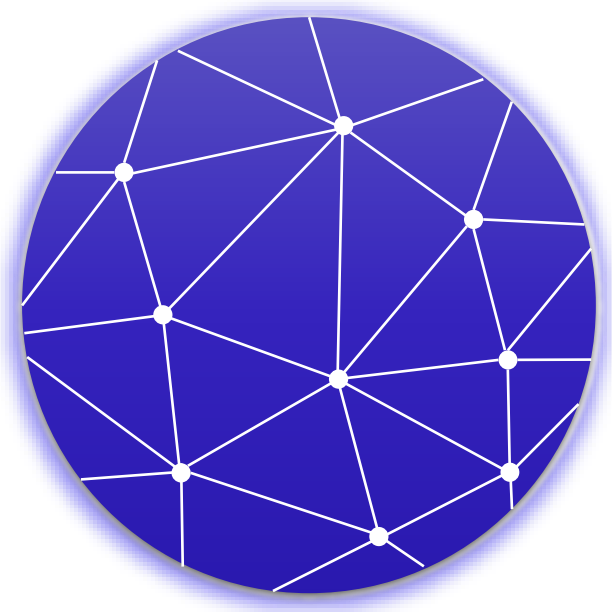
- Lab development of new tests is resource intensive
- Denied or delayed payment for performed tests
- Costs for other tests increase



Genetic Network Management

Curated network of lab providers

Focused solely on genetic testing



Nationwide provider network

Tiered Preferred Provider program

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Precision Management Capabilities Are Necessary to Address Complexity

Genetic network management

A curated, nationwide network of genetic labs that supplements a health plan's preexisting routine lab network with vetted providers and pre-negotiated pricing.

Policy development

More than 65 evidence-based genetic policies ***plus*** an exclusive partnership with Palmetto GBA to expand on MoIDX used by CMS.

Test identification and quality

A scalable framework to classify a discrete test and evaluate the test based on the manufacturer's claims leveraging industry-standard DEX Z-Codes®.

Utilization Management

NCQA Accredited Utilization Management and Prior Auth (pre & post service).

Automated provider decisions and clinical reviews based on health plan policies.

Payment accuracy

Automated claim coding rules to enforce policy adherence and validate authorization decisions during claim adjudication.

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Scalable Solutions

- Precision medicine innovation is not slowing down
- Containing costs while promoting positive health outcomes is increasingly challenging
- Biomarker legislation will continue to spread
- Interpretation and implementation requires a flexible and scalable solution

Q&A

Michele Norton, Senior Vice President, Product Marketing

Thank you

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SAVE THE DATE

Avalon Webinar – January 23, 2024| 2:00 - 3:00 PM EDT

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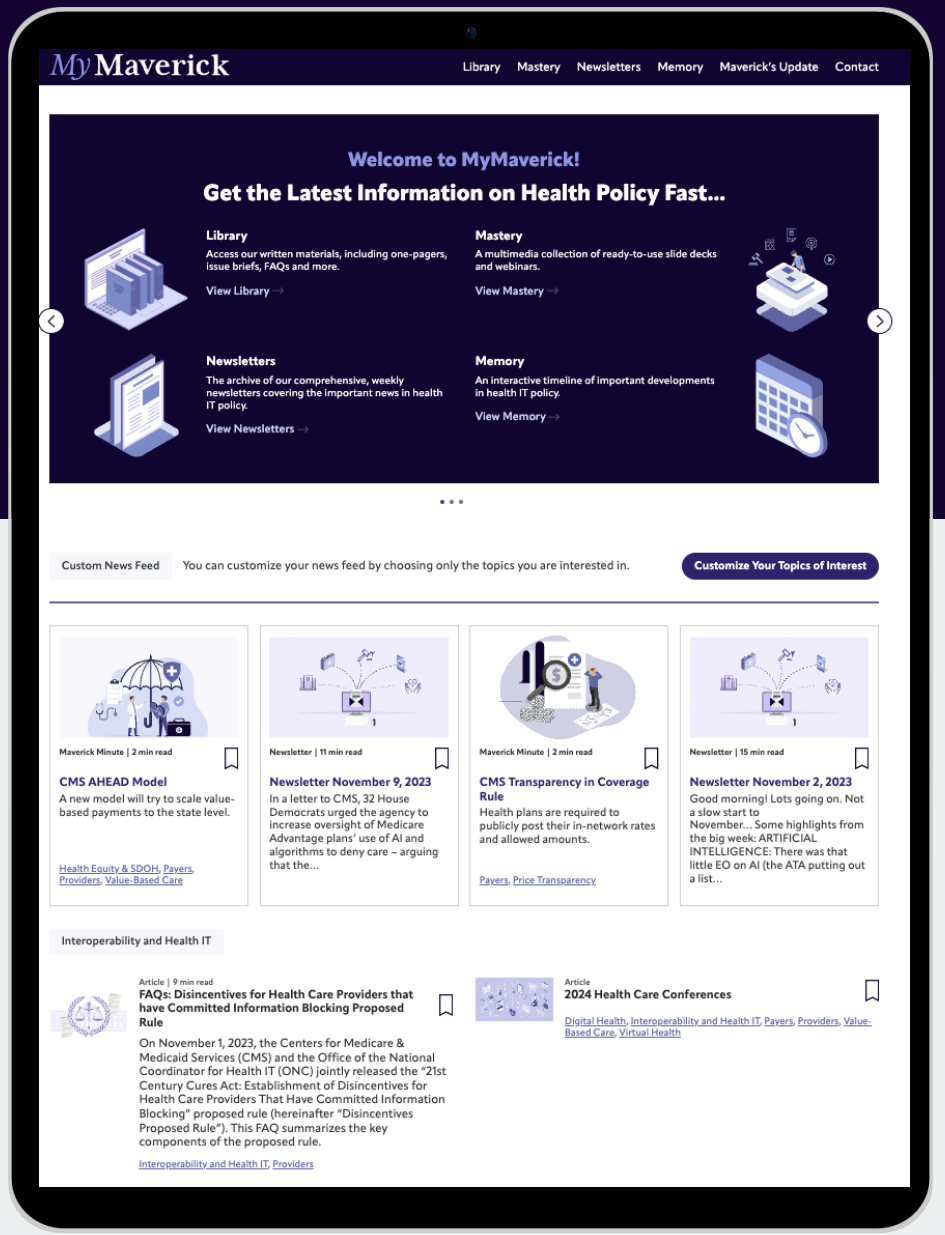

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- **Mastery:** A multimedia collection of webinars and ready-to-use slide decks
- **Newsletters: T**he archive of our comprehensive, weekly newsletters covering the important news in health IT policy
- **Memory:** An interactive timeline of important developments in health IT policy