

Clinical Lab 2.0

Policy Committee Report

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Mission Statement

The CL2.0 Policy Committee mission is to establish and advance federal and state policy frameworks that recognize and appropriately oversee, regulate, and compensate diagnostics as critical to individual and population health — focused on both acute and chronic disease prevention, early detection, and a more active role in informing clinical decisions.

The Committee will develop policy briefs and partner on advocacy campaigns that successfully align the value of diagnostics with the goals of CMS/CMMI and FDA — framing the CL2.0 movement, clinical lab initiated care models, proactive risk stratification, disease prevention, improved outcomes, cost avoidance, and personalized management strategies.

Transforming diagnostics: from reactive testing to proactive, value-based care

Policy Landscape: Federal & State Developments

FEDERAL: CMS / CMMI / FDA

CMS Innovation Models

- ACCESS, ELEVATE, LEAD
- Focus: Value-based care, outcomes

FDA Oversight Evolution

- AI/ML guidance (Jan 2026 update)
- LDT final rule implementation

Payment Reform

- Lab-initiated care pathways

STATE POLICY PRIORITIES

Scope of Practice

- MLS/pathologist clinical authority
- Diagnostic stewardship

Medicaid Innovation

- Value-based lab contracts
- Care coordination models

Regulatory Alignment

- CLIA modernization
- Telehealth lab services

2026 Core Policy Priorities

1

Federal Education & Awareness Campaign

ACTION: Develop a formal education plan for HHS/CMS/CMMI/FDA and key Congressional committees (Energy & Commerce, HELP).

RATIONALE: Current FFS models ignore laboratory's strategic value in early risk identification, care gap closure, and Total Cost of Care reduction. Labs act as 'First Responders' — identifying rising-risk patients before acute episodes — yet receive no compensation for this upstream intervention aligned with MAHA strategy.

2

Payment Model Innovation & Lab-Initiated Care Recognition

ACTION: Advocate for payment models that compensate longitudinal biomarker monitoring, proactive risk stratification (CKD, pre-diabetes, maternal health), and lab-initiated clinical interventions that drive population health outcomes and cost avoidance.

Policy Committee Structure & Processes

COMMITTEE STRUCTURE

Leadership Team

- Chair, Vice-Chair, Coordinator

Working Groups

- Policy & Regulatory
- Advocacy & Communications
- Payment Reform

Liaison Roles

- Industry Coalition representative
- Optional: Advisory board

KEY PROCESSES

1. Policy Brief Development

- Research → Draft → Review → Finalize

2. Regulatory Monitoring

- Track CMS/FDA guidance & models
- Evaluate state-level proposals

3. Advocacy Campaign Planning

- Coordinate messaging with Industry
- Manage Hill visits and comment letters

Policy Committee Framework

FEDERAL GOVERNMENT JURISDICTION

CLIA Certification

CMMI Innovation

CMS/Medicare/
Medicaid

FDA Oversight

CDC/Other

POLICY COMMITTEE

- Federal/State Frameworks
- Regulatory Oversight
- CMS/CMMI/FDA Alignment
- Policy Briefs
- Advocacy Campaigns
- Reimbursement Models

SHARED MISSION

- ★ Value-Based Care
- ★ Better Outcomes
- ★ Data-Driven Decisions
- ★ Disease Prevention
- ★ Early Detection
- ★ Risk Stratification
- ★ Lab-Initiated Care
- ★ Personalized Management

INDUSTRY COALITION

- Laboratory Suppliers
- Technology Innovation
- Growth & Sustainability
- Responsible Adoption
- Shared Learning
- Ecosystem Development

STATE GOVERNMENT JURISDICTION | Scope of Practice · State Licensure · State Regulations

Transforming diagnostics from reactive testing to proactive prediction through collaboration across jurisdictional boundaries

Proposed KPIs & Measures of Success

How we will track progress against our 2026 policy priorities

Policy Education & Federal Engagement

- # of formal meetings held with HHS/CMS/CMMI/FDA officials
- # of Congressional briefings delivered (target: tbd)

Policy Brief & Advocacy Output

- # of policy briefs completed and published
- # of formal CMS/FDA comment letters submitted

Payment Model & Reimbursement Progress

- Would like to see how business model aligns with this

Coalition & Stakeholder Growth

- # of industry coalition partners formally engaged (target: tbd)
- % of working group deliverables completed on schedule

KPIs to be reviewed quarterly by the Committee Chair and reported at each Policy Committee session.

Action Planning & Next Steps

Q1 2026

- Finalize advocacy toolkit
 - Identify priority federal agencies/congressional members/committees
- Draft policy briefs topics/priorities

Q2–Q3 2026

- Execute Hill visit campaign
- Quarterly progress reports

Q4 2026

- Refine 2027 priorities
- Expand coalition partners
- Measure policy wins & publish outcomes report

Let's transform diagnostics from reactive testing to proactive, value-based care