

GUIDE Alliance

Guidance for the Utilization of Intelligent Diagnostics & Evidence-Based Care

A Non-Profit National Alliance Advocating for Responsible IVD Testing & Clinical Decision Support to Improve Patient Outcomes, Strengthen Antimicrobial Stewardship, and Reduce Total Cost of Care

The Centers for Medicare & Medicaid Services (CMS) has made clear its commitment to improving patient outcomes, reducing unnecessary healthcare spending, strengthening program integrity, and leveraging technology to modernize healthcare delivery.

We support those goals. As healthcare policymakers seek to eliminate low-value utilization and wasteful spending, an important question emerges:

How can CMS distinguish low-value testing from high-value diagnostics and clinical decision support that improve outcomes while lowering total healthcare costs?

The Responsible IVD Testing & Clinical Decision Support Alliance, a 501(c)(6), seeks to answer that question through data, evidence, and collaboration.

Why This Matters: Improving Outcomes, Lowering Costs

Infectious diseases remain one of the largest drivers of avoidable healthcare spending in America. Every day, clinicians make critical treatment decisions *before* complete diagnostic information and proper clinical decision support is available. The consequences often include:

- Broad-spectrum antibiotic overuse
- Antimicrobial resistance (AMR)
- Avoidable emergency department visits
- Preventable hospital admissions
- Increased length of stay
- Higher readmission rates
- Poorer outcomes for Medicare beneficiaries

These challenges are particularly acute in:

- Skilled Nursing Facilities (SNFs)
- Long-Term Care Facilities
- Rural healthcare systems
- Immunocompromised populations
- High-risk Medicare beneficiaries

The result is higher downstream healthcare spending and worse patient outcomes.

The Solution: Evidence-Based Precision Medicine

Modern infectious disease diagnostics, when paired with real-time clinical decision support, allow providers to move beyond empirical treatment toward evidence-based precision medicine.

Rapid molecular and phenotypic diagnostics can identify pathogens and resistance mechanisms earlier.

AI-enabled clinical decision support systems can then analyze those results in real time and guide clinicians toward:

- The most clinically effective therapy
- The narrowest appropriate therapy
- The safest therapy for the patient
- The most cost-effective therapy available

This combination allows providers to make better decisions faster while supporting responsible antimicrobial stewardship. The objective is simple: **The right test, the right guidance, the right treatment, at the right time.**

The Initiative

Arkstone Medical Solutions, together with leading diagnostic laboratories, healthcare providers, infectious disease experts, antimicrobial stewardship leaders, and policy stakeholders, is forming the: **Responsible IVD Testing & Clinical Decision Support Alliance**

The Consortium of IVD labs and providers will develop an evidence-based framework demonstrating how responsible utilization of infectious disease diagnostics and clinical decision support will:

- Improve patient outcomes
- Reduce unnecessary healthcare utilization
- Reduce antimicrobial resistance
- Support clinician decision-making
- Lower total cost of care
- Advance CMS objectives around value-based healthcare

The initiative will be led by healthcare policy strategist **Chuck Coolidge**, whose team has successfully organized national healthcare alliances and influenced CMS policy on major reimbursement and coverage issues.

Deliverables

National Policy White Paper

The Consortium will publish a comprehensive white paper evaluating:

- The economic impact of infectious disease diagnostics
- The role of real-time clinical decision support in improving care
- Effects on hospitalization rates and length of stay
- Antimicrobial stewardship outcomes
- Impact on antimicrobial resistance trends
- Cost avoidance across the Medicare population
- Public health implications for SNFs and long-term care facilities
- Opportunities to align diagnostics with CMS value-based care objectives

Policy Recommendations

The Consortium will develop actionable recommendations designed to help CMS:

- Reduce waste without restricting access to high-value diagnostics
- Improve patient outcomes
- Support responsible utilization standards
- Encourage evidence-based antimicrobial stewardship
- Leverage AI and clinical decision support to improve healthcare efficiency
- Lower total Medicare spending through earlier and more effective interventions

Aligning With CMS Priorities

The Consortium supports CMS's goals of:

- ✓ Improving beneficiary outcomes
- ✓ Strengthening preventive and proactive care
- ✓ Reducing unnecessary healthcare spending
- ✓ Advancing technology-enabled healthcare delivery
- ✓ Supporting evidence-based medicine
- ✓ Preserving Medicare sustainability
- ✓ Protecting vulnerable patient populations

Our objective is **not to increase testing utilization or reimbursement**. Our objective is to identify and support the specific diagnostic and clinical decision support interventions that demonstrably improve outcomes while reducing downstream healthcare costs.

Expected Outcomes

For Patients

- Faster diagnosis
- More effective treatment
- Fewer complications
- Better outcomes

For Providers

- Better decision support
- Improved antimicrobial stewardship
- Reduced uncertainty
- More efficient care delivery

For IVD Labs

- Evidence-based reimbursement frameworks that reward high-value testing and patient outcomes
- Greater differentiation between responsible testing programs and low-value utilization
- Stronger alignment between laboratory services and value-based care initiatives
- Increased recognition of diagnostics as a tool for reducing total healthcare costs
- Better integration of diagnostics into antimicrobial stewardship programs
- Participation in the development of objective standards for "Responsible IVD Testing"

For CMS and Medicare

- Reduced hospitalization costs
- Lower readmission rates
- Better resource utilization
- Reduced antimicrobial resistance burden
- Lower total cost of care

For Public Health

- Improved outbreak prevention
- Stronger antimicrobial stewardship
- Better protection for vulnerable populations

Join the Consortium

We are seeking participation from:

- Independent Diagnostic Laboratories
- National Laboratory Organizations
- Health Systems
- Infectious Disease Physicians
- Antimicrobial Stewardship Leaders
- Skilled Nursing Organizations
- Long-Term Care Organizations
- Public Health Experts
- Healthcare Policy Leaders

For Founding Membership, the one-time cost is **\$5,000** to support our research efforts. Founding Members will have a direct view into our research plan and output.

For Advisory Council Membership, the one-time cost is **\$2,500** to support our research efforts.

Participation may include data contribution, clinical expertise, case studies, advisory involvement, organizational endorsement, or policy collaboration.

Together, we can help establish a national framework for Responsible IVD Testing and Clinical Decision Support that improves patient outcomes, strengthens antimicrobial stewardship, advances CMS priorities, and lowers total healthcare costs.

From Cost Per Test to Cost Per Outcome. From Reactive Care to Precision Care. From Data to Better Decisions.