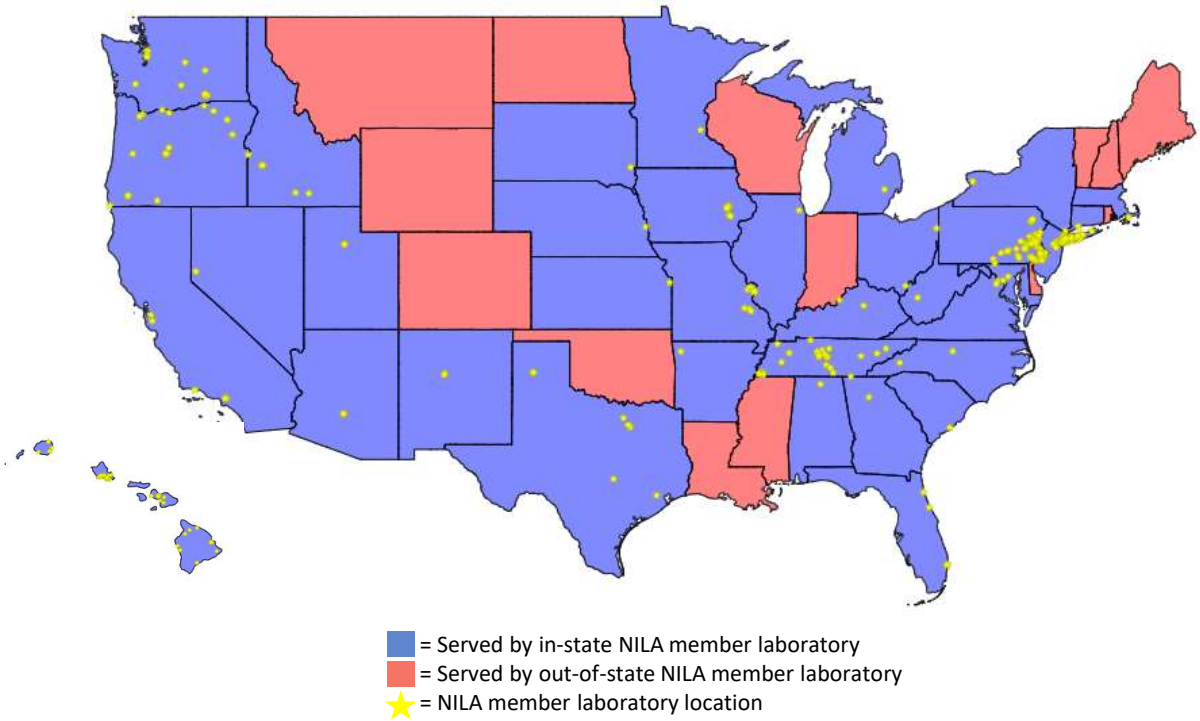
Independent Community and Regional Clinical Laboratories – Backbone of the COVID-19 Response

Who are Independent Community and Regional Clinical Laboratories?

Community and regional clinical laboratories are integral players in the U.S. health care system. They are responsible for examining human specimens to provide information for the diagnosis, prevention, and treatment of diseases. **Many serve specific populations, including underserved urban areas, small communities, and rural areas. Community and regional laboratories provide a unique set of services that are not often provided by larger, national laboratories.** Together, community and regional laboratories create a critical network within the health care industry by providing flexible, fast, accurate, and "close-to-the-patient" laboratory services.

NILA Member Laboratory Service Area



What types of services do NILA member laboratories provide?

Community and regional clinical laboratories provide a wide variety of vital laboratory services, including:

- **General biochemistry testing**, such as metabolic and lipid panels;
- **Genetic testing**, including prenatal testing, pharmacogenetic testing, and DNA/RNA sequencing;
- **Infectious disease testing**, including testing for COVID-19 and other infectious diseases;
- **Toxicology**, including testing for therapeutic drug monitoring, substance use disorders, screening for drugs of abuse, and detecting toxins;
- **Reproductive biology testing**, including services for fertility preservation and in vitro fertilization;
- **Hematology**, including blood counts and blood diseases and disorders;
- **Immunology,** including immune disorders, allergy testing, and the presence or absence of antibodies;
- **Anatomic Pathology**, including biopsies and cytology; **and**
- **Molecular/Genetic,** including biomarkers, genotypes, and genetic diseases.

The National Independent Laboratory Association (NILA) is a trade association for community and regional independent and health system clinical laboratories. NILA's members range in size from small laboratories that serve a particular metropolitan area, to medium-sized laboratories that serve one state, to large, multi-state regional laboratories that serve a number of states.

Issues Impacting Independent Community & Regional Laboratories

Protecting Access to Medicare Act (PAMA): Hollowing Out the Nation's Laboratory Industry

The Problem

The goal of the PAMA statute was to tie Medicare Part B reimbursement for clinical laboratory services to private market rate payments. However, when the Center for Medicare & Medicaid Services (CMS) implemented PAMA, only 0.7% of the laboratory market was represented in CMS's data collection and analysis. The final rates for Medicare Part B's Clinical Laboratory Fee Schedule (CLFS) did not represent a full market-based payment system for laboratory services as Congress intended in PAMA. This resulted in broad cuts to the CLFS, because 60% of the data was derived from just two large national laboratories, and that data reflected low private market rates based on "loss leader" discounts used by those two laboratories.

The Impact

- **Understaffed laboratories and longer turnaround times.** Lost revenues result in reduced hiring, leaving laboratories understaffed and with longer turnaround times for test results to get back to the ordering physicians.
- **Limiting hours and services.** Understaffing also requires laboratories to limit hours on weekends and to cut back on personalized services, such as house calls and emergency services, especially when patients are very ill.
- **Market consolidation harms patients.** Steep cuts to Medicare reimbursement rates have caused unprecedented laboratory buy-outs and closures, increasing market consolidation and reducing consumer choice. Community and regional laboratories provide cost-effective and "close-to-the-patient" services to their communities. As community and regional laboratories close, the bargaining power of the large national laboratories increase, harming patients and the Medicare program.
- **Access for Medicare patients is reduced.** As community and regional laboratories are stressed due to cuts in Medicare's Part B CLFS, laboratories may decline business from physician offices, or long-term health care facilities where reimbursement is not covering the costs of services. Many community and regional laboratories cannot afford to provide testing under the lower Medicare Part B payment rates created by PAMA.
- **Decreased investment.** Lower revenues force laboratories to cut back on investing in new, more efficient equipment and innovation.

COVID-19: Exposing Gaps in Laboratory Infrastructure

Supply Shortages

The COVID-19 pandemic exposed serious weaknesses in the nation's medical and laboratory supply chains. Throughout the emergency, laboratories struggled to access needed supplies – including reagents, test kits, and pipette tips – to meet the nation's COVID-19 testing needs. The federal government must immediately provide more transparency in supply distribution and invest in laboratory supply manufacturing to ensure that clinical laboratories have access to the supplies they need.

Because of supply shortages, many laboratories have not been able to complete as many COVID-19 tests as are needed – leading to longer test turnaround times. In response, the federal government implemented short-sighted reimbursement requirements that punish laboratories that are unable to return COVID-19 test results quickly, even if the delay is due to the lack of necessary supplies to perform the testing. The federal government should avoid punitive measures and instead invest in the clinical laboratory supply chain to ensure that laboratories can meet their communities' needs.

Neglected IT Infrastructure

Public health agencies rely on data from clinical laboratories to guide the response to the COVID-19 pandemic. In pursuit of this data, the federal government has imposed test result reporting obligations on laboratories that are difficult to meet, given many laboratories' unique information technology systems and needs. Unlike hospital and physician-facing electronic health records, the federal government has not invested in, or set standards for, laboratory information systems (LIS). As a result, clinical laboratories have had to scramble to update and make their own investments in these technologies to meet the needs of public health agencies. To improve the COVID-19 pandemic response, and to prepare for the next public health emergency, the federal government must provide robust investment in laboratory information technology infrastructure.

Ineffective Data Exchange

The current public health data reporting structure is inefficient and forces clinical laboratories to divert time and attention from testing services to data management. A new strategy is needed to streamline, simplify, and lower the time and cost of reporting test results and data to public health agencies.

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