Clinical Laboratory Quick Reference Guide

Community and regional laboratories provide vital diagnostic testing services to their communities – but jargon and acronyms unique to clinical laboratories can get in the way of important policy discussions. Here are the concepts to understand when working on laboratory-related policies:

- **CLFS.** The Clinical Laboratory Fee Schedule, or CLFS, establishes Part B Medicare fee-for-service reimbursement rates for clinical laboratory services. The CLFS is separate from Medicare's Physician Fee Schedule (PFS), which establishes reimbursement rates for physicians and some services. Many private payors base their clinical laboratory reimbursement rates on the Medicare Part B CLFS.
- **CLIA.** The Clinical Laboratory Improvement Amendments, or CLIA, establish federal standards applicable to facilities or sites that test human specimens for health assessment or to diagnose, prevent, monitor or treat diseases. CLIA also authorizes federal enforcement of these standards.
- **Diagnostic Test.** A diagnostic test searches for the presence of an infectious organism, detects diseased cells (e.g., cancer cells), or helps distinguish between causes of a patient's symptoms. Not all diagnostic tests are clinical laboratory tests.
- **Independent Clinical Laboratory.** Independent clinical laboratories are clinical laboratories located outside a hospital or physician's office. Independent clinical laboratories employ laboratorians that conduct a wide variety of tests for patients.
- **LDT.** Laboratory Developed Tests, or LDTs, are clinical laboratory tests that are designed, manufactured and used within a single laboratory and are not sold to other laboratories. Non-LDT clinical laboratory tests typically use test kits or laboratory devices that are designed, manufactured, and sold by medical device companies to more than one laboratory.
- **LIS.** A Laboratory Information System, or LIS, is the software used by laboratories to record, manage, and store data. Unlike electronic health records, the federal government has not invested in standardizing or developing LIS, leading to challenges in responding to the COVID-19 pandemic.
- **NILA.** The National Independent Laboratory Association, or NILA, represents community and regional laboratories that provide clinical laboratory services. NILA members provide a wide range of services, with many specializing in providing testing for patients who are underserved by the large national laboratories – including nursing facilities, rural communities, and underserved urban centers.
- **PA.** Prior Authorization, or PA, is a utilization management technique used by health plans to prevent billing of medically unnecessary services, including laboratory tests. PA requires payment approval by the insurance company for the test being performed. Laboratories are frequently denied reimbursement when physicians and other providers order tests that must be performed, for the health of the patient, before a PA can be obtained. If subsequent to performing the test the insurance company denies a PA, the laboratory usually cannot get paid for doing the test.
- **PAMA.** The Protecting Access to Medicare Act, or PAMA, was signed into law in April 2014. PAMA overhauled the reimbursement structure for Medicare's Part B laboratory services and, following a flawed rollout, deep cuts to clinical laboratory reimbursement rates ensued, leading to layoffs, consolidation, and a weakening of the nation's laboratory infrastructure.
- **PCR.** Polymerase Chain Reaction (PCR) is a technique in nucleic acid biochemistry that permits the analysis of short sequences of DNA or RNA, even in samples containing only minute quantities of DNA or RNA. PCR is used to reproduce or "amplify" selected sequences of DNA or RNA for analysis.
- **PT.** Proficiency Testing, or PT, is the testing of unknown samples forwarded by an approved PT provider to a clinical laboratory. Proficiency testing is required for certain CLIA-certified laboratories and helps evaluate how tests perform in "real world" settings. The laboratory performs tests on the samples as if they are patient samples and returns the results to the PT provider. The PT provider then grades the results for accuracy and reliability, and reports the results to the laboratory and federal/state regulatory agencies.

Source: Institute of Medicine (2000). Medicare Laboratory Payment Policy: Now and in the Future.

NATIONAL INDEPENDENT LABORATORY ASSOCIATION
906 Olive Street · Suite 1200 · St. Louis MO · 63101-1448 | www.nila-usa.org | P: 314-241-1445 | nila@nila-usa.org