

Community and Regional Clinical Laboratories Face Layoffs and Increased Testing Time Due to PAMA



What are Community and Regional Clinical Laboratories?

Community and regional clinical laboratories are integral players in the healthcare infrastructure in the United States. They are responsible for examining human specimens to provide information for diagnosis, prevention, and treatment of diseases. **Many serve specific populations including inner cities and smaller, rural communities; they provide a unique set of services that are not often provided by larger, national laboratories.** Together, community and regional laboratories create a critical network to the healthcare industry by providing flexible, fast, accurate, and local laboratory services.

Impact of PAMA on Community and Regional Laboratories

The Problem

The goal of the PAMA statute was to tie Medicare reimbursement for clinical laboratory services closer to private market rates. 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 (1). The final rates for the 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 reflected lower private market rates based on higher volume.

Common set of tests NILA members conduct and the % cuts under CMS's final CLFS implemented 01/01/2018

Test name	Description	Uses	% Cut
Complete blood count	Measures vital blood related biodata, including red and white blood cell counts	Critical for patients with leukemia, anemia, autoimmune disorders, cancer and conditions that require regular blood monitoring	35%
Prothrombin time	A blood test that measures how quickly a patient's blood clots	Checks for bleeding problems, monitors blood thinning medication and diagnoses disorders such as leukemia, liver problems and immune disorders	20%
Comprehensive metabolic panel	Blood tests that measure glucose levels, electrolyte and fluid balances	Examines liver and kidney function; can diagnose diabetes; monitors high blood pressure or effect of medications	37%
Lipid panel	Blood tests that measure and detect abnormalities in cholesterol and triglyceride levels	Used in screening and treatment for high cholesterol, diabetes, heart disease, kidney disease and obesity	39%
Assay of ferritin	Blood tests used to determine the amount of iron stored in the body	Checks for iron storage disorders such as hemochromatosis, liver disease, rheumatoid arthritis, hyperthyroidism and some types of cancer	35%
Urine bacterial culture	A test used to identify bacteria in the urine that cause infection	Used to diagnose a urinary tract infection, which is a frequent infection in long-term care facilities	35%
Hemoglobin A1c	Blood tests that measure blood glucose levels	Used to manage and control diabetes	37%
Definitive drug tests	Blood tests to identify specific drugs or metabolites in the bloodstream	Used in suspected drug overdoses and treatment and monitoring of substance abuse disorders	59%

The National Independent Laboratory Association (NILA) is a trade association for community, regional and health system clinical laboratories. NILA's members serve small, rural communities and multi-state regions

The Impact

Community and regional laboratories cannot sustain cuts of this magnitude because much of their revenue comes from serving Medicare and Medicaid populations. **NILA member laboratories have already made staffing reductions and cut back services as they anticipate ongoing implications of PAMA.**

- Layoffs have caused understaffing
 - With layoffs and the inability to hire due to loss in revenue, laboratories are understaffed resulting in longer turnaround times for test results to get back to the ordering physicians. For example, a typical turnaround time for one NILA member lab was 4-6 hours pre-PAMA, but has increased to 12 hours post-PAMA.
- Limiting hours and services
 - Understaffing has also caused laboratories to limit hours on weekends and cut back on the personalized services such as house calls and emergency services when patients are very ill. If laboratories suffer a second year of a 10% cut, some will stop providing house calls for homebound patients. Some labs provide upwards of 200 house calls per day, leaving a void of service in a community.
- Increasing the burden on the healthcare system
 - NILA members fear that long-term care facilities will send more patients directly to the hospital because of increased turnaround times and the inability to get STAT (emergency) testing done in a timely manner. This creates a greater burden on emergency rooms and the healthcare system as patients are admitted when they might not need to be.
- Access to healthcare for Medicare and Medicaid patients
 - As community and regional laboratory business models are stressed due to cuts in the CLFS, laboratories will begin to self-select clients and may turn down business from physician offices or long-term healthcare facilities that have most of their patient population covered under Medicare or Medicaid, simply because they cannot afford to provide testing under the new CLFS rates.

Community and regional clinical laboratories are a vital component of the nation's network of clinical laboratory testing facilities, providing essential services

The Impact of PAMA on NILA Members

- Layoffs
- Reduction of testing services to physician offices and nursing homes
- Increased test turnaround time to report results back to ordering physicians
- Broader patient access issues because laboratories are hesitant to do business with physician offices that bill Medicare and Medicaid
- Increased hospitalization of patients because STAT testing has been dropped or limited

to small and medium-sized communities, underserved inner city and rural areas, homebound patients, residents of adult homes and Medicare/Medicaid beneficiaries in skilled nursing facilities. **Some NILA members cannot survive a sustained 10% cut over the next two years and would have to file for bankruptcy or go out of business creating a void in the testing market.** Unlike community and regional clinical laboratories, large national laboratories customarily have centralized operations that are not as flexible at meeting the unique needs of community-based hospitals, nursing homes and other local providers (2). In many cases, large national laboratories do not serve, or have chosen not to serve, these geographic areas and types of patients. The magnitude of PAMA CLFS cuts will reduce, or eliminate, beneficiary access to laboratory services. In the long run, this will increase costs to the Medicare program because beneficiaries will either utilize higher cost services, e.g., ambulance transportation to hospitals from skilled nursing facilities, or will forgo essential clinical laboratory testing that will result in medical complications from lack of detection or monitoring of serious diseases or medical conditions.

PAMA must be revised in order to preserve community and regional clinical laboratories that provide essential services to the nation's healthcare network.

References

1. Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>
2. Herriman, E.J., Xu, J., Musumeci, J. (2015). *U.S Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts*. New London, CT: G2 Intelligence.