



Understanding the 2025 CLIA Overhaul:

What Labs Need to Know—and How Bula
Helps You Stay Ahead

Executive Summary

In December 2025, the most significant update to CLIA regulations in over 20 years will go into effect. These long-anticipated revisions aim to modernize the Clinical Laboratory Improvement Amendments (CLIA) program in response to advances in laboratory medicine—especially in molecular diagnostics and decentralized testing.

For labs, pharmacies, and healthcare organizations, these changes will require significant operational updates—from re-evaluating personnel qualifications to revising SOPs for test complexity, quality systems, and training. The stakes are high: compliance failures can result in survey deficiencies, suspended reimbursements, and even operational shutdowns.



That's where Bula comes in.

Bula, TRC Healthcare's regulatory intelligence platform, offers the tools, alerts, and clarity needed to track and implement the new CLIA rules efficiently. This blog breaks down what's changing and how Bula helps ensure compliance is proactive, not reactive.

What Is CLIA and Why Are the 2025 Changes So Important?

The **Clinical Laboratory Improvement Amendments (CLIA)** are federal regulations that set quality standards for all laboratory testing performed on humans in the U.S., except for clinical trials and basic research. CLIA aims to ensure accurate, reliable, and timely test results—regardless of the location or size of the testing site.



Why the update now?

The current framework hasn't kept pace with technological advances. Since the early 2000s, diagnostic testing has transformed—especially in the areas of:

- Molecular diagnostics
- Point-of-care (POC) testing
- Direct-to-consumer and at-home collection kits
- Telehealth-enabled lab services
- AI-assisted interpretation tools

Recognizing these gaps, CMS published its final rule in 2024, with an effective date of **December 30, 2025**.



Key Changes in the 2025 CLIA Regulations

The final rule introduces new requirements across four core areas:



1 Personnel Qualifications

CMS has modernized requirements for lab directors, technical consultants, and testing personnel. Highlights include:

- **Updated degree requirements** to reflect changes in lab science education
- **New pathways for competency** based on experience and continuing education
- **Clearer requirements** for remote supervision and multistate operations
- **Defined responsibilities** for AI-supported diagnostic environments

Example: A bachelor's degree in a non-lab science field may no longer qualify someone to perform moderate-complexity testing without additional certification.



2 Test Complexity Categorization

CLIA classifies tests as waived, moderate complexity, or high complexity. The new rule:

- Revises how complexity is assigned, especially for **molecular tests**, **LDTs**, and **AI-driven tools**
- Requires additional documentation and validation when AI or automated interpretations are used
- Includes **more rigorous review** for test kits with at-home components

Example: A pharmacy offering flu and COVID-19 tests using digital interpretation tools must now determine whether those tests fall under moderate or high complexity—requiring more stringent oversight.



3 Proficiency Testing and Quality Control

New requirements tighten expectations around:

- **Proficiency testing frequency**
- **Analytical validation standards**
- **Documentation of test accuracy, precision, and linearity**
- **Ongoing competency assessment** for all testing personnel

CMS emphasized that quality systems must include real-time documentation and review processes to ensure accuracy and rapid error correction.



4 Inspection and Enforcement

The updated regulations clarify:

- **Enforcement authority** and surveyor scope
- **Deficiency levels** and citations
- **Corrective action timelines** for identified noncompliance
- **Use of remote inspections and document reviews**

This means organizations must keep **well-organized, accessible compliance records**—and expect more detailed inspections moving forward.





What This Means for Labs, Pharmacies, and Decentralized Testing Sites

Whether you're operating a central hospital lab, a physician office lab (POL), or offering CLIA-waived tests in retail pharmacies, these changes will affect your operations.

Key implications include:

- **Reassessing your testing portfolio** and CLIA certificate type
- **Verifying personnel credentials** against updated rules
- **Revising SOPs and internal quality policies**
- **Retraining staff** on new procedures and documentation expectations
- **Monitoring state-level alignment**, especially where CLIA is administered by state agencies

Don't assume that if you're only doing waived testing, you're unaffected. Many organizations with multiple test types may need to recertify or update documentation before the deadline.

The State Complexity: When Federal Meets Local

Although CLIA is a federal program, states may enforce more stringent standards or manage compliance independently through a CMS-approved State Agency.

For example:

- **California and New York** both have state laboratory oversight programs that can differ in scope and enforcement timelines.
- **New York** requires licensure and registration even for moderate-complexity tests, adding an additional layer of compliance.
- **Pharmacies expanding testing across state lines** must navigate overlapping and conflicting state regulations—especially in controlled substances, home collection, and test reporting.

Staying compliant isn't just about CLIA—it's about **knowing what applies in every state where you operate**.



How Bula Helps You Navigate CLIA and Beyond

Bula is the regulatory backbone for healthcare organizations that need real-time, accurate, and actionable compliance intelligence. When it comes to CLIA, Bula provides:



Daily Monitoring of Federal and State Updates

- Stay current on all CLIA-related changes at the federal and state levels
- Track relevant proposed rules, final regulations, and enforcement trends



Customizable Reporting Tools

- Build CLIA-specific compliance reports for internal audits or inspections
- Share tailored insights with your quality team, lab directors, or C-suite



Real-Time Alerts and Notifications

- Receive clear, actionable summaries—no legalese, no guesswork



Multistate and Cross-Agency Insights

- View how CLIA changes impact your organization's operations across jurisdictions
- Understand the overlap between CLIA, FDA, and state public health regulations



Searchable Compliance Database

- Access hundreds of FAQs, rule summaries, and cross-referenced laws
- View requirements by topic, state, and regulatory category



Final Thoughts: Don't Wait Until Q4

The CLIA deadline may seem far away—but preparing your team, reviewing credentials, and updating SOPs takes time. Bula helps compliance teams stay ahead of the curve by:

- Reducing time spent interpreting regulations
- Ensuring timely responses to compliance deadlines
- Supporting staff education with clear, centralized information
- Providing peace of mind that you're not missing critical updates

Get a Head Start on 2025 CLIA Compliance with Bula

Let our experts monitor the regulation so you can focus on what matters—accurate testing and quality patient care.