



# CMS CLIA Update



*Gregg Brandush*

*Division of Clinical Laboratory  
Improvement and Quality*

*November 9, 2023*

# Disclaimer

- This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.
- This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.
- The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

# CMS Leadership Team

- CMS CLIA Leadership has stabilized.
  - The CLIA leadership team from the previous meeting consists of:
    - Raelene Perfetto—Policy Branch Manager
    - Angie Daubert—Policy Branch Manager
    - Dan Hesselgesser—Southern Operations Branch Manager
    - Karen Fuller—Western and Central Operations Branch Manager
    - Scott Stacey—Data and Systems Technical Advisor
    - Elysse Lessner—Enforcement Technical Advisor
- New additions
  - We have new Technical Advisors and a new manager:
    - Latoya Laing—Northeastern Operations Branch Manager
    - Survey Technical Advisor—Karen Sutterer (Acting)
    - State/AO Oversight Technical Advisor—Kim Weaver (Acting)
    - Policy Technical Advisor—Ann Snyder (Acting)

# How many CLIA labs are there?

318,880\*

Non-exempt: 304,971

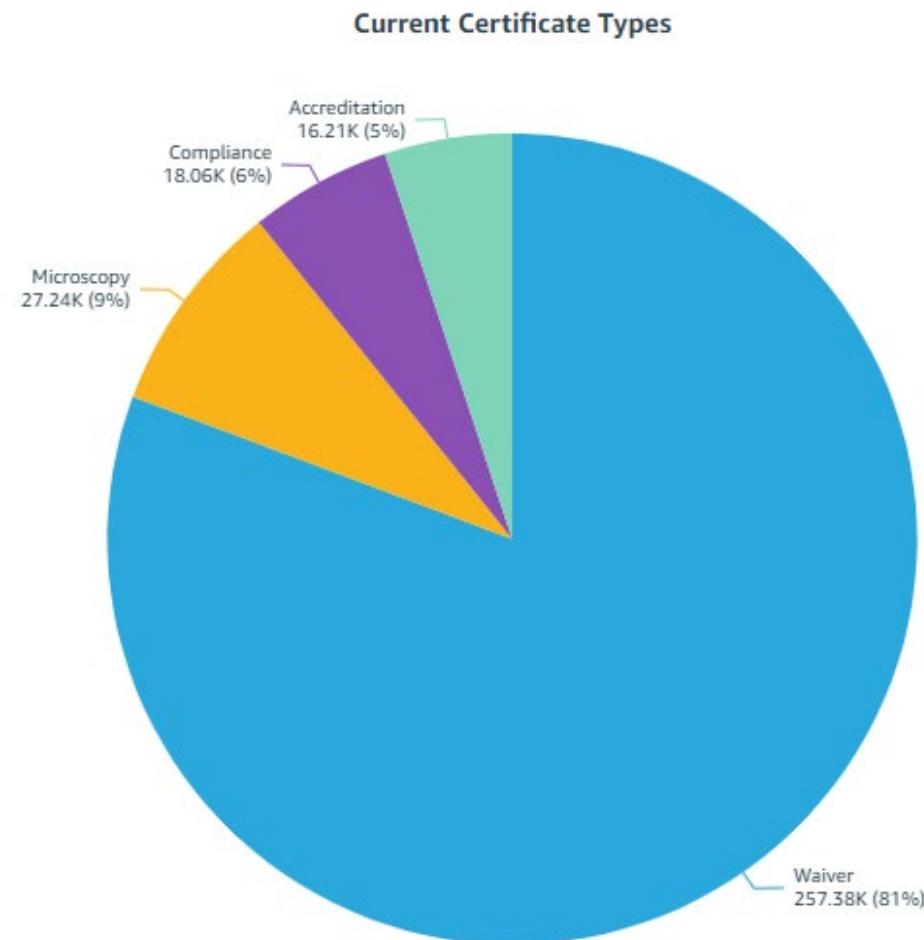
Exempt: 13,909

CoW: 257,378

PPM: 27,236

CoC: 18,055

CoA: 16,211



\* As of October 13, 2023

# CMS CLIA 2023 accomplishments

- Improved processes
  - Enhanced state oversight activities
  - Centralized Enforcement Decisions
  - Vastly enhanced data access and utilization
- Modernizing CLIA
  - PT Rule implementation
  - Electronic Certificates
  - RFI
- Continuing our stakeholder engagement efforts
  - COLA Laboratory Enrichment Forum
  - National Surveyor Training
  - The Joint Commission Education Roundtable
  - APHL Board

## CLIA Policy/Admin Memos of note:

- QSO 23-14-AO/CLIA AO Report to Congress
- QSO 23-15 CLIA Post PHE Guidance
- Admin Info-23-07-CLIA
- Admin Info-23-16-CLIA
- Admin Info-24-01-ALL FMS Guidance

# Additional questions?

Thank you!

Gregg Brandush

[Gregg.Brandush@CMS.HHS.GOV](mailto:Gregg.Brandush@CMS.HHS.GOV)

312-353-1567