CMS CLIA Update

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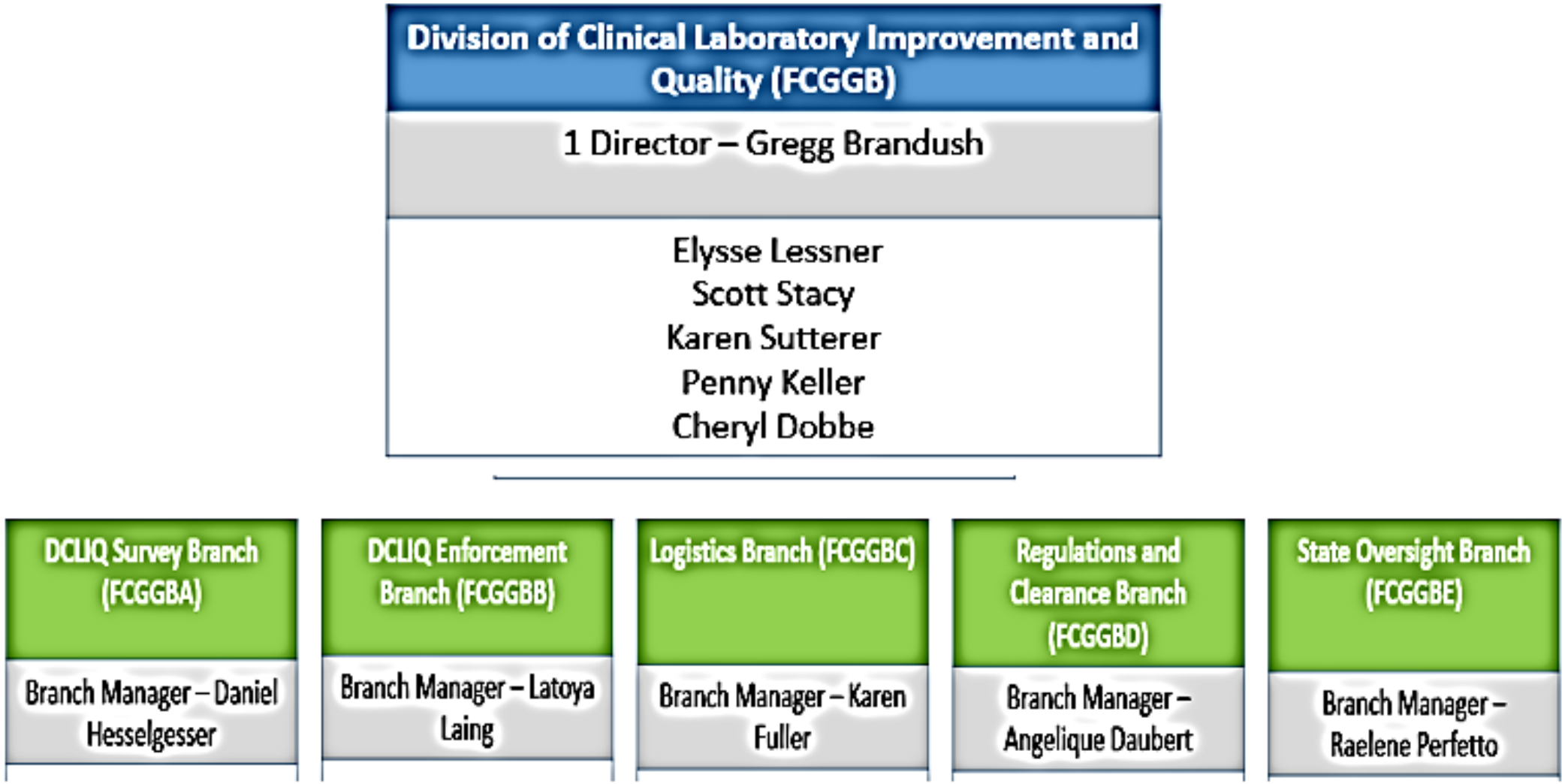
CMS DCLIQ ORGANIZATION



How many labs are there?

Approximate Number—Laboratories	314,895
Exempt States (New York and Washington)	15,317
Total Non-Exempt	299,578
CoC	17,603
CoW	255,549
CoA	16,082
PPM	25,661

Source: CMS database—October 2024

CMS CLIA goals for 2023

- Improved processes
  - Use of data to identify outliers in terms of survey findings, time spent on survey, team size
  - Adherence to enforcement timelines
  - Enhanced state oversight activities
- Modernizing CLIA
  - PT Rule implementation
  - Electronic Certificates
- Assessing the use of enforcement discretion and flexibilities during the PHE:
  - Remote review of pathology slides/data
  - Expedited review of CLIA applications
  - Contiguous site flexibilities
  - University non-CLIA COVID testing
  - COW testing authorization as soon as CLIA application is filed
  - COVID test result reporting
- Continuing our stakeholder engagement efforts

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Enforcement Timelines

March 1, 2022, through February 28, 2023:

Cases	97
Average pre-enforcement days	50.07
Average proposed days	120.73
Average imposed days	128.03
Average total enforcement days	138.49

Enforcement Timelines

March 1, 2022, through September 30, 2024:

Cases	30
Average pre-enforcement days	24.89
Average proposed days	22.1
Average imposed days	57.58
Average total enforcement days	66.29

Enforcement timeline improvements

Measure	Pre-reorganization	Since Reorganization	Percentage improvement
Average Pre-enforcement days	50.07	24.89	50.29%
Average Proposed Days	120.73	22.1	81.69%
Average Imposed Days	128.03	57.58	55.03%
Average Total Enforcement Days	138.49	66.26	52.15%

CMS CLIA goals for 2024

Year One Goals	Year Three Goals	Year Five Goals
• 50% of CLIA certificates will be electronic and available on-line • Issue Interpretive Guidance on the new Fee, histocompatibility, Personnel and Alternative Sanction rule. • Initiate action plan to address data that demonstrates survey inconsistencies related to team size, time spent on survey, citation rates. • Track enforcement actions to ensure consistency • Make CLIA Certificate of Compliance survey findings available of QCOR	• Implement Lab Director University • Revise enforcement letters for plain language and readability • Assess state budget allocations for consistency and fairness	• Develop other educational resources such as Technical Supervisor University, Technical Consultant University, etc. • Develop standardized survey process that is objective, consistent and computer assisted.

Additional Accomplishments

- Evaluated all proficiency testing providers to ensure compliance with the new PT regulations and are ready for implementation on 1/1/25
- We are currently 35% electronic and have developed a plan to convert to a fully electronic process in 2025
- Published guidance to address concerns with the BD Bactec blood culture vial shortage
- Approved additional certification for cytotechnologists based on stakeholder feedback
- Eliminated survey backlogs in 8 states
- Created the State Agency Monitoring database to track and assess communication with state agencies
- Re-engaged our regular communication with Accrediting Organizations and Exempt States

New Policy Memos

One policy memo since the last meeting:

- REVISIONS TO QSO-22-21-CLIA ORIGINALLY RELEASED ON JULY 11, 2022

This revision updates the table found on page 4 of this memo to correctly list two analytes, Cancer antigen (CA) 125 and Carcinoembryonic antigen (CEA), under Endocrinology (§§ 493.933).

This revision also corrects the reported units for CEA from “ng/dL” to “ng/mL”. The units were previously revised in the Federal Register, and this memo reflects the revision on page 9.

New Administrative Memos

Five Administrative memos were released since the last meeting:

- State Agency Performance Review (SAPR)—Fiscal Year 2024 (FY 2024)
- Fiscal Year (FY) 2025 Clinical Laboratory Improvement Amendments (CLIA) Budget Call Letter
- American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Specialist in Cytology (SCT) as an Approved Board Certification for the Clinical Laboratory Improvement Amendments (CLIA) for Individuals Performing Testing in the Subspecialty of Cytology
- 2025 Clinical Laboratory Improvement Amendments (CLIA) Budget Call Letter
- Revisions to the Review and Approval of Plans of Correction (POCs) and CLIA Allegations of Compliance (AOCs)

Additional questions?

Thank you!

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Policy memos can be found here:
https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states-and-cms-locations

Administrative memos can be found here:
https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/administrative-information-memos-states-and-regions