CMS DCLIQ REORGANIZATION

- DCLIQ Reorganization--what has changed:

- 2 Policy Branches and 3 Operations Branches have been restructured

- New structure consists of 5 branches along the primary product lines:

    - Survey Branch

    - Enforcement Branch

    - Logistics Branch

    - Regulations and Clearance Branch

    - State Oversight Branch

CMS DCLIQ REORGANIZATION

Division of Clinical Laboratory Improvement and Quality (FCGGB)
1 Director – Gregg Brandush
Elysse Lessner Scott Stacy Karen Sutterer Penny Keller Cheryl Dobbe

DCLIQ Survey Branch (FCGGBA)	DCLIQ Enforcement Branch (FCGGBB)	Logistics Branch (FCGGBC)	Regulations and Clearance Branch (FCGGBD)	State Oversight Branch (FCGGBE)
Branch Manager – Daniel Hesselgesser	Branch Manager – Latoya Laing	Branch Manager – Karen Fuller	Branch Manager – Angelique Daubert	Branch Manager – Raelene Perfetto

How many labs are there?

Approximate Number—Laboratories	317,740
Exempt States (New York and Washington)	14,508
Total Non-Exempt	303,232
CoC	17,833
CoW	257,043
CoA	16,073
PPM	26,791

Source: CMS database—February 2024

Visual Breakdown of Certificate Types

Current Certificate Types
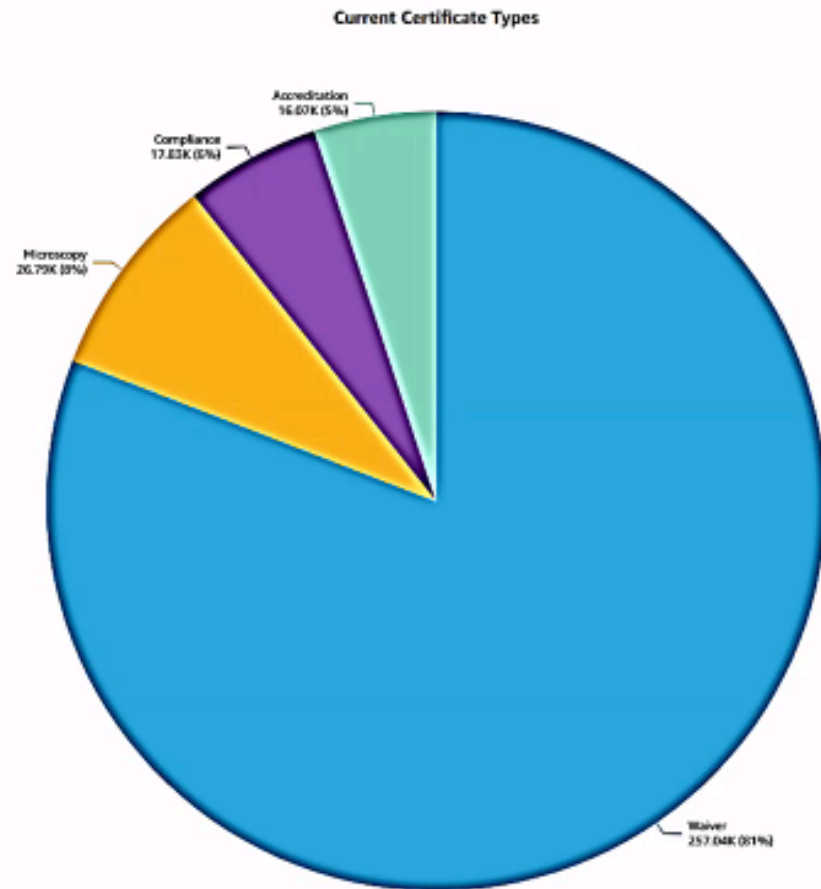
CMS CLIA goals for 2023

- 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

Additional CMS accomplishments FY23

- Electronic Certificates and QCOR links
- CDC Data Exchange
- Fee rule
- RFI *(Histopathology, Cytology, and Clinical Cytogenetics Regulations)*
- Budget process
- Backlog plan
- Dashboards

Certificate of Compliance survey findings

Top Ten Conditions Nationwide (10/1/19 to 9/30/21):

Tag Number	Count	Tag Identification
2016	1,263	Condition: Successful PT participation
6000	839	Condition: Lab Director qualifications and responsibilities for moderate complexity testing at 493.1405 and 493.1407.
6076	452	Condition: Lab Director qualifications and responsibilities for high complexity testing at 493.1443 and 493.1445.
5400	380	Condition: Analytic Systems—Must meet requirements at 493.1251-1289.
2000	298	Condition: PT enrollment and testing of samples
6033	257	Condition: Technical Consultant qualifications and responsibilities for moderate complexity testing at 493.1411 and 493.1413.
6063	230	Condition: Testing personnel qualifications and responsibilities for moderate complexity testing at 493.1423 and 493.1425.
6168	204	Condition: Labs performing high complexity testing; testing personnel
3000	169	Condition: Facility Administration—must meet 493.1101-1105.
6108	103	Condition: Technical Supervisor qualifications and responsibilities for high complexity testing at 493.1449 and 493.1451.

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 questions?

Thank you!

Gregg Brandush

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