



Ensuring Quality Patient Testing at the Point of Care



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New Jersey Point-of Care Testing Coordinators
July 23, 2010



Objectives

- Identify the roles that CMS, the Division of Laboratory Services, Regional offices and State agencies provide to assure the safety and quality of patient testing in laboratories.
- Describe the current climate of waived testing
- Identify additional issues for laboratories performing point-of care testing.
- Identify on-line resources available to assist with administering a POC program.



The ARCHITECT OF THE CAPITOL

IS RESPONSIBLE TO THE
U.S. CONGRESS FOR PRESERVING,
MAINTAINING, AND ENHANCING
THE NATIONAL TREASURES
ENTRUSTED TO OUR CARE.

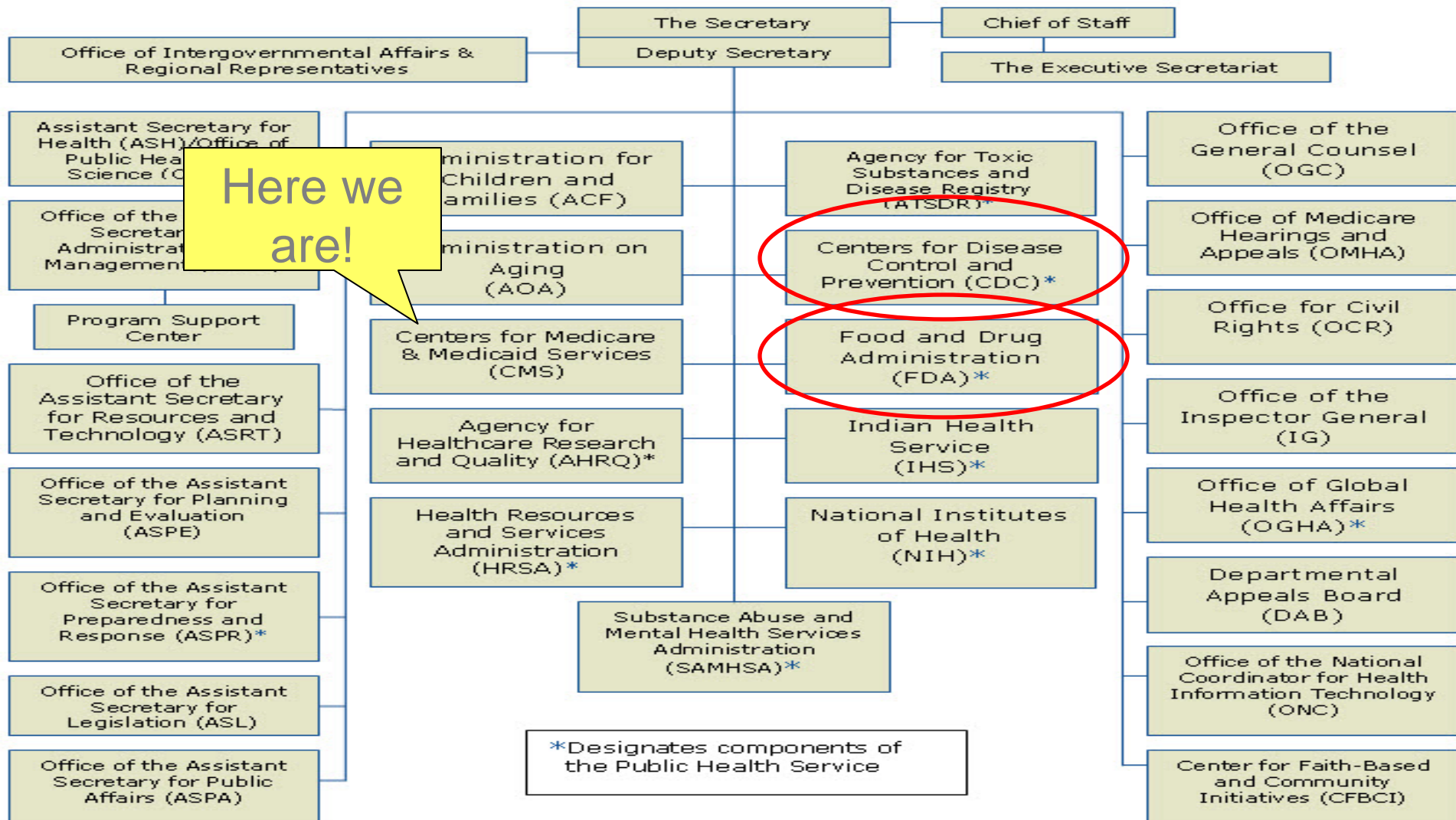




- Federal civil servants take an oath of office to support and defend the Constitution that established our system of government and the principles that govern our nation.



US Department of Health and Human Services Organizational Chart



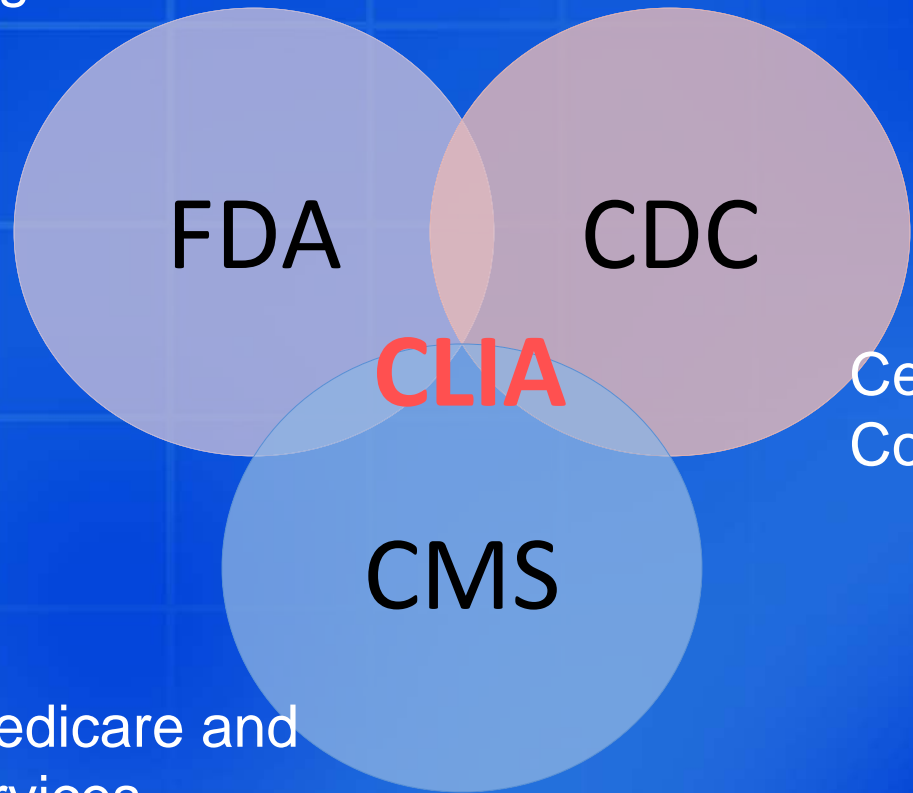


- GAO – Government Accountability Office
 - Judicial branch
 - Govt oversight body
- HHS – Health and Human Services
 - Executive branch
- OIG – Office of the Inspector General
 - Perform internal reviews



Tri-agency Relationship

Food & Drug Administration



Centers for Disease Control & Prevention

Center for Medicare and Medicaid Services



FDA

Food & Drug Administration

- Performs test categorization and develops corresponding regulations and guidance
(CMS assigns the specialties and subspecialties)
- Consults with CMS & CDC on CLIA technical issues
- Regulates devices, blood, biologics and tissue banks

CDC

Centers for Disease Control & Prevention

- Provides....
 - scientific & technical consultation to CMS
 - technical assistance in the promulgation of CLIA regulations
 - education to the general public on good laboratory practices and standards
- Collects data for Certificate of Waiver Project
- Monitors and evaluates approved proficiency testing provider programs





CDC

Clinical Laboratory Improvement Advisory Committee (CLIAC)

- Scientific and technical advice and guidance to the Secretary, HHS; the assistant Secretary for Health; the Director, CDC; the Commissioner, FDA; and the Administrator, CMS
 - regarding the need for, and the nature of, revisions to the CLIA standards
 - For ex., technological advances, other laboratory-related issues
 - the impact on the quality of medical and laboratory practice of proposed revisions to the standards and issues



CLIAAC STRUCTURE & MEMBERSHIP



WELCOME TO BALTIMORE.....HON!

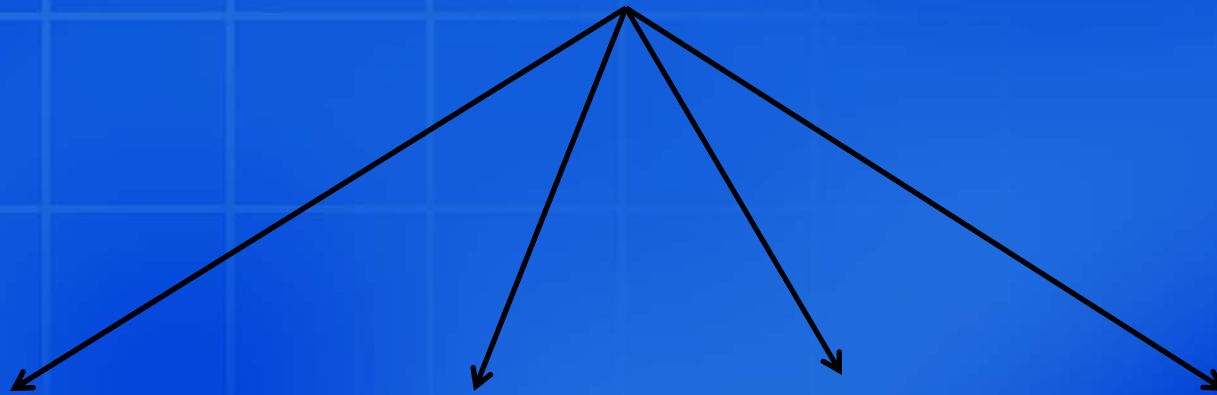




CMS' ROLE



CMS



MEDICARE

MEDICAID

SCHIP

CLIA



Do You Know.....

- Facilities seeking payment for laboratory services under the Medicare and/or Medicaid programs must meet applicable CLIA requirements.
- Entities which perform laboratory testing and do not receive Medicare and/or Medicaid reimbursement, must also hold the appropriate valid CLIA certificate and
- All must meet the applicable CLIA requirements for the testing offered.



Do You Know.....

- The objective of the CLIA program is to ensure quality laboratory testing.
- Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid responsibilities.

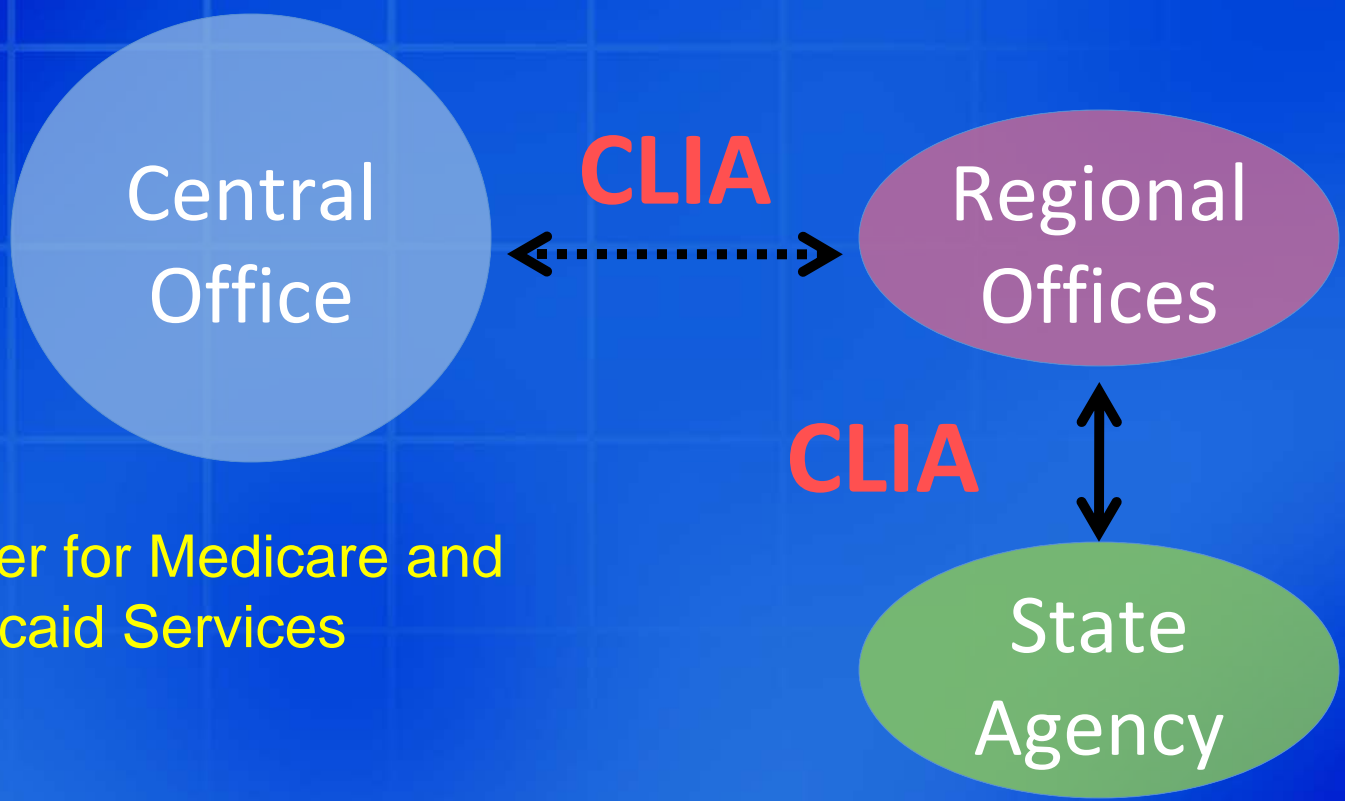


Do You Know.....

- CLIA lab oversight does not include
 - Forensic labs
 - Research labs (where individual results are not reported to the client)
 - Substance Abuse and Mental Health Services (SAMHSA) certified labs
 - Paternity testing
- Because.....”Laboratory” §493.2 Definitions



Federal & State Relationship



Center for Medicare and
Medicaid Services



CMS

“CENTRAL OFFICE”

Division of Laboratory Services

- Implement, manage & monitor the CLIA program
- Develop & implement regulations
- Approve/Re-approve
 - Accreditation Organizations/ Exempt States
 - Proficiency Testing programs



CMS

“CENTRAL OFFICE”

- **Appendix C Interpretive Guidelines**
- **State Operations Manual**
- **Policy Memos**
- **Training for SA Surveyors**
- **RO/SA CLIA Oversight and Guidance**



CMS

“CENTRAL OFFICE”

- We Participate in.....
 - Workgroups that are internal and external to CMS and HHS.
 - CLSI Standards development
- Program Evaluation and Monitoring
- State Agency Performance Review
 - 1864 Agreement



CMS

“CENTRAL OFFICE”

- Design data system to accommodate the registering, billing & certification of laboratories
- Collaborate with govt and non-govt partners to address laboratory issues
 - Partners in Laboratory Oversight
 - <http://www.cms.hhs.gov/CLIA/downloads/090606%20RevPartners%20Lab%20Oversight.pdf>



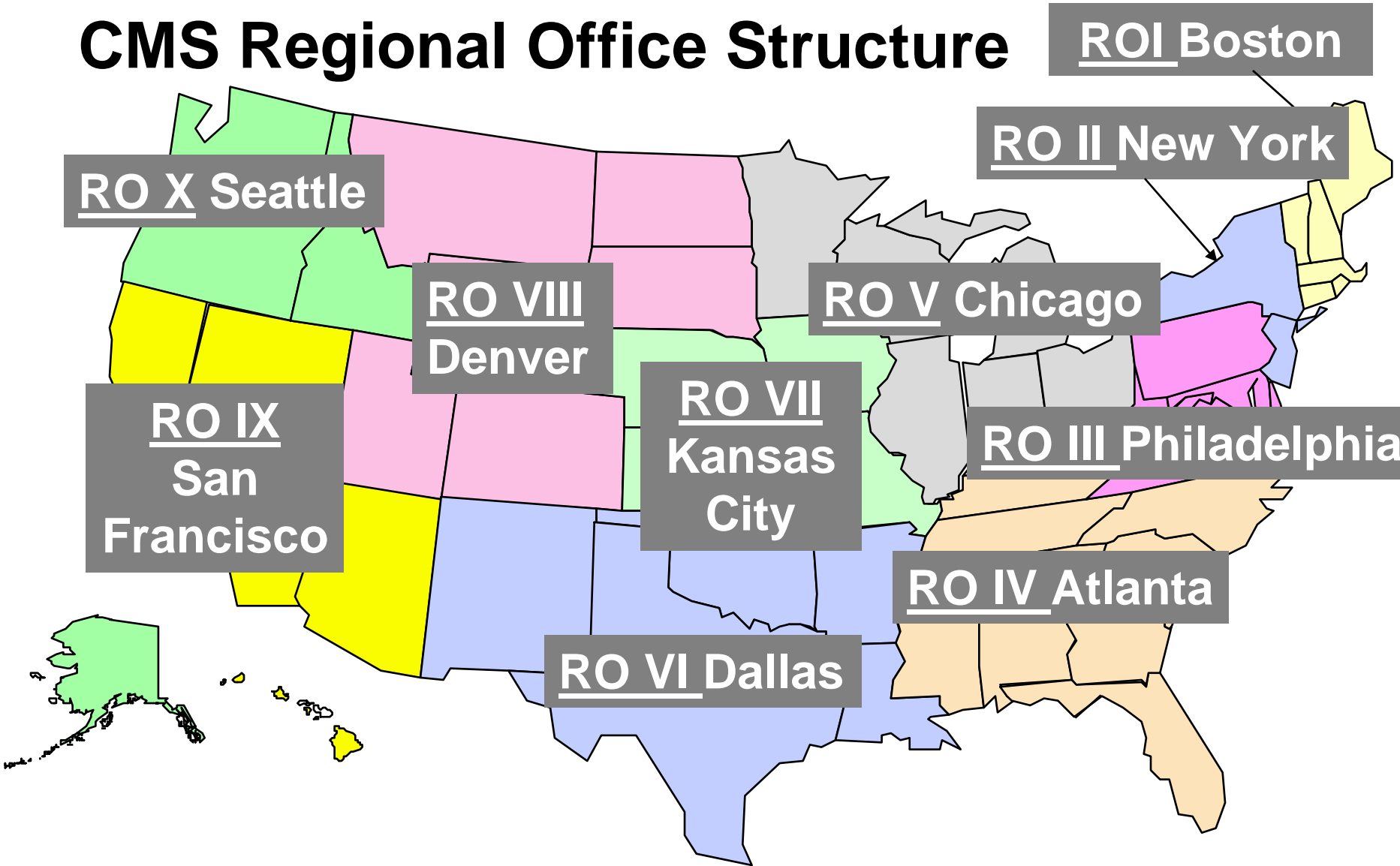
CMS

“CENTRAL OFFICE”

Provide public education

- Presentations
- CLIA Brochures
- On-line resources
 - CLIA Website

CMS Regional Office Structure





Regional Offices

THE REGIONAL OFFICES

- Liaison to state agencies for policy dissemination and technical assistance
- Approve, deny, or terminate certification
- Interpret guidelines, policies, and procedures
- Levy enforcement actions which may have Medicare reimbursement impact
- Oversee SA CLIA activities and
- Conduct surveyor orientation



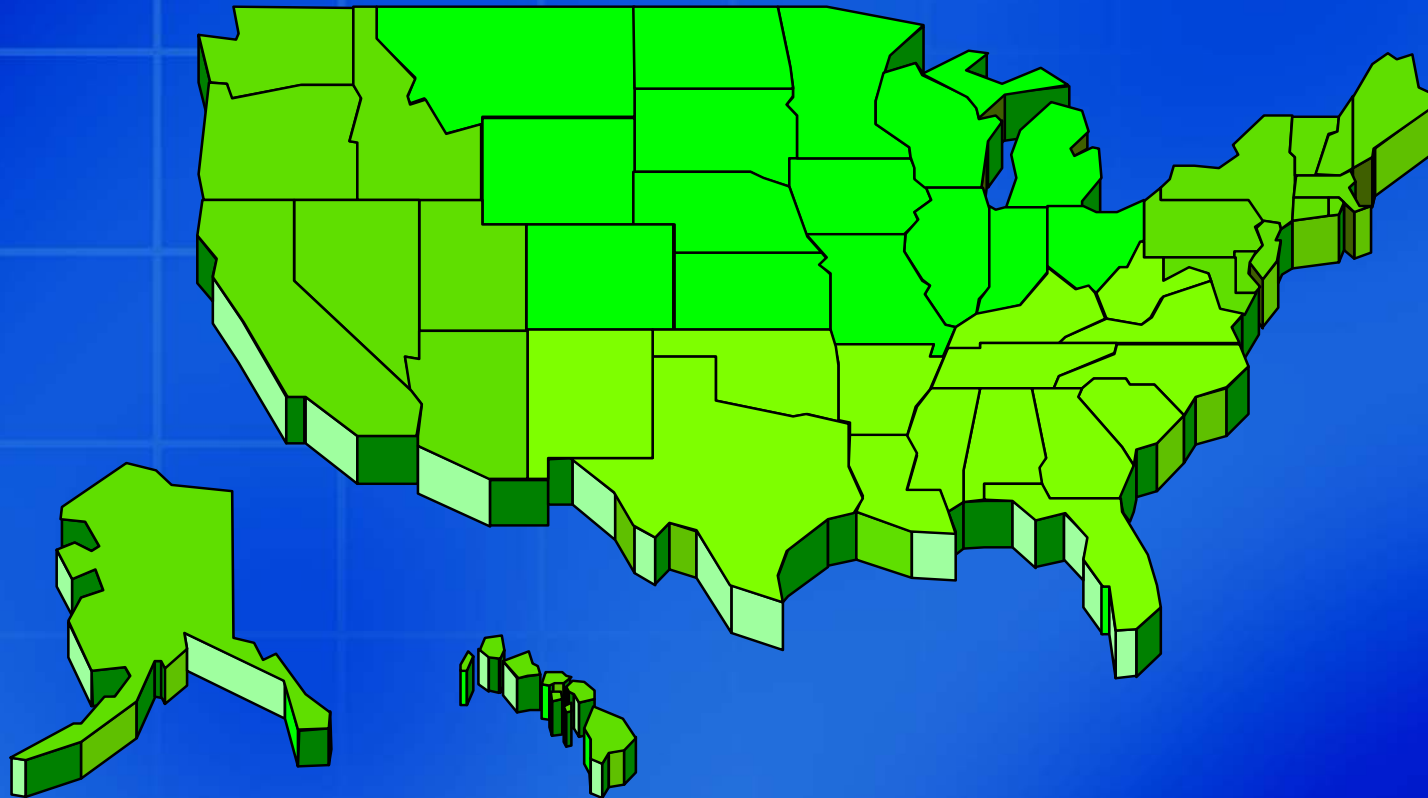
Regional Offices

Regional Offices

- Assist CO in training, with projects, policy development and distribution.
- Perform on-site surveys of laboratories, e.g., validations and State operated laboratories
- Oversee SA performance
 - State Agency Performance Review
 - Federal Monitoring Surveys



State Agencies





State Agency

State Agency

- Initiate enrollment process, verify and enter data
 - Receipt of CMS 116
- Perform PT desk review
 - What's PT Desk Review?
- Participate in federally directed projects
- Provide technical assistance to laboratories

State
Agency

State Agency

- Following surveys the SA will:
 - Certify and recertify laboratories
 - Solicit a Plan of Correction (POC) and other follow-up actions
 - Recommend sanctions to RO, if applicable



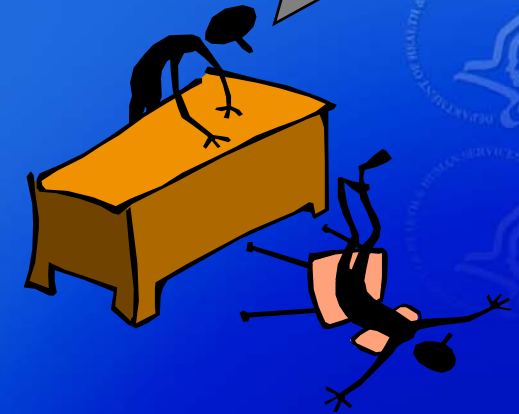


TYPES OF STATE AGENCY SURVEYS

Schedule and conduct.....

- Certification
- Recertification
- Revisit
- Complaint
- Validation Surveys

You're surprised
that we review
validation reports?





The Current Climate of Waived Testing





By CLIA definition.....

Waived tests are:

“.....simple laboratory examinations & procedures which employ methodologies that are so simple & accurate as to render the likelihood of erroneous results negligible...”

--Or risk of harm to the patient if performed incorrectly.



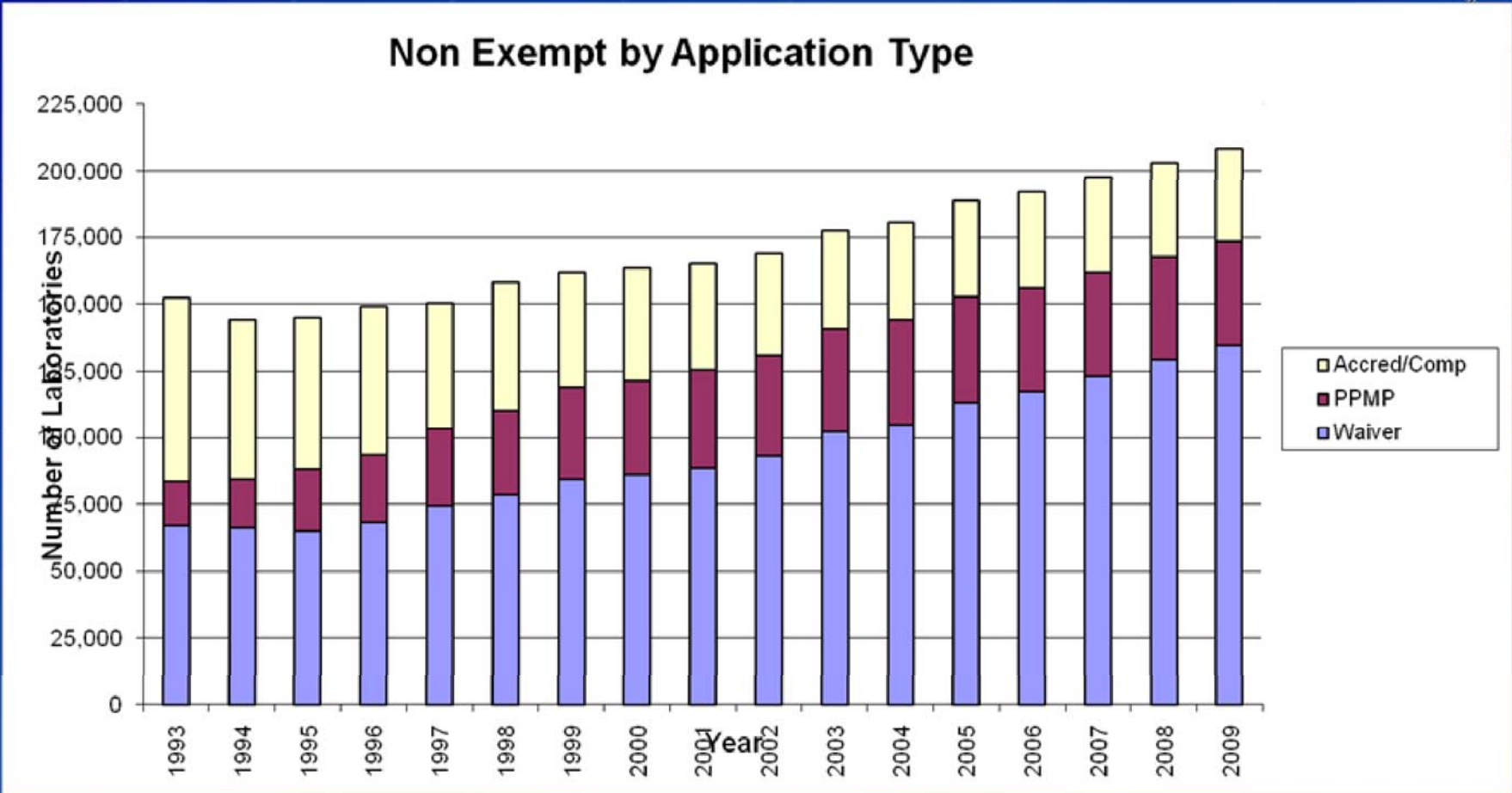
CLIA requirements for waived laboratories.....

The only standards for CW laboratories:

- *Follow manufacturer's instructions*
- Register w/ CMS
- Pay small certificate fee every 2 years



Number of Non-Exempt Labs by Certification Type





Current CLIA Statistics

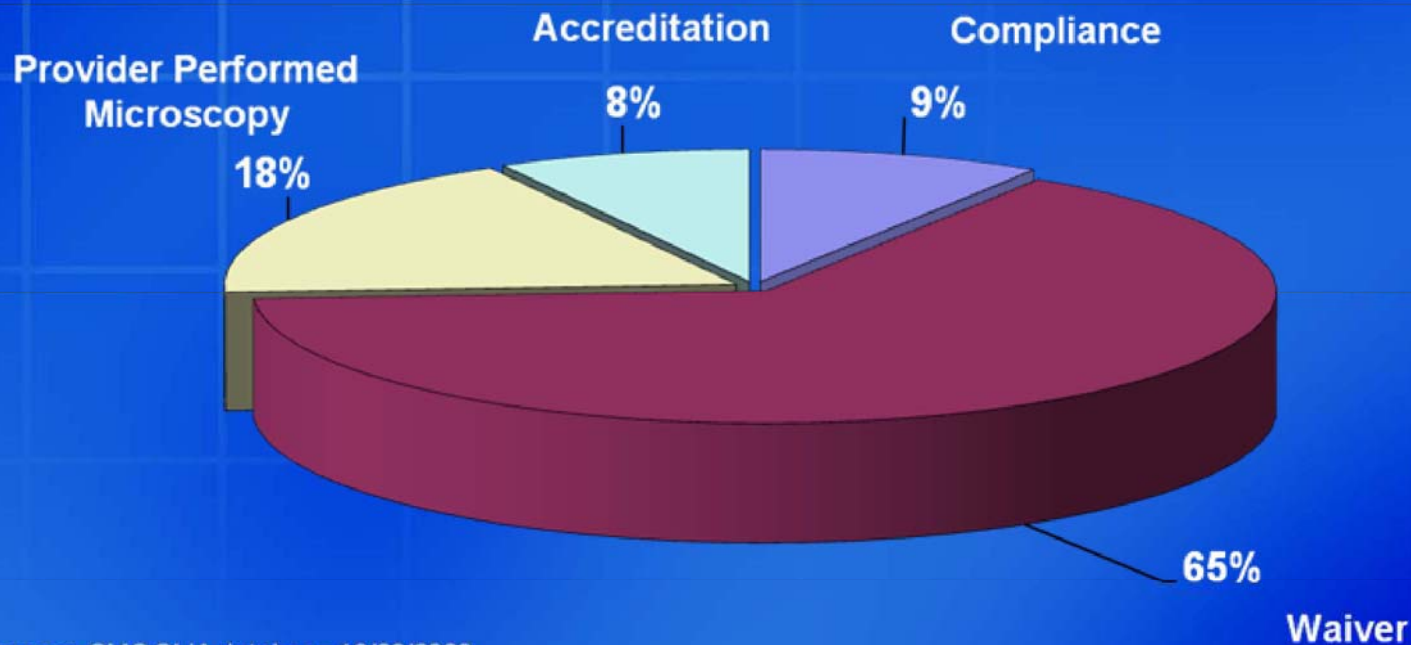
<u>Total Number of Laboratories:</u>	214,875
– <u>Compliance</u>	19,178
– <u>Accredited</u>	16,095
– <u>Waived</u>	134,778
– <u>Provider Performed Microscopy</u>	38,509
– <u>Exempt</u>	<u>6,315</u>
• NY	3,103
• WA	3,212

CMS data base 10/2009



Current CLIA Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)

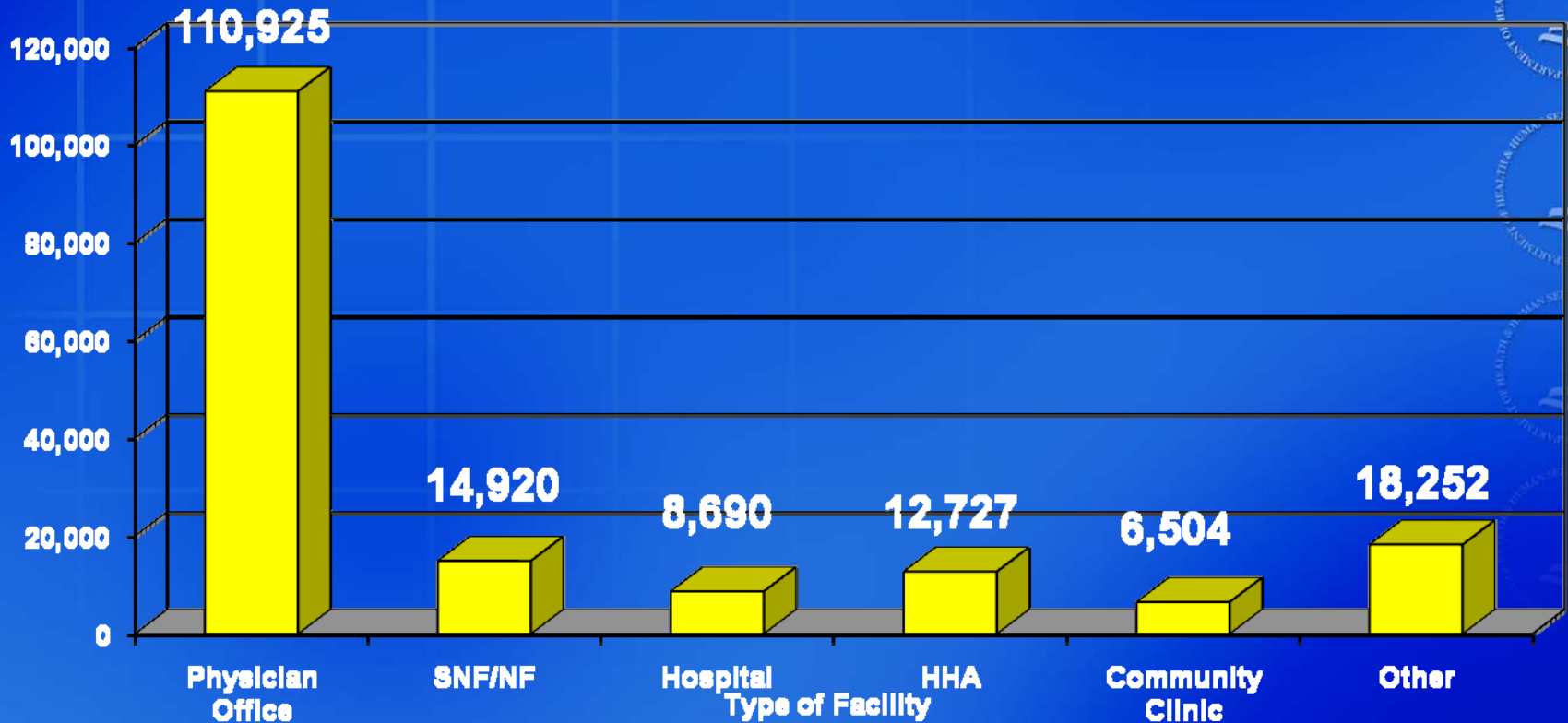


Source: CMS CLIA database 10/22/2009



Current CLIA Statistics

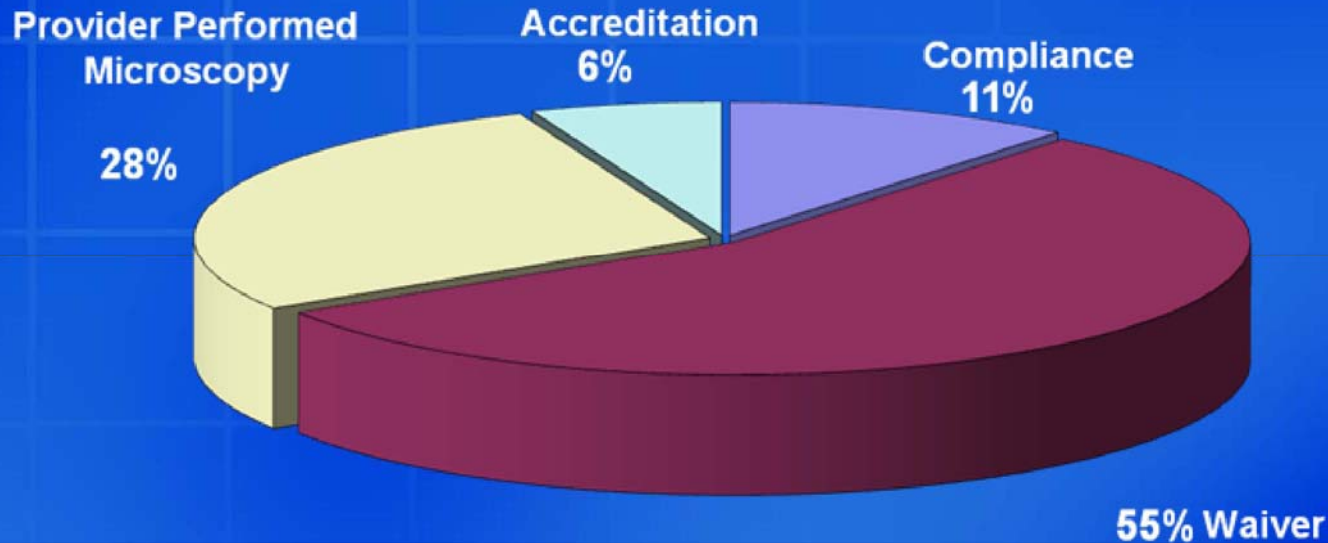
Total CLIA Laboratories Registered
(Self-selected Laboratory Types)





Current CLIA Statistics

Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)

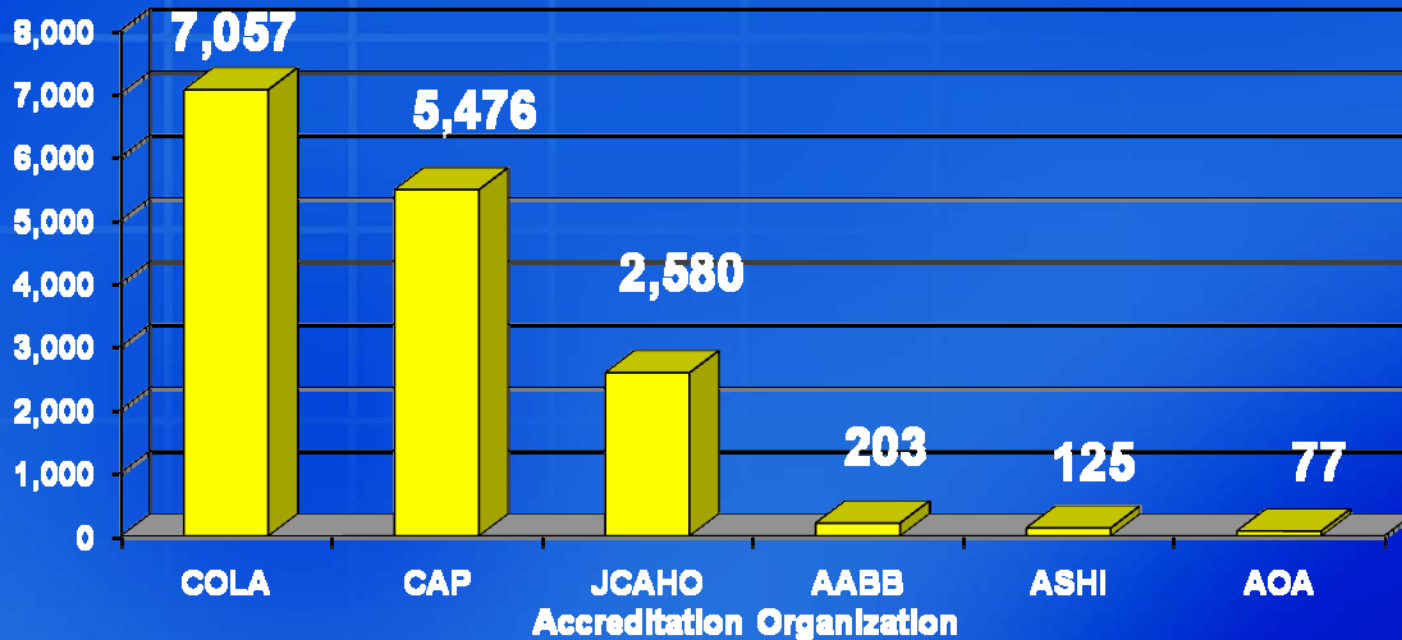


Source: CMS CLIA database 10/22/2009



Current CLIA Statistics

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



October 2009

Growth of Waived Tests & Laboratories

Since 1992.....

- CLIA-waived tests have increased from 8 to about 100 tests.
 - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 64% of the >209,000 laboratories enrolled.





Top Five Frequently Used Waived Tests

Waived Tests	Test Systems Waived Jan.1, 1988 – Dec. 31,1998	Test Systems Waived Jan.1, 1999 – Dec.31, 2008
Fecal Occult Blood	27	58
Glucose Monitoring Devices	109	475
HcG-pregnancy testing (urine-visual color comparison)	219	279
Hemoglobin (single analyte instrument)	3	24
Ovulation tests	29	34



Current Issues in Waived Testing



Growth of Waived Tests & Laboratories

- Waived tests increased due to new, accurate & robust technologies designed by manufacturers
 - Meet FDA criteria for waiver
 - Tested under ideal conditions
 - Performed by individuals w/without some lab background



Growth of Waived Tests & Laboratories

- Waived labs increased due to growth in numbers & types of waived tests. These are:
 - Most frequently performed tests
 - Tests typically done in POC settings
- Waived status is an incentive due to no government oversight
 - Creates less burden to the lab
 - Decreases cost to the lab
 - No PT
 - No routine survey



CMS Position on Waived Testing



- Continue to increase, POCTs offer timely, efficient, convenient patient care
- Increased testing comes w/ issues:
 - ✓ Testing personnel not trained; may not ID problems
 - ✓ No routine oversight w/ no funding/resources
 - ✓ Minimal QC required
 - ✓ Pre & post analytical issues

Next Steps for Waived Testing.....

- Number of CW labs increasing exponentially
- Education is effective, but resources are lacking
- CMS developed “Issue” paper w/ multi-faceted recommendations for agency mgt.
- CMS to convene w/ Partners (AOs) to develop long & short term plans w/ related studies.
- Stay tuned.....





CMS CERTIFICATE OF WAIVER (CW) PROJECT

- For the CW project, 2% of CW labs/yr.
- Respond to waived testing questions
- Receive education on good laboratory practices
- Approved to continue into 2010

``Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''

- FDA Guidance issued: January 30, 2008
- Federal Register: October 20, 2009 (Volume 74, Number 201)] [Notices]
- Submit written or electronic comments on the collection of information by December 21, 2009.

<http://edocket.access.gpo.gov/2009/E9-25177.htm>



CBC Waiver General Concerns

- Should a CBC be categorized as waived?
Does it meet definition of “*simple*”?
- How does the device perform under real lab conditions w/ actual testing personnel?
- How are varying hematological clinical conditions & patient populations addressed?
- The level of expertise to operate the device & judgment required to interpret the test results





PT Referral WARNING!!

- PT referral results in the most serious CLIA penalties
 - Loss of CLIA certificate for one year.
 - Includes cancellation of Medicare/Medicaid payment
 - Lab dir can't direct ANY lab for 2 yrs
 - Listed on CLIA Annual Lab Registry—
CMS web site



PT Referral **WARNING!!**

- CMS prevailed in all appeals to date
- CMS sent letter to LDs w/ PT FAQs for labs; now on web
- CMS CO reviews all cases for accuracy, consistency & to facilitate better policy



PT Regulation Update

- 2008 CLIAC recommendation
- PT programs met November 2008
- CLIAC WG met March 2010
- Evaluating regulations
 - mechanisms for analyte /test selection
 - target values,
 - grading criteria
 - PT referral
 - alternative assessment
 - genetic tests
- Requires a proposed rule w/ comment & final
- WG will report to CLIAC in September 2010

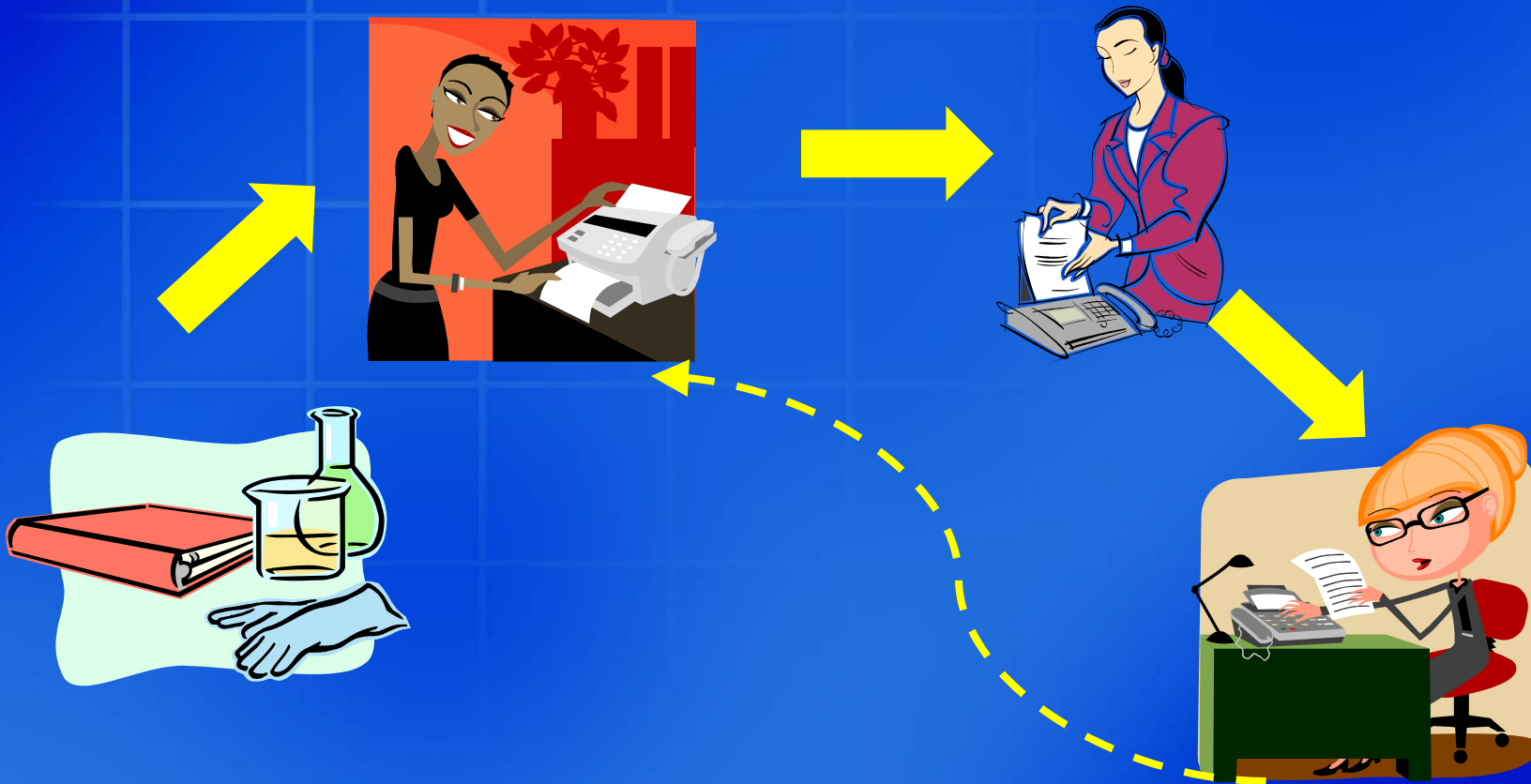


Electronic Health Records



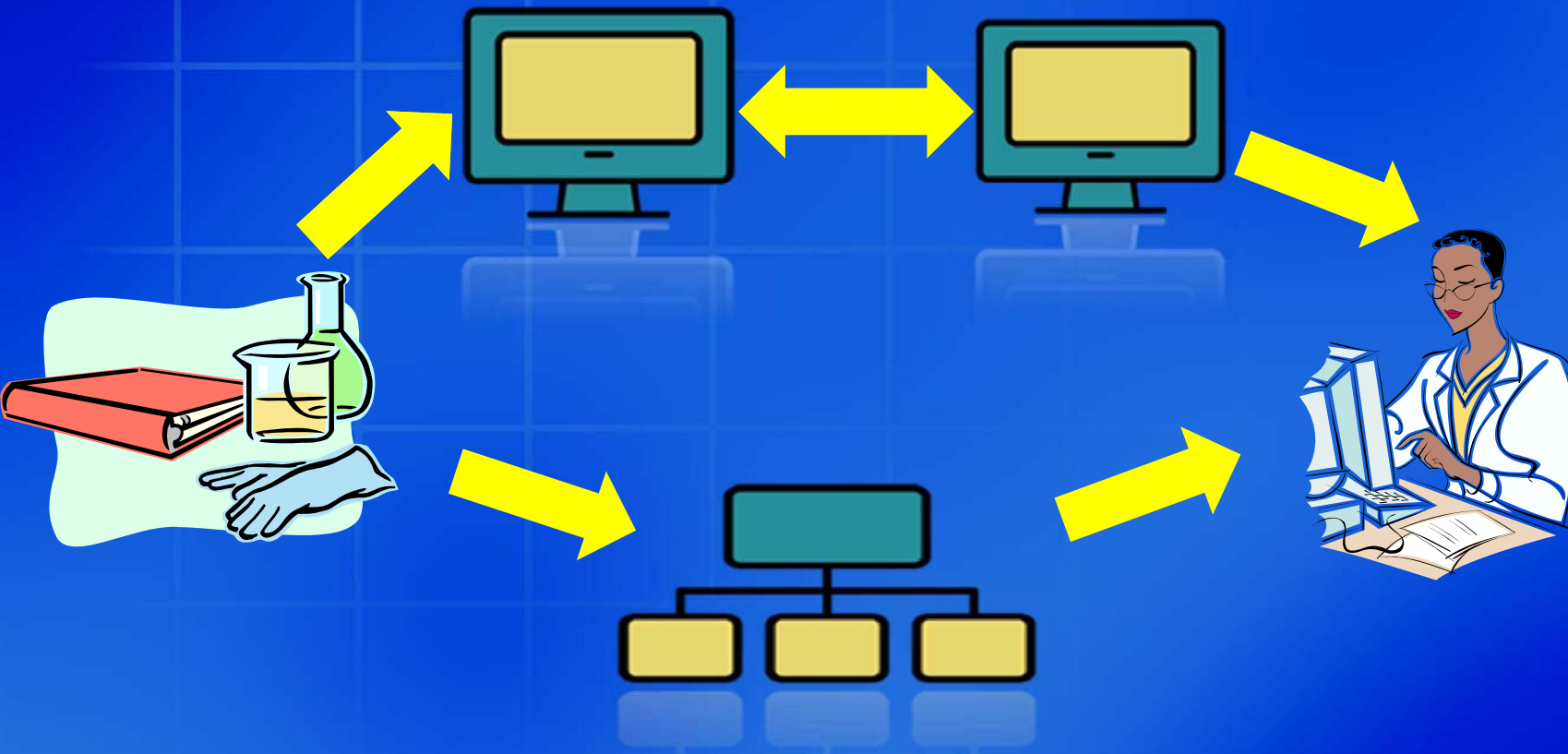


Electronic Health Records





Electronic Health Records



Electronic Health Records



- CLIA requires reporting to State authorized person
 - Or individual who will use them
 - Or referring laboratory
- CLIA requires certain data elements
- CLIA requires accurate, timely, reliable & confidential transmission regardless of mechanism
- **Issues:** State laws, incompatible systems & terminology, lab responsibilities, oversight of EHRs & HIEs

Electronic Health Records

Misperception: CLIA doesn't permit patients to receive test results directly; CLIA regulations should be changed to permit patients to receive their results.

Clarification: Depending on State law, patients may be able to order & receive test results or the authorized person may request a copy for the patient when ordering the test. (493.1241 & 493.1291) This area of the regulations still under discussion with ONC.



Electronic Health Records

- **Newly clarified CMS CLIA Interpretive Guidance for EHRs released Mar. 1, 2010 !!**
 - Contains expanded information, guidance & regulatory interpretations for test ordering, record retention & result reporting
 - Under the current regulations!
- **Accompanied by corresponding FAQs.**
- <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter10-12.pdf>



Electronic Health Records

An agent is an individual or entity legally acting on behalf of the authorized person to receive test results





Electronic Health Records

- Regulations are unchanged
- Interpretive Guidance revised for specific regulations
- Survey Process remains the same
- Laboratories must make sure that all the required data elements are in their test reports
- Laboratories must confirm the accuracy/timeliness of their data transmissions



Electronic Health Records

- Applies to all entities performing human testing regardless of site
- Laboratories performing waived testing are excluded from CLIA standards.
 - This represents 62% of labs that have virtually *no oversight*



Electronic Health Records

- CLIA requires accurate, timely, reliable & confidential transmission regardless of mechanism
 - §493.1291 Test report
- CLIA requires results to “authorized persons” individual who will use them under State law
 - §493.1291(f)



Electronic Health Records

- All State laws are “not created equal” for test ordering and reporting
 - specify only physicians can order tests and receive test results
 - patients may order tests and receive results on themselves
 - law is silent on the subject



Electronic Health Records

- CLIA requires certain data elements on test requisition
 - §493.1241 Test request
- After results are reported to the authorized person,
CLIA oversight and authority ends



Electronic Health Records Data Exchange.....

- U.S. National Health Information Network(NHIN)
- Health Information Exchanges(HIE)
- Regional Health Information Organizations(RHIOs)
- Office for the National Coordinator (ONC)
- National Governors Association (NGA)



Online Resources - CMS Website

Centers for Medicare & Medicaid Services - Windows Internet Explorer
http://www.cms.hhs.gov/

File Edit View Favorites Tools Help

Centers for Medicare & Medicaid Services

U.S. Department of Health & Human Services www.hhs.gov

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 - Coding
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 - [More...](#)
- Medicaid**
 - Medicaid Waiver & Demonstration Projects
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CMS Highlights

- [C M S H1n1 Information](#)
- [Health Reform News And Updates](#)
- [Children's Health Insurance Program Reauthorization Act Of 2009 \(CHIPRA\)](#)
- [Economic Recovery Act Of 2009](#)
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- [MLN Matters Articles](#)
- [Physician Fee Schedule Lookup](#)
- [Physician Quality Reporting Initiative](#)
- [National Provider Identifier Standard](#)

Do you help someone with Medicare?
 Yes No

You are a caregiver. Medicare has information for you. [Learn More](#)

ask Medicare
medicare.gov/caregivers

Trusted sites 100%



CLIA Website

Overview Clinical Laboratory Improvement Amendments (CLIA) - Windows Internet Explorer

http://www.cms.hhs.gov/CLIA/

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Clinical Laboratory Improvement Amendments (CLIA)

- Overview
- Cytology Proficiency Testing
- Interpretive Guidelines for Laboratories
- Policy & Data Reporting Guidance for CMS-2226-F
- CLIA Brochures
- How to Apply for a CLIA Certificate, Including International Laboratories
- Program Descriptions/Projects
- Certificate of Waiver Laboratory Project
- CLIA Regulations and Federal Register Documents
- Categorization of Tests
- CLIA Certificate Fee Schedule
- State Agency & Regional Office CLIA Contacts
- Accreditation Organizations/Exempt States
- Proficiency Testing Providers
- CME Courses for Laboratory Directors of Moderate Complexity Laboratories
- Certification Boards for Laboratory Directors of High Complexity Testing
- CLIA Statistical Tables/Graphs
- Laboratory Registry
- CLIA Related Hearing Decisions and Compliance Topics
- Laboratory Demographics Lookup

Overview

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 200,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations (CMSO) has the responsibility for implementing the CLIA Program.

The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

For the following information, refer to the downloads/links listed below:

- For additional information about a particular laboratory, contact the appropriate State Agency or Regional Office CLIA contact (refer to State Agency or Regional Office CLIA link found on the left-hand navigation plane);
- CMS initiatives to improve quality of laboratory testing under the CLIA program;
- Updated FYI CLIA information is contained in the Current CLIA News download;
- Information about direct access testing (DAT) and the CLIA regulations is included in the Direct Access Testing download;
- OIG reports relating to CLIA;
- Guidance for Coordination of CLIA Activities Among CMS Central Office, CMS Regional Offices, State Agencies (including State with Licensure Requirements), Accreditation Organizations and States with CMS Approved State Laboratory Programs is contained in the Partners in Laboratory Oversight download;
- Quality control (QC) highlights from the regulations published in the *Federal Register* on January 24, 2003 are listed under the QC Highlights download;
- Micro sample pipetting information for laboratories;
- CLIA presentation at NIAID/CMCR Workshop on the FDA Pre-Market Regulatory Process: Applications to Technologies for Radiation Biodosimetry After a Large-Scale Radiological Incident, March 27th, 2006, Bethesda, MD;
- Information on alternative (non-traditional) laboratory is contained in the Special Alert download;
- Survey and Certification memorandum entitled "Doctors of Optometry Serving as Directors and/or Technical Consultants for Laboratories Performing Moderate Complexity Testing";
- Identifying Best Practices in Laboratory Medicine - a Battelle Project for the Centers for Disease Control and Prevention (CDC); and
- Survey and Certification memorandum entitled "Clinical Laboratory Improvement Amendments (CLIA) -- Impact of A/H1N1 Swine Flu on CLIA Operations."

For specific information about the quality assurance guidelines for testing using the OraQuick® Rapid HIV-1 Antibody Test, refer to the CDC Division of Laboratory Systems website listed under the related links outside CMS section below.

Complaint Reporting

CLIA Website

Clinical Laboratory Improvement Amendments (CLIA)

► Overview

- » [Cytology Proficiency Testing](#)
- » [Interpretive Guidelines for Laboratories](#)
- » [Policy & Data Reporting Guidance for CMS-2226-F](#)
- » [CLIA Brochures](#)
- » [How to Apply for a CLIA Certificate, Including International Laboratories](#)
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- » [CLIA Statistical Tables/Graphs](#)
- » [Laboratory Registry](#)
- » [CLIA Related Hearing Decisions and Compliance Topics](#)
- » [Laboratory Demographics Lookup](#)

Overview

The Centers for Medicare & Medicaid Services (CMS) oversees the U.S. through the laboratory entities. The Medicare and Medicaid and State C

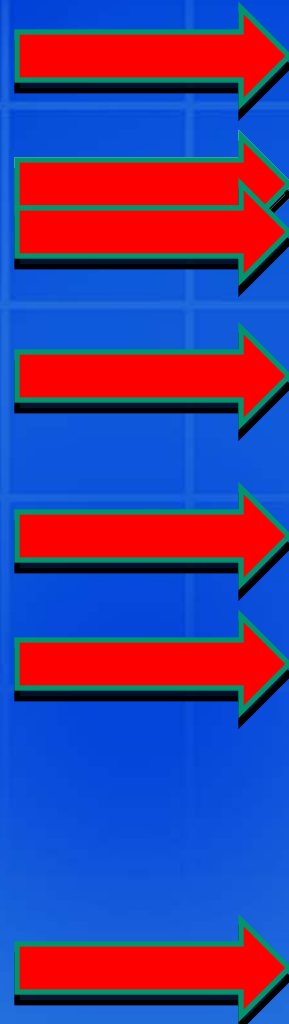
The objective of the CLIA program is to ensure that laboratories certified to receive M

For the following info

- For additional information, contact (refer to the [CLIA Contact List](#))
- CMS initiatives
- Updated FYI CLIA
- Information about the CLIA program; download;
- OIG reports related to the CLIA program;
- Guidance for CLIA State with License Programs is contained in the [CLIA State with License Programs](#)
- Quality control programs in effect in 2003 are listed in the [CLIA Quality Control Programs](#)
- Micro sample proficiency testing
- CLIA presentation on Radiation Biodosimetry
- Information on the CLIA program
- Survey and Certification for Laboratories
- Identifying Best Practices (CDC); and
- Survey and Certification for Swine Flu on CLIA

For specific information, refer to the CDC Division of Laboratory Services

Complaint Reporting





CLIA Brochures



CMS

Clinical Laboratory Improvement Amendments (CLIA)

Updated Regulations Brochure #1*

How do they affect my laboratory?

Changes in the CLIA regulations include a new format, some new terminology, and updated requirements.

Important information to help keep your laboratory in compliance!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final laboratory regulation (CLIA) rules that became effective April 24, 2003. A summary of the updated requirements is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and orders. For more complete information, you may access the regulations on the Internet at <http://www.phhp.usg.gov/CLIA.asp> or <http://www.fda.gov/cdrh/oc/CLIA.asp>.

CDC

*This brochure is one in a series to follow.

CMS

Clinical Laboratory Improvement Amendments (CLIA)

Verification of Performance Specifications Brochure #2

What is it and how do I do it?

The CLIA regulations now include a requirement for verifying the performance specifications of unmodified, moderate complexity tests cleared or approved by the FDA.

Information to assist your laboratory in meeting this CLIA requirement!

NOTE: On January 19, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulation (CLIA) that became effective April 24, 2003. A summary of the updated requirements pertaining to performance specification verification are included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and orders. For more complete information, you may access the regulations on the Internet at <http://www.phhp.usg.gov/CLIA.asp>.

CMS **CDC**

Clinical Laboratory Improvement Amendments (CLIA)

Calibration and Calibration Verification Brochure #3

What is calibration, and how do I do it?

Information to assist your laboratory in meeting this CLIA requirement for nonswab (moderate and high complexity) test systems!

NOTE: On January 19, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulation (CLIA) that became effective April 24, 2003. A summary of updated requirements pertaining to calibration and calibration verification are included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and orders. For more complete information, you may access the regulations on the Internet at <http://www.phhp.usg.gov/CLIA.asp>.

CMS **CDC**

Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures Brochure #4

What are they, and when can I use them?

Information to assist your laboratory in meeting this CLIA quality control requirement option for nonswab (moderate and high complexity) test systems!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulation (CLIA) that became effective April 24, 2003. A summary of equivalent quality control options is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and orders. For more complete information, you may access the regulations on the Internet at <http://www.phhp.usg.gov/CLIA.asp>.

CMS **CDC**

Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate Required?

When is a CLIA Certificate Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.

CDC

CMS

Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate of Waiver

When is a CLIA Certificate of Waiver Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.

CDC

CMS

Clinical Laboratory Improvement Amendments (CLIA)

Laboratory Director Responsibilities

What Are My Responsibilities As A Laboratory Director

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.

CDC

CMS

Clinical Laboratory Improvement Amendments (CLIA)

PROFICIENCY TESTING

DOs and DON'Ts

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CDC

CMS

Clinical Laboratory Improvement Amendments (CLIA)

COMPLAINTS

Do You Have a Concern About a Laboratory's Operation?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.

CDC



Laboratory Demographics Lookup

[CMS Home](#) > [Research, Statistics, Data and Systems](#) > [Clinical Laboratory Improvement Amendments \(CLIA\)](#) > Laboratory Demographics Lookup

Clinical Laboratory Improvement

Laboratory Demographics Lookup

Look up by.....
Number
Name
Geography
Application Type
Exemption Status

This website provides demographic information about laboratories, including CLIA number, facility name and address, where the laboratory testing is performed, the type of CLIA certificate, and the date the certificate expires. For additional information about a particular laboratory, contact the appropriate State Agency or Regional Office CLIA contact (refer to State Agency or Regional Office links found on the left-hand navigation pane).

Data source: OSCAR database, CLIA subsystem as of 10/02/2009

Lab Look-up data updated quarterly

Select laboratory report criteria:

By Number:

CLIA Number:

By Name:

Laboratory Name:

If a laboratory name is entered and the all states box is checked, every state that has that laboratory name will be displayed. If the all states box is unchecked, only laboratories in the state selected in the geography section will be displayed.

Check this box if you want to search all states (Must enter a laboratory name or partial name to search all states).

By Geography:

City:






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Other DLS Resources

- > [Resource Links](#)

Division of Laboratory Systems

 Best Practices in Laboratory Medicine DLS is leading a national effort to evaluate best practices in Laboratory Medicine... more	 National Laboratory System A nationwide laboratory system is crucial to the future health and safety of our communities... more	 International Laboratory Related Resource and Activity Directory... more
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- [MMWR - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions \[HTML | PDF\]](#)

- [MMWR - Good Laboratory Practices for Waived Testing Sites](#)

- [Coagulation Laboratory Testing Practices](#)

- [Antimicrobial Susceptibility Testing: A self-study program](#) - an interactive CD-ROM experience from the producers of [MASTER](#).

- [A New Era in Newborn Screening: Saving Lives, Improving Outcomes - Webcast, Program Materials Now Available on CD ROM and VHS](#)

- [Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa \(PDF\)](#)

- [Public Health Teleconference Series on Infectious](#)

Quick Links



- > [Biosafety](#)
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- > [Guidelines](#)

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USA



About FDA

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Centers & Offices

About the Center for Devices and Radiological Health

CDRH Offices

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Office of Communication, Education, and Radiation Programs

Office of Compliance

Office of Device Evaluation

▶ **Office of In Vitro Diagnostic Device Evaluation and Safety**

Office of Management Operations

Office of Science and Engineering Laboratories

Office of Surveillance and Biometrics

Office of In Vitro Diagnostic Device Evaluation and Safety

The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) regulates all aspects of in-home and laboratory diagnostic tests (in vitro diagnostic devices, or IVDs). The Office was formed November 17, 2002, in order to consolidate all regulatory activities for IVDs. OIVD has a dual charge to foster the rapid transfer of new IVDs into the marketplace while preventing marketing of unsafe or ineffective devices. To accomplish this OIVD combines the functions of all the offices within CDRH into one organizational unit for cradle-to-grave regulation of in vitro diagnostic devices (IVDs). OIVD carries out this Total Product Life Cycle approach by combining the pre-market review responsibilities of the Office of Device Evaluation (ODE), the enforcement responsibilities of the Office of Compliance (OC), and the post-market surveillance responsibilities of the Office of Surveillance and Biometrics (OSB). To support these regulatory responsibilities, OIVD maintains strong ties to the Office of Science and Engineering Laboratories (OSEL) for technical assistance, the Office of Communication, Education, and Radiation Programs (OCER) for communication and outreach assistance, and the Office of Management Operations (OMO) for program management assistance. The result is a multi-disciplinary and cross-linked organization which fosters efficient cradle-to-grave oversight of IVDs grounded in good science.

OIVD consists of a multidisciplinary group of scientists, medical technologists, policy analysts, engineers, pathologists, and clinicians who are collectively dedicated to promoting and protecting public health. Regardless of discipline, the staff strives to ensure that the medical and laboratory communities as well as other product users affected by their decisions have useful and safe products and they understand that information can foster better use of products. Consequently, the Office strives to ensure the work is transparent in order to allow all stakeholders to obtain the knowledge required to make informed decisions about the development, production, and



Where to Find CLIA Info:

CMS CLIA Web site:

- www.cms.hhs.gov/clia/

CLIAC

- <http://wwwn.cdc.gov/cliac/>

CDC/DLS

- <http://wwwn.cdc.gov/dls/default.aspx>

FDA/OIVD

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115904.htm>

Contact me at:

ann.snyder@cms.hhs.gov



CLIA

Questions??

THANK YOU!!

