DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Ensuring Quality Patient Testing at the Point of Care

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Medical Technologist
Division of Laboratory Services
Centers for Medicare and Medicaid Services

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA

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.

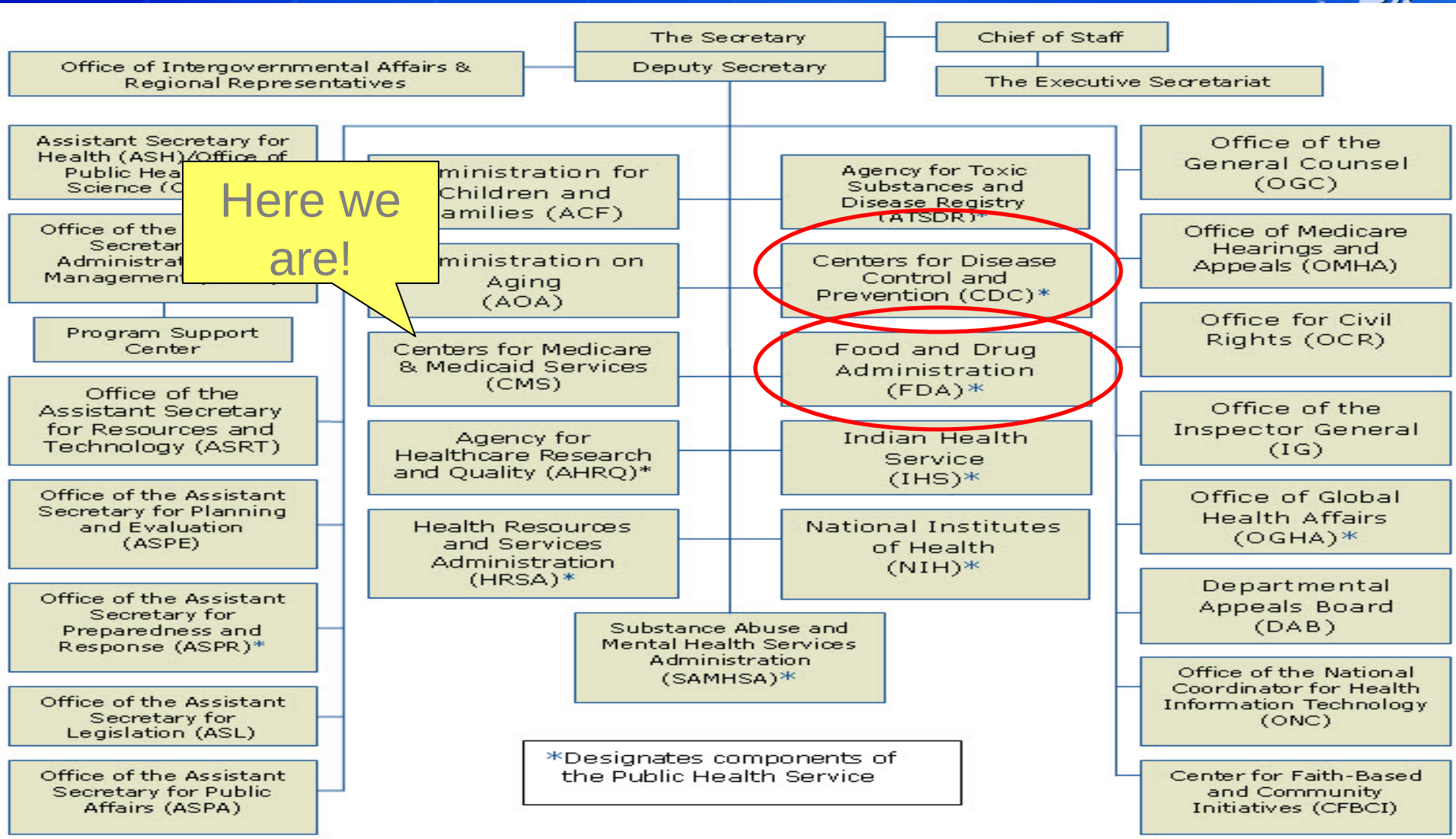
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

- 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Kathleen Sebelius
Secretary, U.S. Department of Health and Human Services

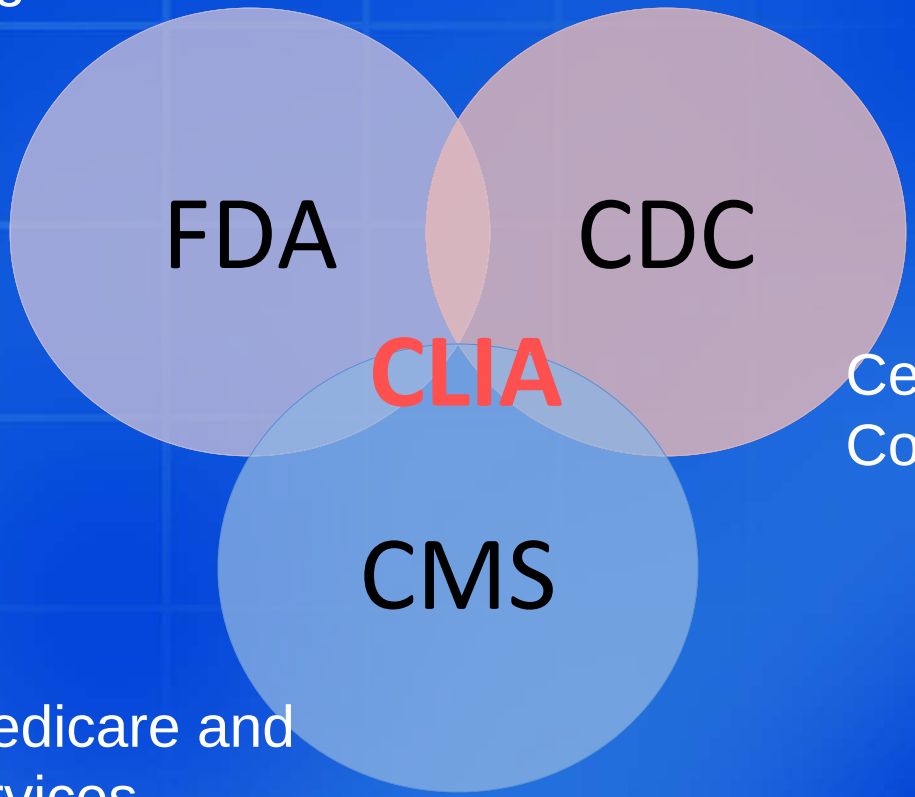
US Department of Health and Human Services Organizational Chart



- 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**

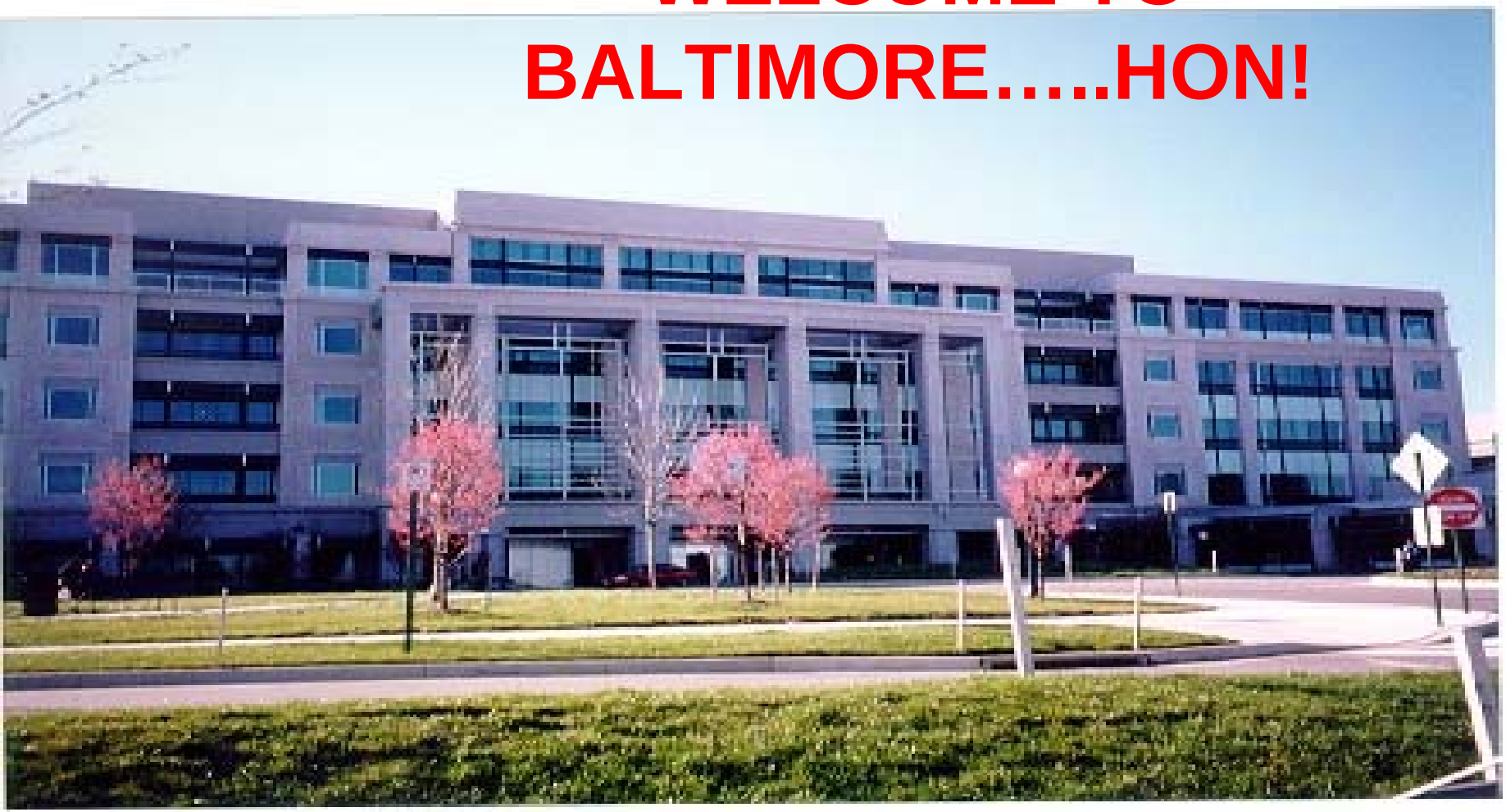
CDC

Clinical Laboratory Improvement Advisory Committee (CLIAC)

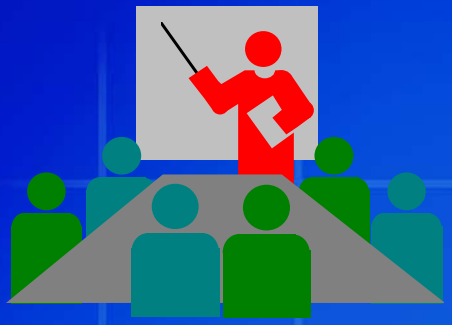
- Scientific and technical advice and guidance to the Secretary, HHS; the assistant Secretary for Health; the Director, CDC; the Commissioner, FDA; and the Administrator, CMS
  - regarding the need for, and the nature of, revisions to the CLIA standards
    - For ex., technological advances, other laboratory-related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

CLIAC 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.

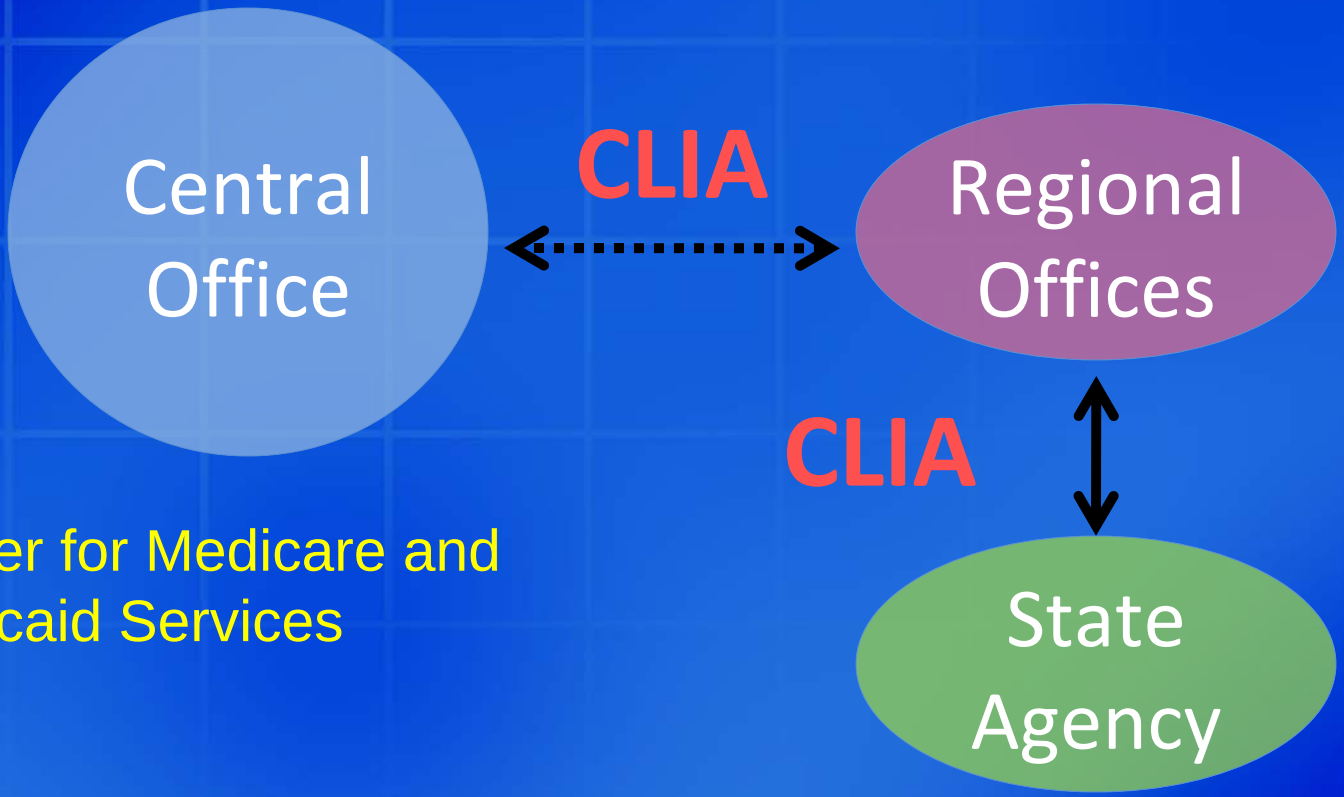
Do You Know……..

- 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

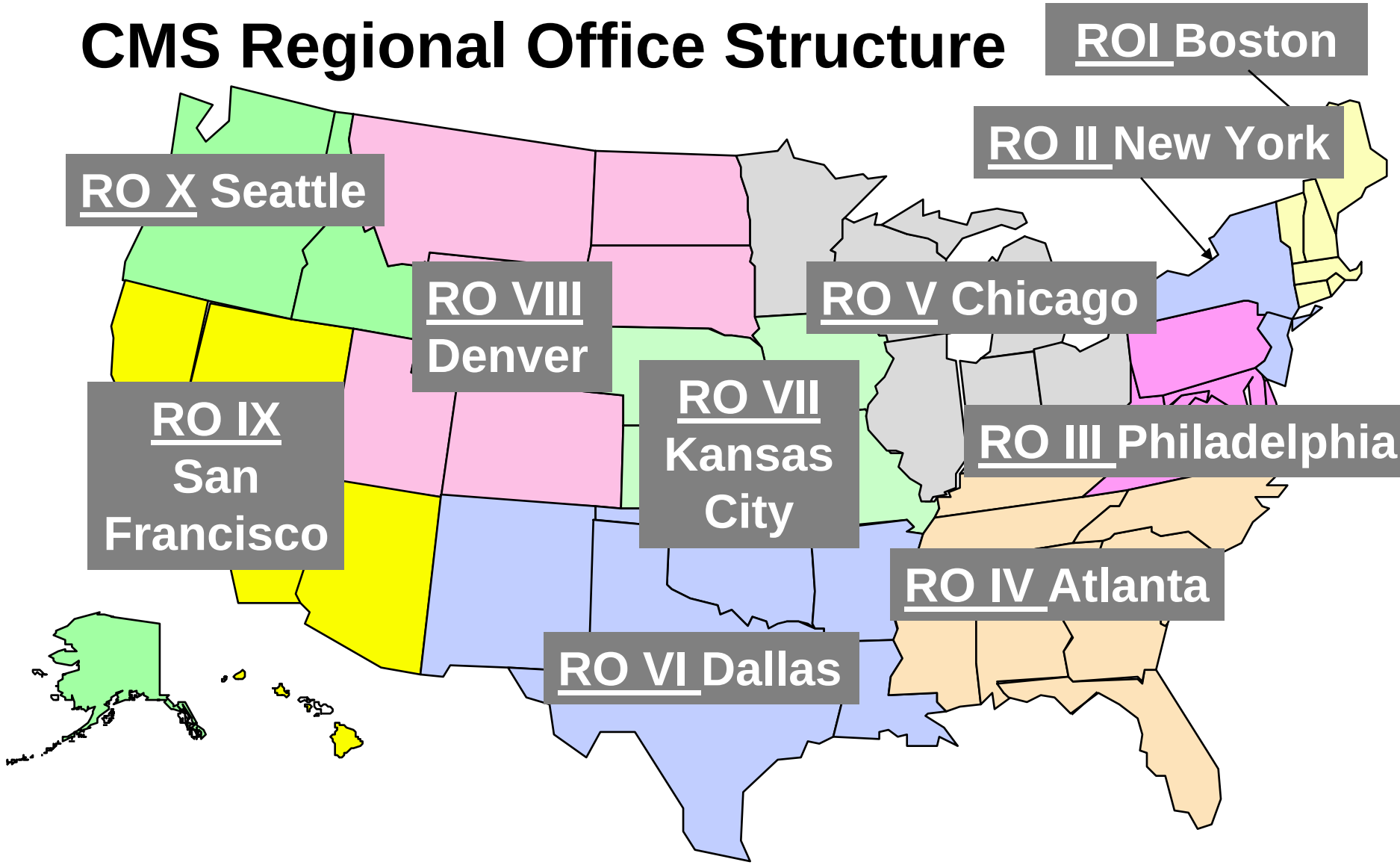
CMS

"CENTRAL OFFICE"

Provide public education

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

CMS Regional Office Structure



Regional Offices

THE REGIONAL OFFICES

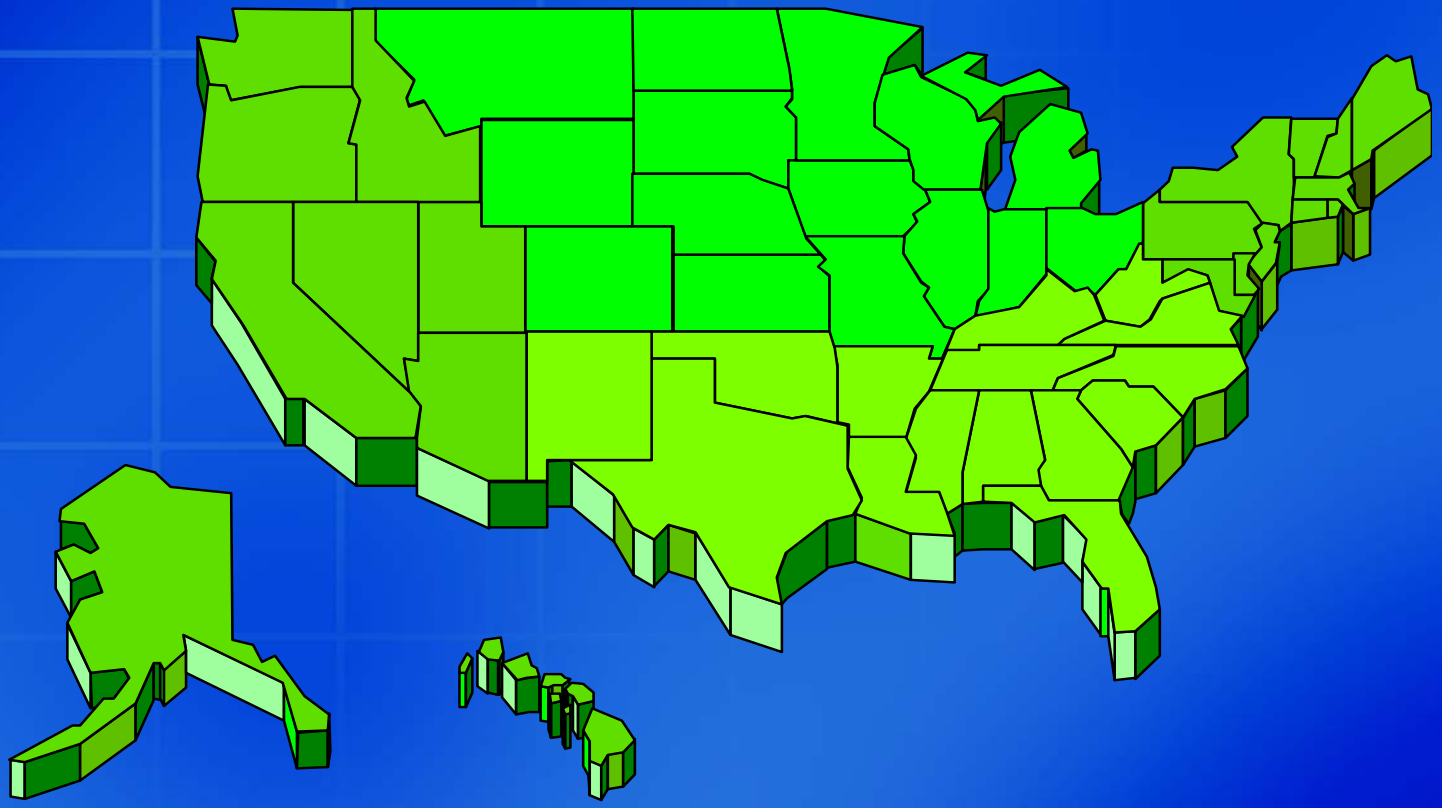
- Liaison to state agencies for policy dissemination and technical assistance
- Approve, deny, or terminate certification
- Interpret guidelines, policies, and procedures
- Levy enforcement actions which may have Medicare reimbursement impact
- Oversee SA CLIA activities and
- Conduct surveyor orientation

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

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…"

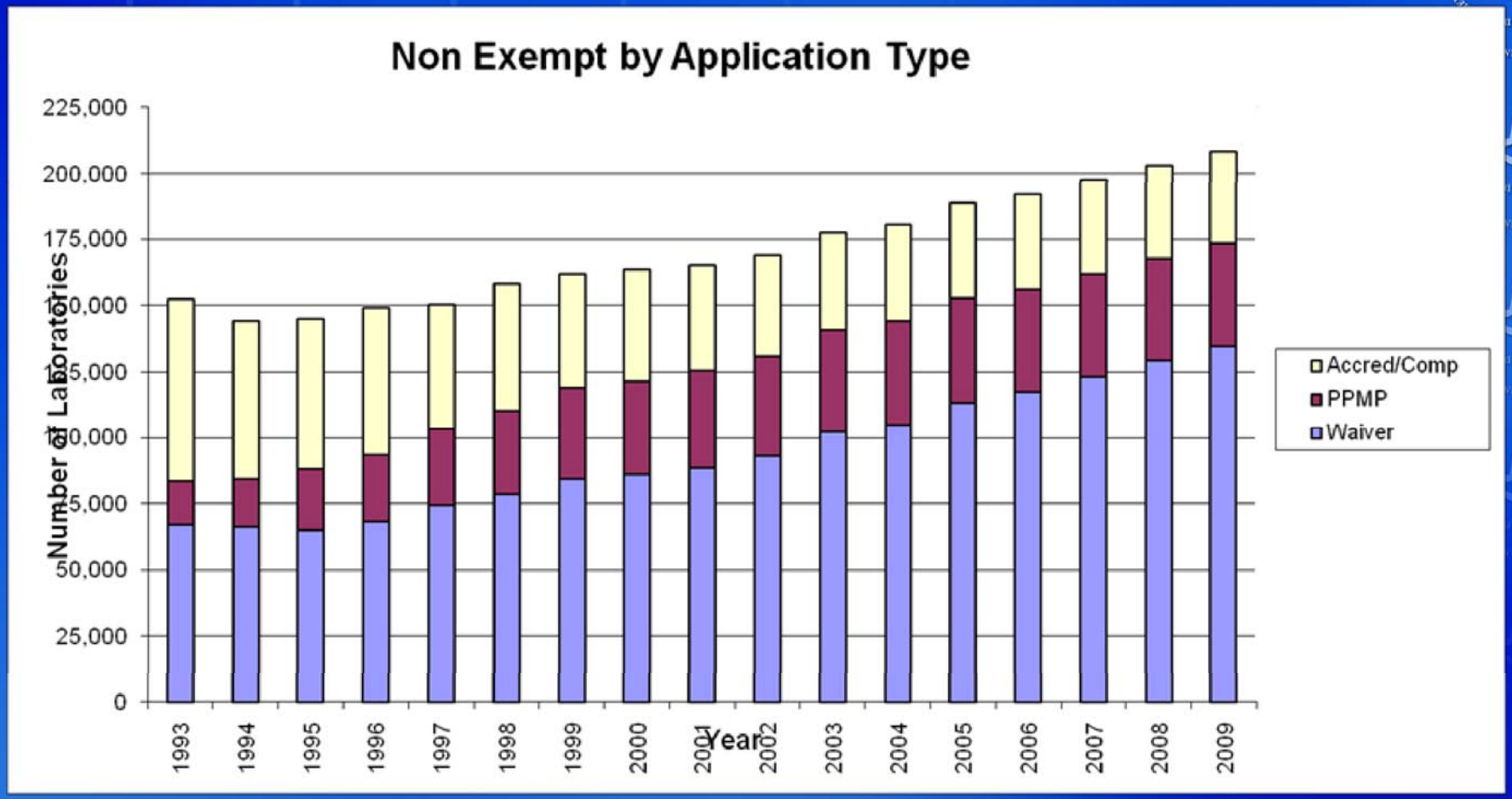
--Or risk of harm to the patient if performed incorrectly.

CLIA requirements for waived laboratories…..

The only standards for CW laboratories:

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

Number of Non-Exempt Labs by Certification Type

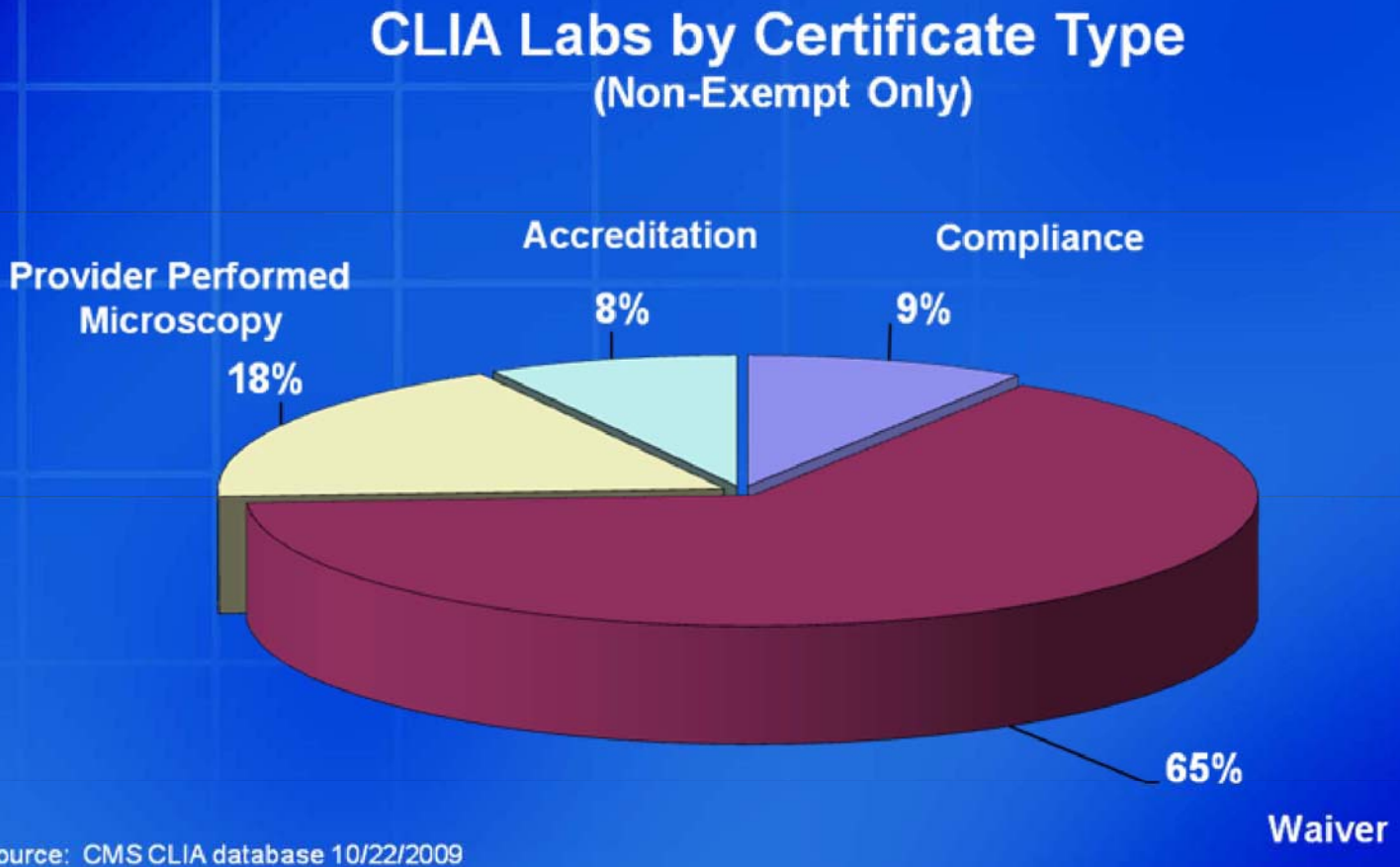


Current CLIA Statistics

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

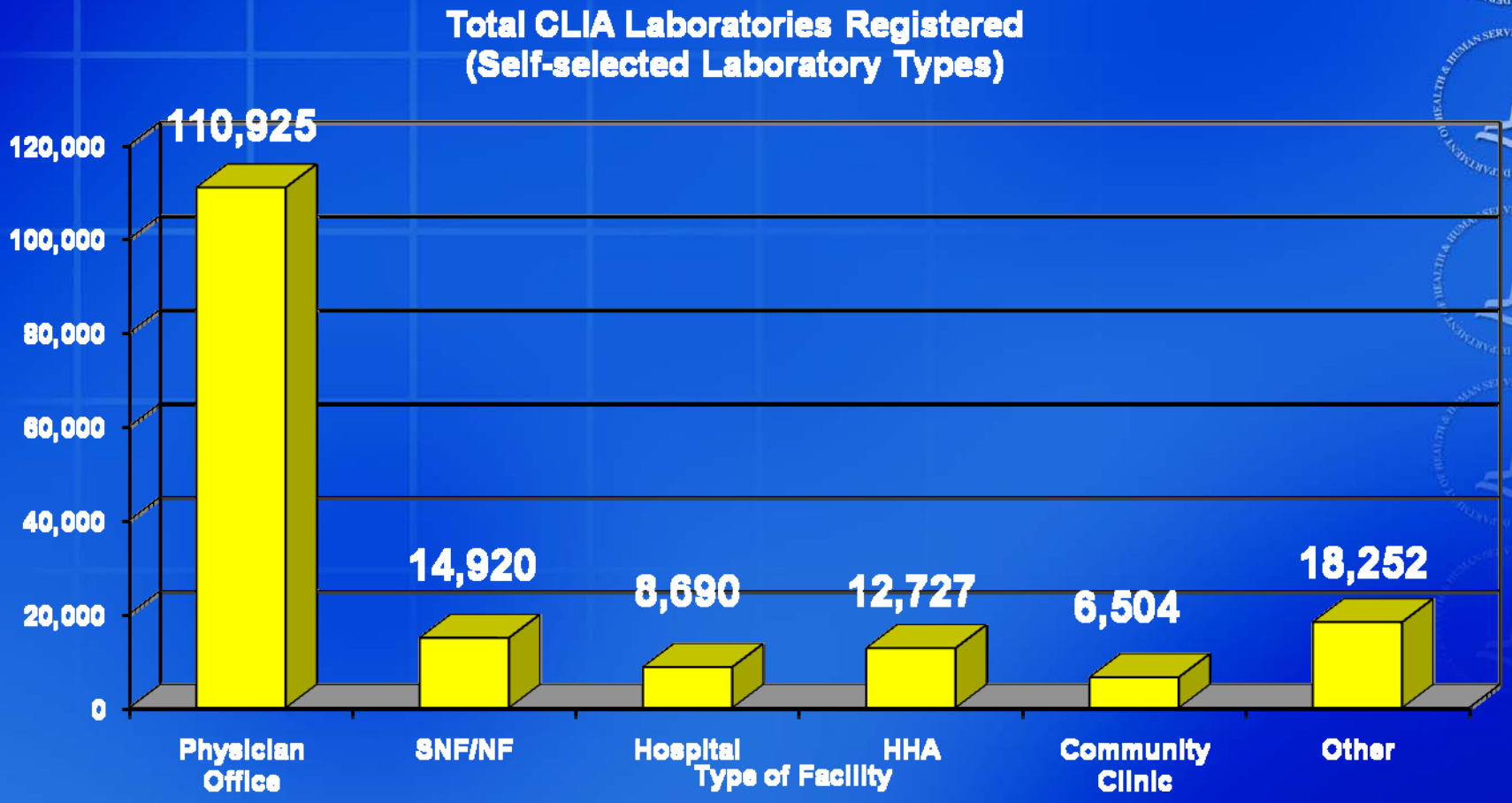
CMS data base 10/2009

Current CLIA Statistics



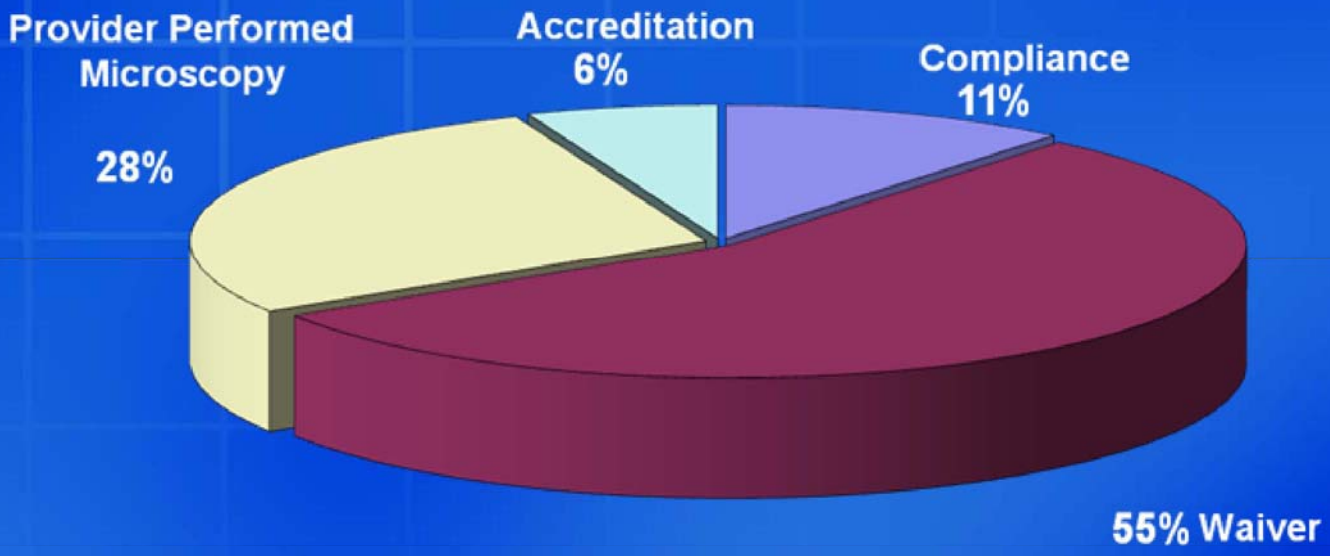
Source: CMS CLIA database 10/22/2009

Current CLIA Statistics



Current CLIA Statistics

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



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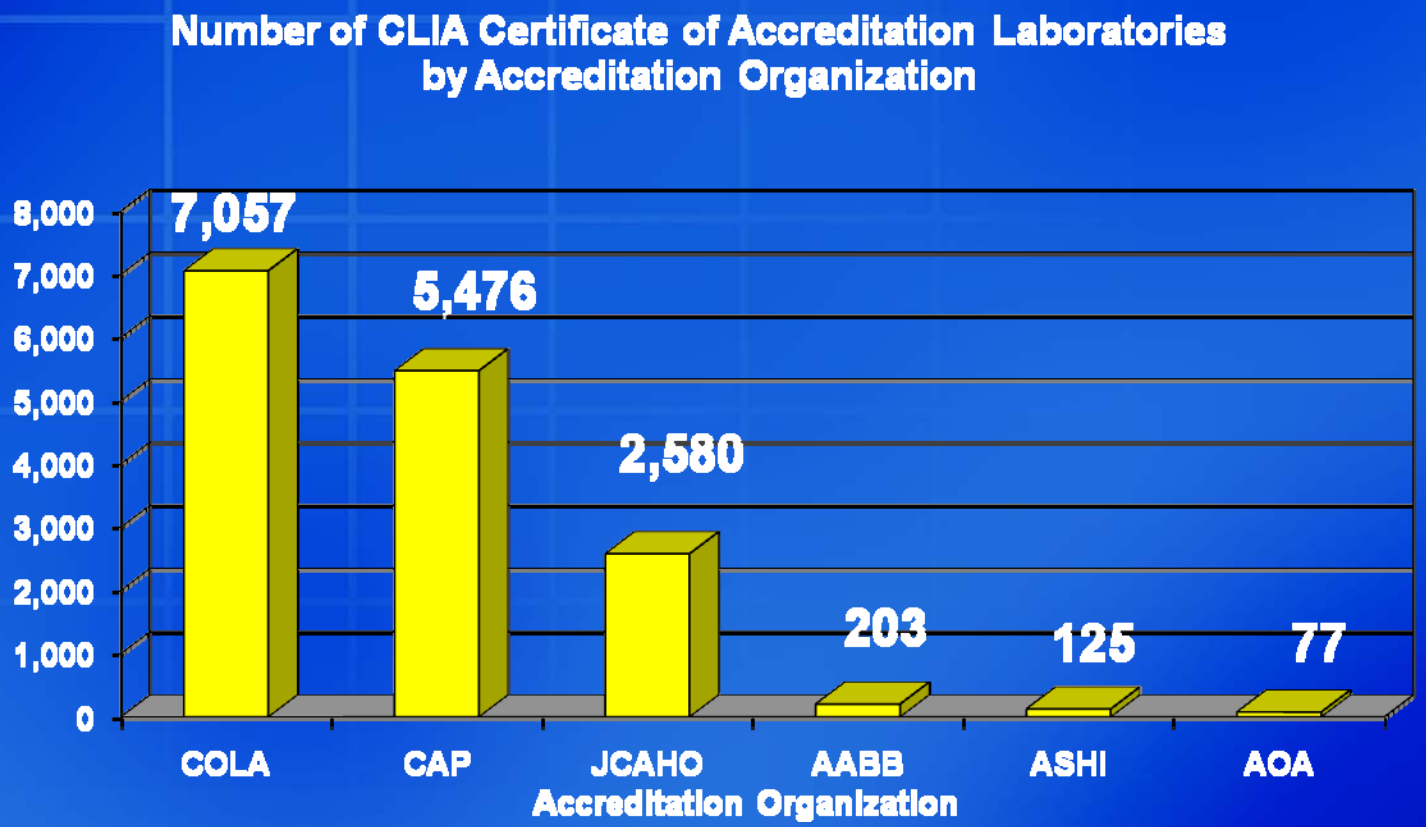
Current CLIA Statistics



October 2009

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CLIA

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

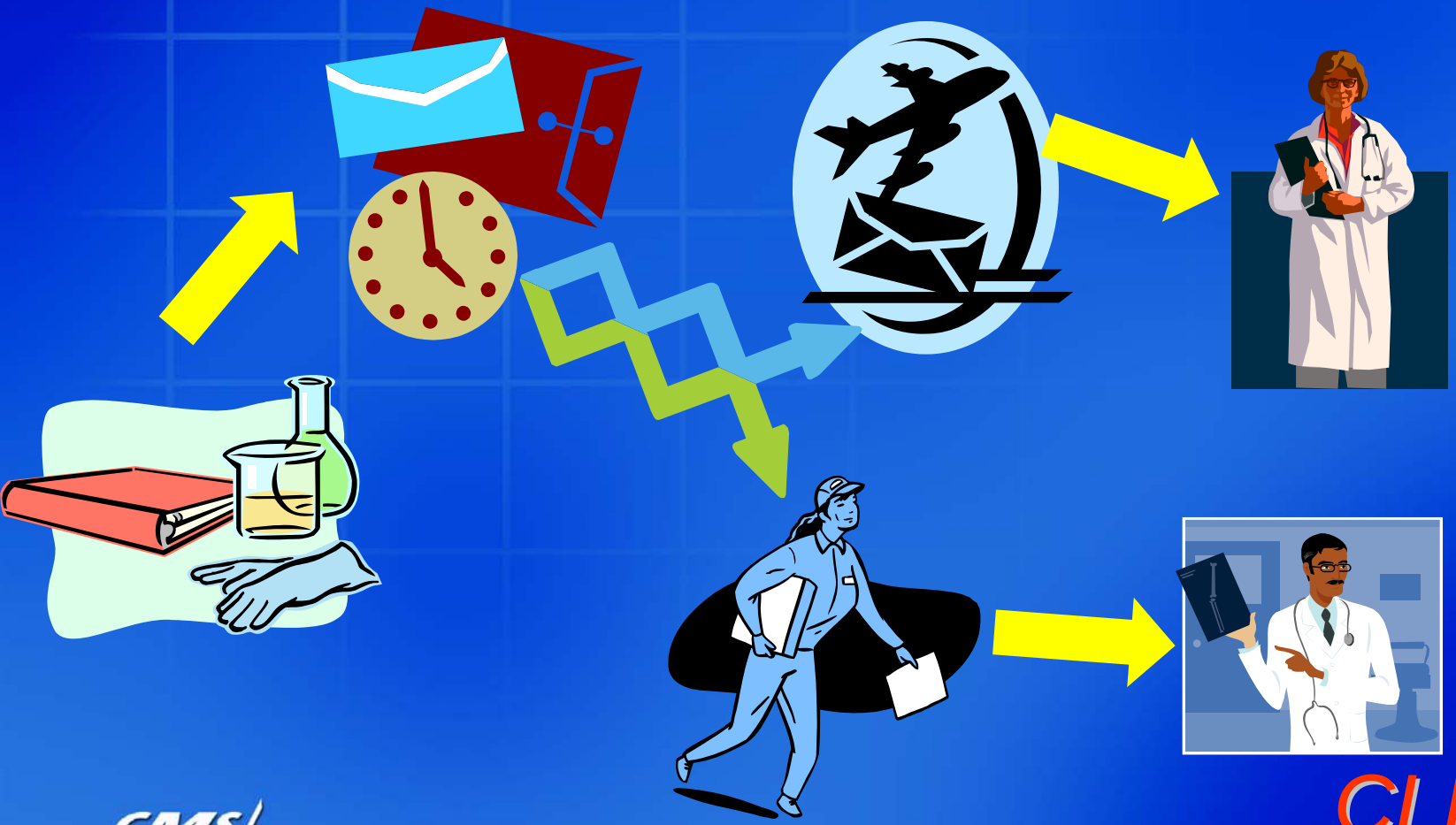
PT Referral WARNING!!

- 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

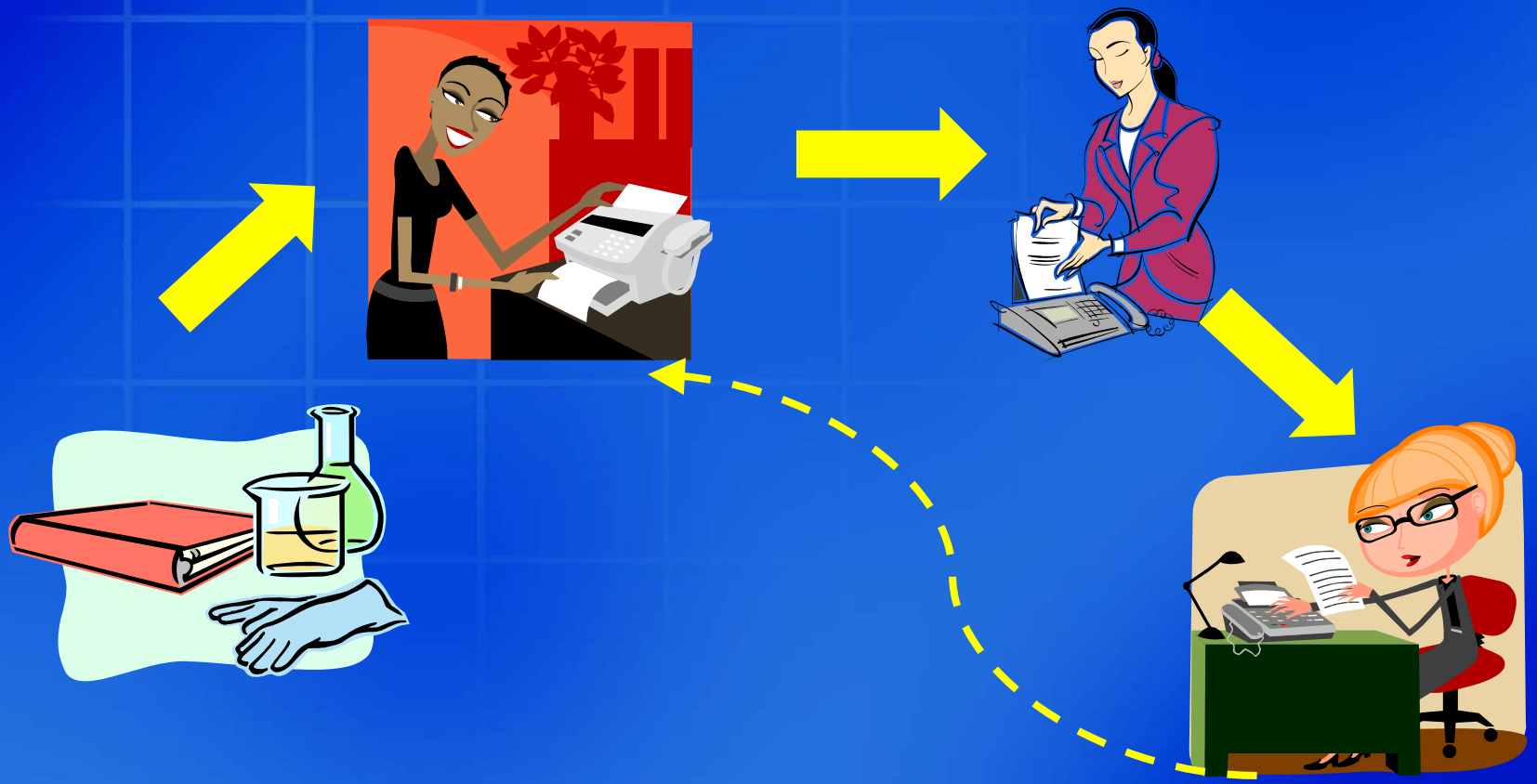
- 2008 CLIAC recommendation
- PT programs met November 2008
- CLIAC WG met March 2010
- Evaluating regulations
  - mechanisms for analyte /test selection
  - target values,
  - grading criteria
  - PT referral
  - alternative assessment
  - genetic tests
- Requires a proposed rule w/ comment & final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

Electronic Health Records

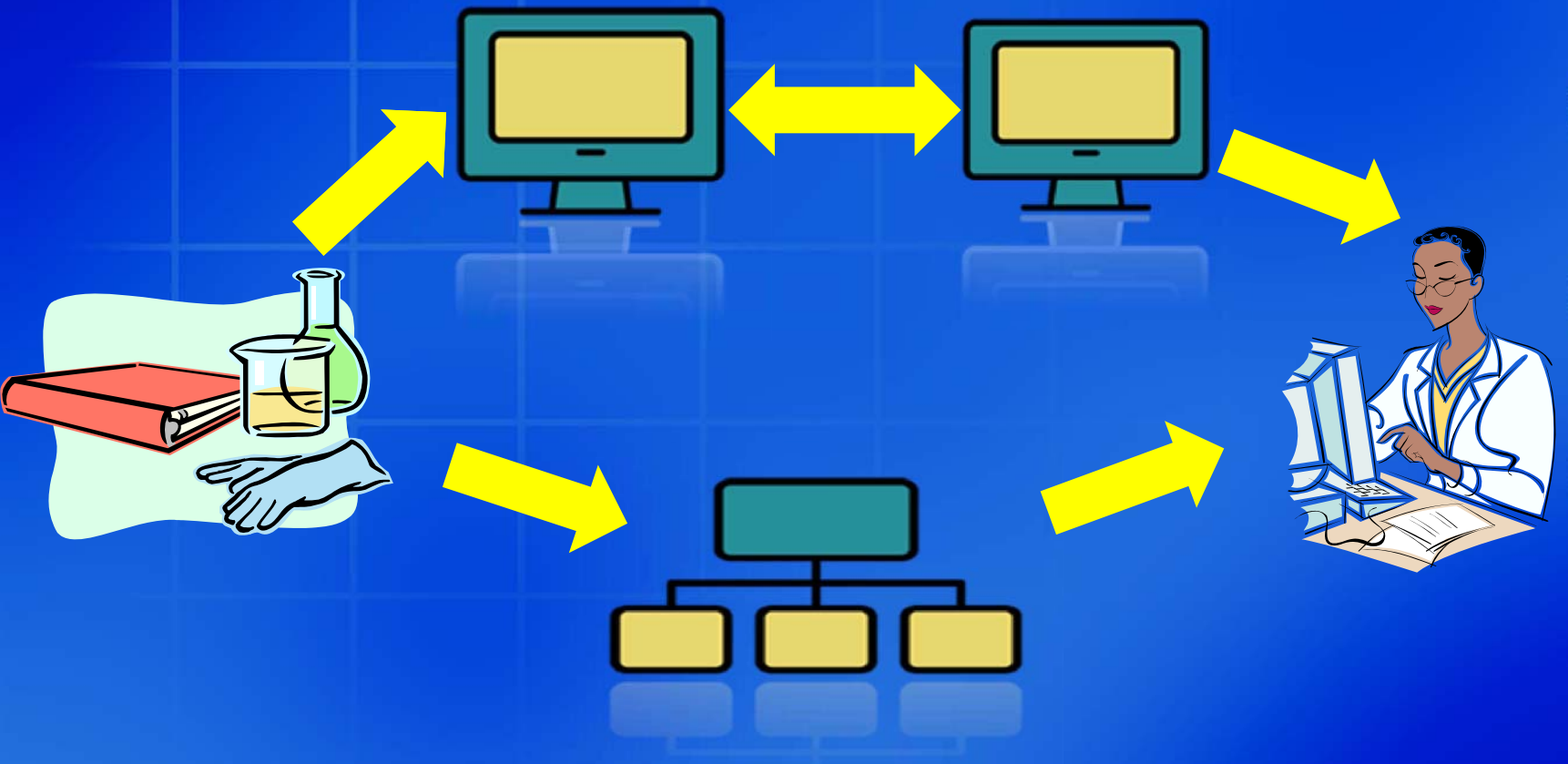


CLIA

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)

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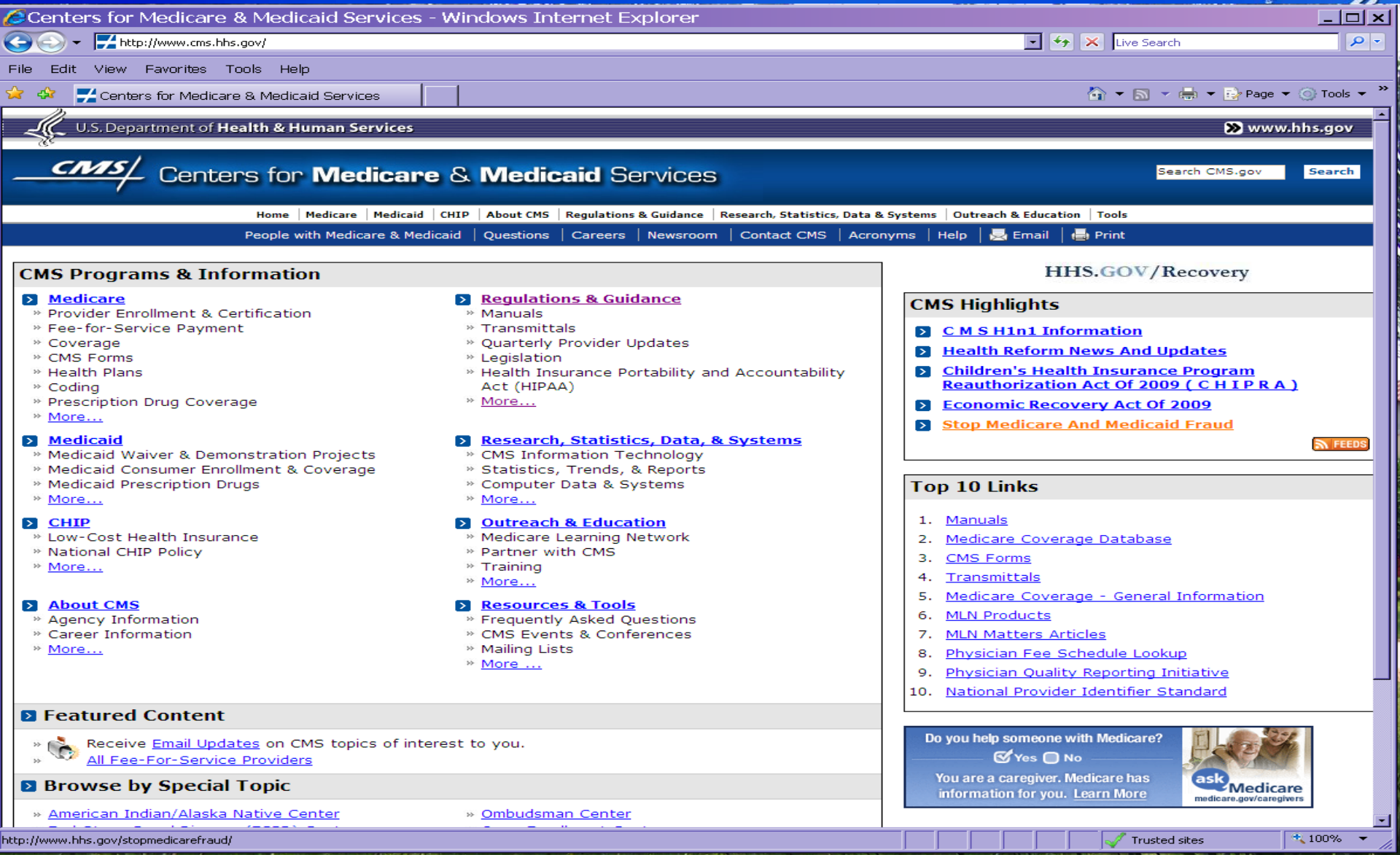
Online Resources - CMS Website



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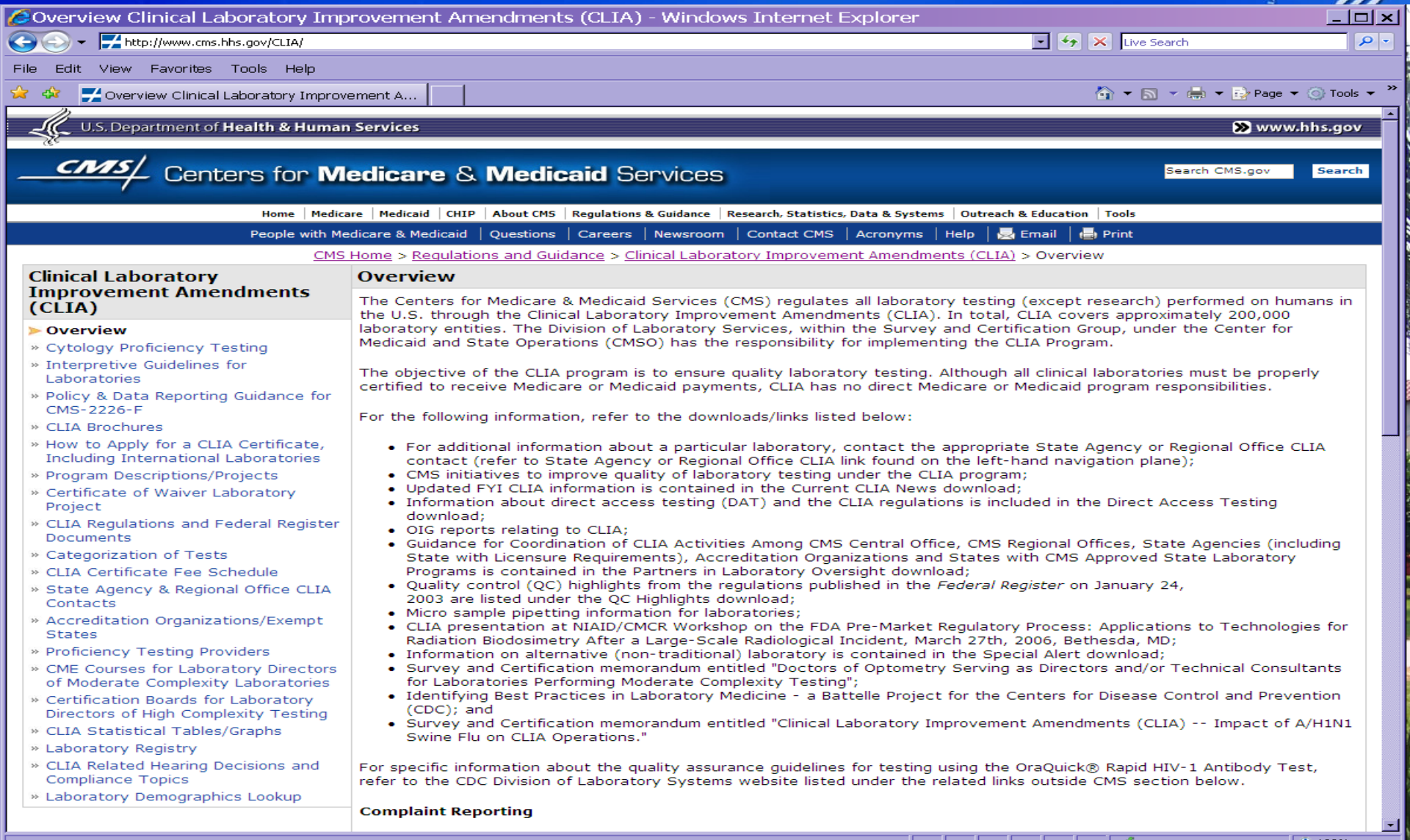
CLIA Website



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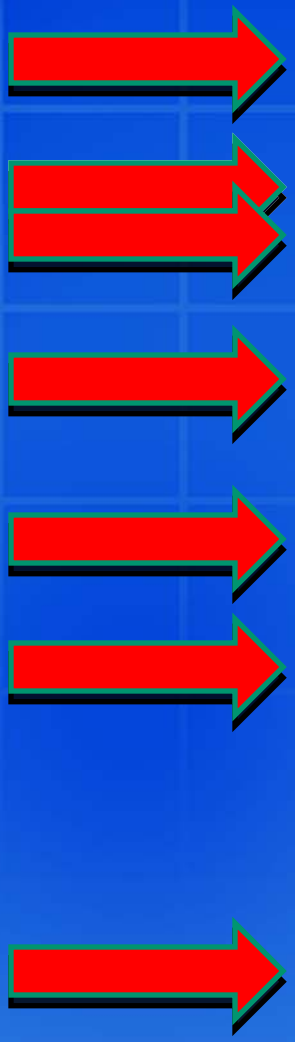

CMS Home > Regulations an

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 Medi
the U.S. through the
laboratory entities. T
Medicaid and State C

The objective of the
certified to receive M

For the following info

- For additional i
  contact (refer
- CMS initiatives
- Updated FYI CL
- Information abo
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- OIG reports rel
- Guidance for C
  State with Lice
  Programs is co
- Quality control
  2003 are listed
- Micro sample pi
- CLIA presentat
  Radiation Biodo
- Information on
- Survey and Cer
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- Identifying Bes
  (CDC); and
- Survey and Cer
  Swine Flu on CL

For specific informati
refer to the CDC Divis

Complaint Reportin

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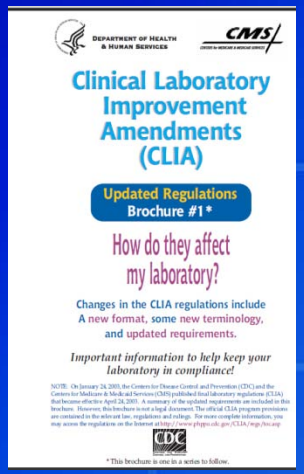
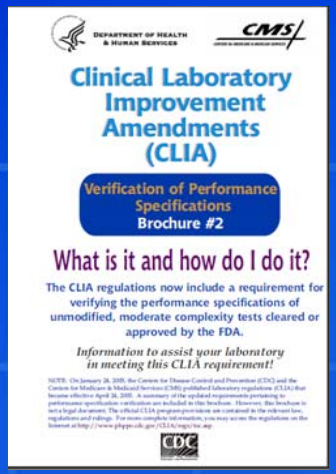
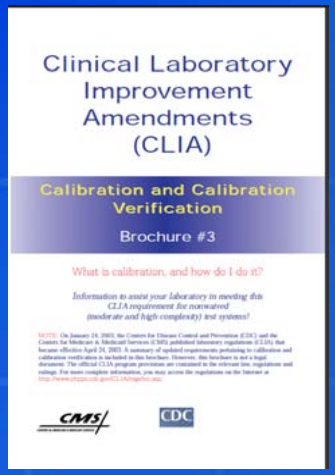
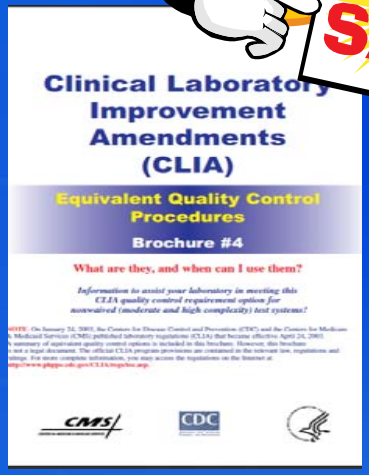
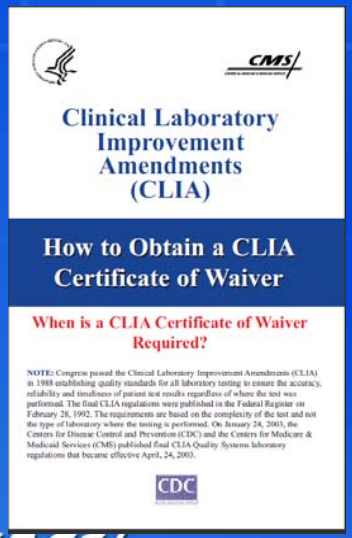
CLIA Brochures

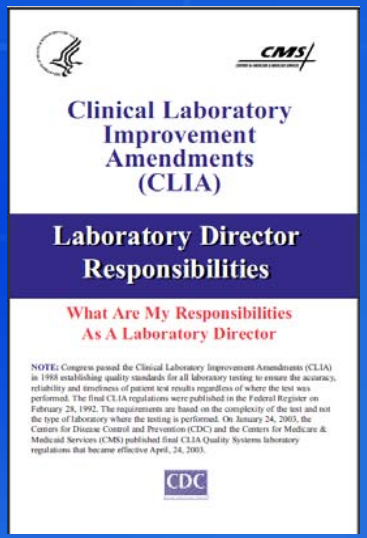


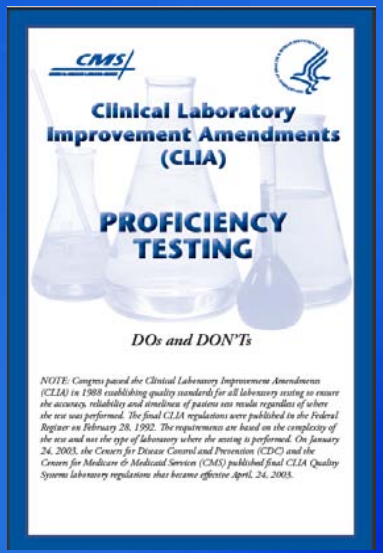


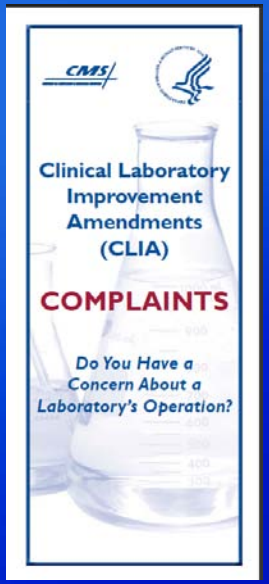












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CLIA

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Laboratory Demographics Lookup

Clinical Laboratory Improvement

- 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

Laboratory Demographics Lookup

website provides demographic information about laboratories, including CLIA number, facility nd address, where the laboratory testing is performed, the type of CLIA certificate, and the certificate expires. For additional information about a particular laboratory, contact the ate State Agency or Regional Office CLIA contact (refer to State Agency or Regional Office k 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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CDC

Department of Health and Human Services
Centers for Disease Control and Prevention

DLS Content

- DLS Home
- Best Practices
- CLIA
- Genetics
- Institutes
- International
- MASTER
- Monitoring
- MPEP
- NLTN
- Publications
- Quality Conferences
- Training
- Waiver

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

- 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
- DPDX
- Upcoming Events
- Guidelines

Contact Info
NCPDCID
1600 Clifton Road, MS-C82
Atlanta, GA 30333
USA

Centers & Offices
About the Center for Devices and Radiological Health
CDRH Offices
- Office of the Center Director
- 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:

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Questions??

THANK YOU!!