Ensuring Quality Patient Testing at the Point of Care

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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.
Here we are!
• 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

FDA

CDC

CLIA

Center for Medicare and Medicaid Services

CMS

Centers for Disease Control & Prevention
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
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
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

CLIAC
- 20 voting members
- 1 liaison member
- 3 ex officio members

Secretary
HHS

FDA

CMS

CDC

APPOINTS

ADVISES on CLIA

COMMITTEE SUPPORT

CLIA
WELCOME TO BALTIMORE.....HON!
CMS’ ROLE

CMS

MEDICARE  MEDICAID  SCHIP  CLIA

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
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
“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
“CENTRAL OFFICE”

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

“CENTRAL OFFICE”

Provide public education

- Presentations
- CLIA Brochures
- On-line resources
  - CLIA Website
CMS Regional Office Structure

- RO X Seattle
- RO IX San Francisco
- RO VIII Denver
- RO VII Kansas City
- RO VI Dallas
- RO V Chicago
- RO IV Atlanta
- ROI Boston
- RO II New York
- RO III Philadelphia
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

• 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

- 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

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
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

Non Exempt by Application Type

- Accredited/Competent
- PPMP
- Waiver

Year: 1993-2009
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

CLIA Labs by Certificate Type (Non-Exempt Only)

- Provider Performed Microscopy: 18%
- Accreditation: 8%
- Compliance: 9%
- Waiver: 65%

Source: CMS CLIA database 10/22/2009
Current CLIA Statistics

Total CLIA Laboratories Registered (Self-selected Laboratory Types)

- Physician Office: 110,925
- SNF/NF: 14,920
- Hospital Type of Facility: 8,690
- HHA: 12,727
- Community Clinic: 6,504
- Other: 18,252

October/2009
Current CLIA Statistics

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

- Provider Performed Microscopy: 28%
- Accreditation: 6%
- Compliance: 11%
- 55% Waiver

Source: CMS CLIA database 10/22/2009
Current CLIA Statistics

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

- COLA: 7,057
- CAP: 5,476
- JCAHO Accreditation: 2,580
- AABB Organization: 203
- ASHI: 125
- AOA: 77

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

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Fecal Occult Blood</td>
<td>27</td>
<td>58</td>
</tr>
<tr>
<td>Glucose Monitoring Devices</td>
<td>109</td>
<td>475</td>
</tr>
<tr>
<td>HcG-pregnancy testing (urine-visual color comparison)</td>
<td>219</td>
<td>279</td>
</tr>
<tr>
<td>Hemoglobin (single analyte instrument)</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Ovulation tests</td>
<td>29</td>
<td>34</td>
</tr>
</tbody>
</table>
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 with 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.

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.
  • [Website Link]

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)
Laboratory Demographics Lookup

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

Data source: OSCAR database, CLIA subsystem as of 10/02/2009
Lab Look-up data updated quarterly

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### 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:**
Division of Laboratory Systems

- Best Practices in Laboratory Medicine
- National Laboratory System
- International Laboratory

- MMWR - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions
- 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
- Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa (PDF)
- Public Health Teleconference Series on Infectious
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

FDA/OIVD
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115904.htm

Contact me at:
ann.snyder@cms.hhs.gov
Questions??

THANK YOU!!