Topics for Discussion

• CLIA Statistics/CMS Survey Deficiency Data
  – Compliance Tips
• Personnel & Competency Assessment Guidance
• PT Regulation Changes & Referral Update
• CW Project Update
  – Ready, Set, Test Project
• Patient Access Rule Update
• Physician Signature Issue
• IQCP--New CLIA QC Policy Coming!

Where to Find Info/Questions?
## Current Statistics-Enrollment

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Number of Laboratories</strong></td>
<td>229,815</td>
</tr>
<tr>
<td><strong>Total Non-Exempt</strong></td>
<td>222,899</td>
</tr>
<tr>
<td>- <strong>Compliance</strong></td>
<td>19,387</td>
</tr>
<tr>
<td>- <strong>Accredited</strong></td>
<td>15,697</td>
</tr>
<tr>
<td>- <strong>Waived</strong></td>
<td>150,256</td>
</tr>
<tr>
<td>- <strong>Provider Performed Microscopy</strong></td>
<td>37,559</td>
</tr>
<tr>
<td>- <strong>Exempt</strong></td>
<td>6,802</td>
</tr>
<tr>
<td>• <strong>NY</strong></td>
<td>3,469</td>
</tr>
<tr>
<td>• <strong>WA</strong></td>
<td>3,447</td>
</tr>
</tbody>
</table>

CMS data base 1/2012
Current Statistics

CLIA Labs by Certificate Type
(Non-Exempt Only)

Source: CMS CLIA database 01/2012
Current Statistics

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

- Provider Performed Microscopy: 27%
- Accreditation: 5%
- Compliance: 11%
- Waiver: 57%

Source: CMS CLIA database 01/2012
CLIA Update - General

Decade Trend

- Total Labs
- Compliance Labs
- Accreditation Labs
Current Statistics

CLIA Laboratory Registration
Self-Selected Laboratory Types

Number of Laboratories

- Physician Office: 115,745
- Skilled Nursing Facility/Nursing Facility: 14,896
- Hospital: 8,777
- Home Health Agency: 14,060
- Community Clinic: 6,390
- Other: 19,882

Source: CMS CLIA database 01/2012
Current Statistics

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

<table>
<thead>
<tr>
<th>Accreditation Organization</th>
<th>Number of Laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>COLA</td>
<td>6,566</td>
</tr>
<tr>
<td>CAP</td>
<td>5,670</td>
</tr>
<tr>
<td>TJC</td>
<td>2,409</td>
</tr>
<tr>
<td>AABB</td>
<td>215</td>
</tr>
<tr>
<td>ASHI</td>
<td>122</td>
</tr>
<tr>
<td>AOA</td>
<td>118</td>
</tr>
</tbody>
</table>

Source: CMS CLIA database 01/2012
Future of CLIA & EHR’s Proposed Patient Access Rule

- Standards, practices & technology for electronic exchange of lab information are still evolving.
- CMS will revisit CLIA Interpretive Guidelines, to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.
- Proposed rule for patient access to laboratory results was published 9/12/11 by CMS, CDC & OCR. Comments analyzed & responses drafted for final.
Helpful EHR Links

• **Health Information Technology**
  – http://healthit.gov/portal/server.pt

• **CLIA EHR S&C package**

• **OCR Posting of Security Breaches**

• **FDA Safety Portal**
  – https://www.safetyreporting.hhs.gov
Topics for Discussion
- CLIA Personnel Policies
- Rationale for Policies
- Outcomes
- Goal of Discussion
- Competency Assessment
CLIA Personnel Policies

- Qualification evaluations are done at the highest level of academic achievement for the position.
- All required positions & a sample of TP are reviewed once.
  - Review additional TP on subsequent surveys along with any changes or new personnel.
  - If a LD changes, qualifications are reviewed by the appropriate AO/SA upon notification prior to approval.
  - LD responsibilities correspond to all quality standards.
CLIA Personnel Policies

- Phlebotomists, micro plating personnel, clerks, reagent & specimen prep, etc. who do not test are NOT reviewed.
- Documentation must be available w/in 1 wk. of the survey.
- MT(ASCP) & nursing licenses alone aren’t acceptable.
- Even if certification is required by CLIA; e.g., CT, degrees & transcripts, etc. are still required.
- If a State license is required by CLIA, it alone is acceptable. Most States do an extensive review.
- Surveyor may still request documentation.
CLIA Personnel Policies

- Consider test complexity when evaluating creds.
- Agency evaluations aren’t acceptable, except for foreign credentialing equivalency purposes.
- Foreign educated individuals must be evaluated by a nationally recognized agency for equivalency.
- If an individual doesn’t meet edu., training or experience requirements, position not filled or responsibilities not met, a condition level deficiency is cited.
- Competency is assessed per the regulations for TC/TS. Solo practitioners are not assessed.
CLIA Personnel Policies

Rationale:

- Individuals downloaded quals. from the Web, used them fraudulently to obtain CLIA certificates & billed Medicare for mllions of $$.  
- Number of false apps recorded thus far: >100!!  
- Many shell labs caught by pre-approval review of application credentials.  
- ASCP discovered individuals who submitted false creds. for their certification. Has changed its credentialing process.
CLIA Personnel Policies

Rationale:

- There is great risk to CLIA & patients if an individual in a regulated position is ID as unqualified & quality issues are also found.
- Lab w/ multiple, consecutive PT failures had TP w/ falsified HEW card. All lab results had to be reviewed.
- VA discovered falsified degrees.
CLIA Personnel Policies

Rationale:

- Offshore operation upgrades degrees for a fee; diploma mills; quickie degrees.
- TP not following mfgr’s. instructions for intended use (endocervical) testing males for GC/Chlamydia only has 10th grade edu.
- Lab w/ all personnel unqualified for high complexity micro testing it performed.
CLIA Personnel Policies

Rationale:

• **IJ** in lab where GS had no foreign equivalency done.

• TP w/ no HS degree or GED – test results impacted.

• POL w/ repeated deficiencies w/ MDs son who has no HS degree performing testing.

• Etc., etc., etc.
GOALS:

1. All oversight agencies have & enforce consistent personnel policies.
2. Patients are protected by qualified personnel at all levels.
CLIA Competency Assessment

- Competency is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout the regulations.
- Competency is NOT the same as a performance evaluation/training.
- Quality management includes personnel, processes, & procedures, as does competency.
CLIA Competency Assessment

- Studies indicate that more education & training produce higher quality results.
- The means to confirm training effectiveness is competency evaluation.
- In CLIA, laboratory director’s qualifications are stringent due to overall quality responsibility.
- But qualifications for testing personnel are minimal, based on test complexity.
CLIA Competency Assessment

• CLIA survey experience indicates many problems caused by personnel errors; may have a patient impact.

• Routine competency evaluations help prevent errors; highlight importance of competency, regardless of education.
CLIA Competency Assessment - Key Requirement

493.1413(b)(8)(9) & 1451(b)(8)(9)—

• Technical Consultant/Supervisor Responsibilities—
  • Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.
CLIA Competency Assessment

Competency for all tests performed must include:

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.
CLIA Competency Assessment

- Competency for all tests performed must include:
- 2. Monitoring the recording & reporting of test results
CLIA Competency Assessment

- Competency for all tests performed must include:
  - 3. **Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records**
CLIA Competency Assessment

- Competency for all tests performed must include:
- 4. Direct observation of performance of instrument maintenance & function checks
CLIA Competency Assessment

- Competency for all tests performed must include:

- 5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and*
CLIA Competency Assessment

• Competency for all tests performed must include:
  
• 6. *Assessment of problem solving skills*
CLIA Competency Assessment Tips

• Operator training prior to testing is critical & required
• Competency assessments must be documented
• Individual conducting competency assessments must be qualified (TS/GS or TC)
• Competency is not PT! PT can be used to meet some elements of competency, but not all!
• Pathologists should be evaluated by the laboratory director as technical supervisors.
• If a service contract present, review of records is ok.
CLIA Competency Assessment Tips

• Competency records should match the laboratory’s actual procedures performed by its personnel.
• When observing test performance, use the procedure manual (PM) /package insert (PI) to ensure PM is current.
• Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.
• Laboratory director not subject to competency requirements, but is accountable. Responsibilities checked on surveys.
• Do not have to do all at one time; can combine elements.
• Can often combine analytes on multichannel analyzers.
CLIA Competency Assessment Tips

- Can use competency assessment for QA when confirming tests ordered match reported/charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.
- Personnel performing pre & post analytic activities & not in regulatory positions not subject to competency, but it’s good QA.
## CMS’ Top 10 Condition Level Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mod. complexity LD qualif./respons.</td>
<td>3.8%</td>
</tr>
<tr>
<td>Successful PT participation</td>
<td>3.0%</td>
</tr>
<tr>
<td>PT enrollment</td>
<td>1.7%</td>
</tr>
<tr>
<td>Analytic Systems (QC)</td>
<td>1.4%</td>
</tr>
<tr>
<td>High complexity director qualif./respons.</td>
<td>1.4%</td>
</tr>
</tbody>
</table>
### CMS’ Top 10 Condition Level Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mod. complexity TP</td>
<td>1.2%</td>
</tr>
<tr>
<td>- Technical consultant qualif./respons.</td>
<td>0.8%</td>
</tr>
<tr>
<td>- Hematology</td>
<td>0.6%</td>
</tr>
<tr>
<td>- High complexity TP</td>
<td>0.3%</td>
</tr>
<tr>
<td>- Gen. Lab Systems preanalytic</td>
<td>0.3%</td>
</tr>
</tbody>
</table>
CMS’ Top 10 Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Policy for proper reagent storage</td>
<td>5.3%</td>
</tr>
<tr>
<td>• Analytic Systems’ QA</td>
<td>5.1%</td>
</tr>
<tr>
<td>• Verify accuracy non-PT’d tests</td>
<td>5.0%</td>
</tr>
<tr>
<td>• Follow mfr’s. instructions</td>
<td>4.4%</td>
</tr>
<tr>
<td>• Procedure manual</td>
<td>4.4%</td>
</tr>
</tbody>
</table>

Source CMS CLIA database 2/2012
## CMS’ Top 10 Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration verif.</td>
<td>4.2%</td>
</tr>
<tr>
<td>LD responsibility-QA plan</td>
<td>3.9%</td>
</tr>
<tr>
<td>Mod. complexity LD qualif./respons.</td>
<td>3.8%</td>
</tr>
<tr>
<td>Gen lab systems QA</td>
<td>3.7%</td>
</tr>
<tr>
<td>Use of expired reagents</td>
<td>3.7%</td>
</tr>
</tbody>
</table>
Partners’ Deficiencies 2007-9

Quality System Essentials

CLIA

PT Regulation Update-1

• Plan w/ milestones & timeline developed
  – Includes: test selection, target values, grading criteria, PT programs, labs, PT referral
  – Requires a proposed rule w/ comment & final
  – No firm ETA

• CLIAC recommended to proceed
  – 1st PT providers’ meeting held; 2nd Mar. 2012
  – CLIAC WG w/ SMEs from affected parties
PT Regulation Update-2

• Ongoing work w/ CDC & CMS
• Medicare & lab data reviewed for test frequency
• Evaluated clinical uses & mechanisms to select analytes
• CLIAC WG meeting convened
• WG reported to full CLIAC; Some recommendations rec’d.
• Additional data necessary for determination of grading criteria & target values
PT Referral Update

DO NOT SEND PT SAMPLES TO ANOTHER LABORATORY!!

• CMS Central Office continues to review all cases
• Reflex, confirmation, distributed, referral testing seem to be major causes
• Common personnel across several laboratories/health systems contribute
• Guidance--
  • For Now: Read & Follow CMS PT Brochure
  • For Future: Expect regulatory changes
CMS QC for the Future
IQCP—The ‘Right” QC!

- 2003 regulations allow use of alternative QC policy in Interpretive Guidelines (IG)
  - With equivalent quality testing
- 2004 EQC introduced; rec’d. criticism
- CMS partnered w/ CLSI to develop new guidance
- Project chaired by James Nichols. PhD.
  - CLSI convened expert team
CMS QC for the Future
IQCP—The ‘Right” QC!

- CMS will include key concepts of EP-23 in new QC policy in IG
- Permits individualized QC plans (IQCP) for each laboratory/test
- IQCP is based on patient population, environment, clinical use, test system, etc.
- Uses much of lab’s existing quality practices/data
- Includes current & new tests; exc. pathology
- May not decrease QC, but is the “right “ QC
CMS QC for the Future
IQCP—The “Right” QC!

• New QC is voluntary & applicable to CMS certified non-waived abs; new & existing tests
• Default is 2 levels of external QC/day
• Education/transition period-no citations; begin planning!
• Training & guidance will be available for surveyors & labs
• Once effective, deficiencies cited; EQC sunsets
• No regulation or survey process changes
• Accredited labs meet AO standards, until otherwise notified
Waived Testing Project

- Waived tests offer timely, efficient, convenient patient care
- Continue to increase (ex. 300 pharmacies in 1995 to 6,000 now!)
- Increased testing comes w/ issues:
  - Testing personnel less-trained; may not ID problems
  - No routine oversight w/ no funding/resources
  - Minimal mfr. required QC=quality issues
  - Pre & post analytical issues
Since 1992......

- CLIA-waived tests increased from 8 to ~100 tests.
  - This represents 1000's of test systems!
- The number of laboratories issued a CW has grown exponentially from 20% to 67% of >230,000 laboratories enrolled.
- The only standard for CW laboratories is to *follow manufacturer’s instructions* & register w/ CMS.
CMS Waived Project -- Waived Laboratory Growth
CMS Waived Project

Beginnings

• In 1999 CO & OH visited 100 CW & laboratories; 50% had quality problems!

• As a result, CMS expanded the pilot to the 8 other States.

• That data demonstrated the need for a national & ongoing project.

A 2% sample of CW labs is visited annually by CMS; each CW lab responds to standard questions about its waived testing practices.
CMS Waived Project Findings

CDC & CMS Found Then & Now:

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions (≈55-60%)
- NY studies correspond to CMS’
CMS Waived Project- 2006 & Ongoing

**2006 Initial visits**

Of 1947 labs visited, 69% were following the manufacturer’s instructions.

**2006 Follow-up visits**

Of 414 labs revisited for not following manufacturer’s instructions, 353 or 85% improved upon revisit.
CMS Waived Project - % Performing Non-Waived Tests

- No State Licensure
- State licensure

- 2005: 7.00%
- 2006: 4.00%
- 2007: 7.00%
CMS Waived Project—Immediate Jeopardy Cases!!

- FY 2005: 6 out of 1678 surveys or <1%
- FY 2006: 6 out of 1938 surveys or <0.5%
- FY 2007: 2 out of 1737 surveys or <0.20%
- FY 2008: 3 out of 1902 surveys or <0.16%

Consider if you extrapolate these data to the total CW lab population!
CMS Waived Project - Not Doing Required QC 1st & 2nd Visits Compared

- No State Licensure
- State Licensure
CMS Waived Project-\% w/ Voluntary Proficiency Testing

![Bar chart showing percentage of no state licensure and state licensure over the years 2005, 2006, and 2007.](chart.png)
# CMS Waived Project-Performance w/ Voluntary PT

## CW Survey Response

<table>
<thead>
<tr>
<th></th>
<th>PT</th>
<th>No PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab has current mfgr’s. instructions</td>
<td>98%</td>
<td>88%</td>
</tr>
<tr>
<td>Performs required QC</td>
<td>95%</td>
<td>75%</td>
</tr>
<tr>
<td>Performs req’d function chks/calibrat</td>
<td>75%</td>
<td>62%</td>
</tr>
<tr>
<td>Performs confirmatory testing</td>
<td>25%</td>
<td>15%</td>
</tr>
</tbody>
</table>
CMS’ Plans for Waived Project

**Short term**
- Continue CW project indefinitely
- Provide edu. materials w/ ea. new app, on web site, w/ on-site visits; update CE clearinghouse
- Initiate test menu collection w/ apps
- Collaborate w/ stakeholders, CDC to ID add’l. efforts
- Evaluate data from AO/ES w/ CW standards
- Coordinate w/ FDA on overlapping issues
- Publish comprehensive report
- Ask me about new pilot project: Ready, Set, Test!

**Long term**- Change the CLIA law to enhance oversight
CMS & CDC’s ‘Ready, Set, Test!’ Waived Lab Project

• CDC, w/ CMS input, designed an educational booklet entitled ‘Ready, Set, Test!’ for CW labs
• CMS will send booklet to a small sample of waived labs prior to visit
• CMS will evaluate labs’ performance vs those which received no booklets
• Data will be a CLIA performance measure
• If successful, will share w/ all waived labs
Physician Signature on Test Requisition

- Physician signature required on paper laboratory test requisitions under the CY2011 Physician Fee Schedule proposed rule
- CMS issued memorandum March 31, 2011 notifying Medicare contractors not to enforce the requirement for physician signature
- For remainder of 2011, CMS changed the regulation requiring physician signature
CLIA 20 Year Anniversary!!
1992-2012
For More Information

CMS CLIA Web Site:
www.cms.hhs.gov/clia/
brochures, guidance, lab demographics, app, contacts

CMS CLIA Program
410-786-3531

Judy Yost’s Email:
Judith.yost@cms.hhs.gov

IQCP Link
IQCP@cms.hhs.gov

My gratitude to Karen Dyer, Daralyn Hassan & Cindy Flacks for their contributions.
THE END!!

Thank you!

Questions??