CLIA Update
CLIAC March 2011

Harriet Walsh
Deputy Director
Division of Laboratory Services
Topic Areas

- CLIA Statistics
- CMS Survey Deficiency Data
- Partners in Laboratory Oversight
- CLIA & EHRs
- Physician Signature on Lab Requisitions
- Cytology PT NPRM Update
- Waived Testing Update
- Where to Find Information
# 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>221,793</td>
</tr>
<tr>
<td>Non-Exempt</td>
<td>215,057</td>
</tr>
<tr>
<td>- Compliance</td>
<td>19,404</td>
</tr>
<tr>
<td>- Accredited</td>
<td>15,864</td>
</tr>
<tr>
<td>- Waived</td>
<td>141,994</td>
</tr>
<tr>
<td>- Provider Performed Microscopy</td>
<td>37,795</td>
</tr>
<tr>
<td>Exempt</td>
<td>6,736</td>
</tr>
<tr>
<td>- NY</td>
<td>3,264</td>
</tr>
<tr>
<td>- WA</td>
<td>3,472</td>
</tr>
</tbody>
</table>

CMS data base 12/2010
CLIA Update - General

Decade Trend

- Total Labs
- Compliance Labs
CLIA Update - General

Decade Trend

- Total Labs
- Compliance Labs
- Accreditation Labs

Yearly Trends from 2002 to 2011.
Current Statistics

CLIA Labs by Certificate Type
(Non-Exempt Only)

- Provider Performed: 18%
- Accreditation: 7%
- Compliance: 9%
- Waiver: 66%

Source: CMS CLIA database 12/14/2010
Current Statistics

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

Source: CMS CLIA database 12/14/2010
CLIA Update - General

Total CLIA Laboratories Registered (Self-selected Laboratory Types)

- Physician Office: 113,124
- SNF/NF: 14,831
- Hospital: 8,731
- HHA: 13,433
- Community Clinic: 6,376
- Other: 19,071

Type of Facility

December 2010
Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

- COLA: 6,796
- CAP: 5,580
- Joint Commission: 2,458
- AABB: 107
- ASHI: 215
- AOA: 130

December 2010
## CMS’ Top 10 Condition Level Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mod. complexity LD qual./resp.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Successful PT participation</td>
<td>3.2%</td>
</tr>
<tr>
<td>PT enrollment</td>
<td>1.8%</td>
</tr>
<tr>
<td>Analytic Systems (QC)</td>
<td>1.7%</td>
</tr>
<tr>
<td>Mod. complexity TP</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Source: CMS CLIA Database 12/10
### CMS’ Top 10 Condition Level Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>High complexity director qual./resp.</td>
<td>1.3%</td>
</tr>
<tr>
<td>Technical consultant qual./resp.</td>
<td>1.0%</td>
</tr>
<tr>
<td>Hematology</td>
<td>0.6%</td>
</tr>
<tr>
<td>Gen. Lab Systems QA</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>5.8%</td>
</tr>
<tr>
<td>Analytic Systems’ QA</td>
<td>5.5%</td>
</tr>
<tr>
<td>Verify accuracy non-PT’d tests</td>
<td>5.5%</td>
</tr>
<tr>
<td>Follow mfgr’s. instructions</td>
<td>4.9%</td>
</tr>
<tr>
<td>Procedure manual</td>
<td>4.6%</td>
</tr>
</tbody>
</table>

Source: CMS CLIA database 12/2010
# CMS’ Top 10 Deficiencies

<table>
<thead>
<tr>
<th>Citation</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD responsibility-QA plan</td>
<td>4.4%</td>
</tr>
<tr>
<td>Mod. complexity LD qual./resps.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Calibration verif.</td>
<td>4.2%</td>
</tr>
<tr>
<td>Use of expired reagents</td>
<td>4.1%</td>
</tr>
<tr>
<td>Gen lab systems QA</td>
<td>3.7%</td>
</tr>
</tbody>
</table>
Partners

• Meeting with Partners in Laboratory Oversight since 2004

• Membership:
  • CMS CO&RO
  • AOs, Exempt States, and SAs with Licensure
  • DoD
  • VA

Partners

• Common Goal:
  – Quality Laboratory Testing

• Mutual Commitments:
  – Improved communication mechanisms
  – Enhanced information-sharing opportunities
  – Greater understanding of each entity’s relevant activities and policies
  – Establishment of more effective oversight programs
Partners’ Deficiencies 2007-9

Number of Labs Cited

Quality System Essentials

- Docs/Recs 6.1
- Proc.Imp 6.10
- Cust.Serv 6.11
- Facil/Safe 6.12
- Organ. 6.2
- Person. 6.3
- Equip. 6.4
- Proc.Cont 6.6
- Info.Mgt 6.7
- Assess. 6.9

16
CMS Guidance for EHR’s & CLIA

• Clarified CMS CLIA Interpretive Guidance
  – Survey and Certification Letter introduced the revisions to Appendix C (S&C-10-12-CLIA)
  – List of Frequently Asked Questions (FAQ’s)
  – Expanded information, guidance & regulatory interpretations for test ordering, record retention & result reporting
  – Under the current regulations!
Future of CLIA & EHR’s

- Standards & practices for electronic exchange of laboratory information are still evolving.
- CMS will revisit CLIA Interpretive Guidelines as needed to ensure that laboratories & stakeholders have clear guidance on best practices & resources to implement EHR’s.
- The question of direct patient access arose.
- CMS is working on a regulatory solution.
Major Health Care Reform Goal

Active involvement of patients in their own health care decisions

- Patients in control of their personal health information via access to Electronic Health Records or use of a Personal Health Record
- Access to personal health information to also include access to completed laboratory test reports
- CLIA collaborating with OCR and CDC on the best way to address patient access to laboratory test reports
- Potential changes to CLIA Interpretive Guidelines, CLIA regulations
Helpful EHR Links

- **Health Information Technology**
  - [http://healthit.gov/portal/server.pt](http://healthit.gov/portal/server.pt)

- **CLIA EHR S&C package**

- **OCR Posting of Security Breaches**

- **FDA Safety Portal**
  - [https://www.safetyreporting.hhs.gov](https://www.safetyreporting.hhs.gov)
Physician Signature on Test Requisition

- Physician signature required on **paper** laboratory test requisitions under the CY2011 Physician Fee Schedule proposed rule
  - Reversal of previous Physician Fee Schedule policy
  - Does not concern electronic or telephonic requests
  - CLIA met with CMS staff on Feb.2, 2011 to discuss effects on proposal on laboratories

- **CMS now intends to withdraw the proposed rule before the April 1st effective date**
Cytology PT Update

Cytology PT Proposed Regulation:

- Pub. by CMS Jan. ‘09; comments ended Mar. ’09
- Considered 16 CLIAC recommendations
- 6000 comments rec’d. from 660 commenters
- 77% of comments did not agree w/ NPRM
- Many recommendations can be addressed w/ guidance or administratively
Participant Failure Rate Trends
Initial Test

Year

Percentage

CT    MD(-)CT    MD(+)CT

2005  7    33   10
2006  5    17   5
2007  3    11   3
2008  3    11   3
2009  3    12   3
2010  3    8    3

CLIA

CMS
Failure Rates for Initial Test by Participant Type

- **2005**
  - CT: 7
  - MD(-)CT: 33
  - MD(+)CT: 10

- **2006**
  - CT: 5
  - MD(-)CT: 17
  - MD(+)CT: 5

- **2007**
  - CT: 3
  - MD(-)CT: 11
  - MD(+)CT: 3

- **2008**
  - CT: 3
  - MD(-)CT: 11
  - MD(+)CT: 3

- **2009**
  - CT: 3
  - MD(-)CT: 12
  - MD(+)CT: 3

- **2010**
  - CT: 3
  - MD(-)CT: 8
  - MD(+)CT: 3
CMS Waived Project -- Waived Laboratory Growth

Non-exempt Laboratories by Application Type

Year

Accred/Comp
PPM
Waiver
CMS Waived Project-Complaint Scenario

• Complaint received & investigated by State & CMS regarding corporate labs w/ CW performing A1C waived testing outside its intended use at multiple locations
  -- as screening vs monitoring
• Corporate web site ads misleading
• Labs also doing non-waived procedure
  -- blood typing
CMS Waived Project-Complaint Scenario

• Complaint follow up is a superb example of effective coordination of CMS central (CO) & regional (RO) offices & 2 states (SA)
  • On site visit to lab; communication w/ corporate
  • Conference calls among CO, RO, SA
  • Company cooperating re compliance
  • Ongoing monitoring of test sites
  • FDA addressed intended use issue w/ manufacturer
Next Steps for Waived Testing.....

- Number of CW labs increasing exponentially
- Congress never anticipated this growth
- Education is effective, but resources are lacking
- A CMS “Issue” paper w/ multi-faceted recommendations for agency mgt. was approved
- CMS collaborating w/ stakeholders to complete long & short term plans
CMS’ Plan Waived Project

**Short term**
- Continue CW project indefinitely
- Educate with every opportunity
- Initiate test menu collection w/ apps
- Collaborate w/ Partners/CDC /FDA
- Enlist support of professional & patient advocacy orgs
- Evaluate data from AO/ES w/ CW standards
- Publish comprehensive report

**Long term**
- Change the CLIA law to improve oversight
For More Information

CMS CLIA Web Site:
www.cms.hhs.gov/clia/

CMS CLIA Program:
410-786-3531

Judy Yost or Harriet Walsh via email:
Judith.Yost@cms.hhs.gov
Harriet.Walsh@cms.hhs.gov
THE END

Thank you!