Topics For Discussion

- CMS/CLIA Laboratory Enrollment Data
- Top 10 CMS Survey Deficiencies
- CLIA Regulations Update
  - PT Revisions
  - Patient Access
  - Burden PT Referral
- Test Act Next Steps
- IQCP Implementation Plan & Status
- GPRA Goal—Waived Labs
- Resources
## Current Statistics--Enrollment

<table>
<thead>
<tr>
<th>Category</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Laboratories</td>
<td>244,564</td>
</tr>
<tr>
<td>Total Non-Exempt</td>
<td>236,882</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td>18,959</td>
</tr>
<tr>
<td><strong>Accredited</strong></td>
<td>16,081</td>
</tr>
<tr>
<td><strong>Waived</strong></td>
<td>165,058</td>
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<tr>
<td><strong>Provider Performed Microscopy</strong></td>
<td>36,784</td>
</tr>
<tr>
<td><strong>Exempt</strong></td>
<td>7,682</td>
</tr>
<tr>
<td>NY</td>
<td>3,810</td>
</tr>
<tr>
<td>WA</td>
<td>3,872</td>
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</tbody>
</table>

CMS data base 1/2014
Current Statistics

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

- Waiver: 59.3%
- Provider Performed Microscopy: 24.3%
- Compliance: 10.3%
- Accreditation: 4.9%
Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

<table>
<thead>
<tr>
<th>Accreditation Organization</th>
<th>Number of Laboratories</th>
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<tr>
<td>COLA</td>
<td>6612</td>
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<tr>
<td>CAP</td>
<td>5968</td>
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<tr>
<td>TJC</td>
<td>2347</td>
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<td>AABB</td>
<td>225</td>
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<tr>
<td>AOA</td>
<td>130</td>
</tr>
<tr>
<td>ASHI</td>
<td>121</td>
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</tbody>
</table>
CMS Top Ten Deficiencies (Conditions)

- Mod Complexity LD qualifications: 3.7%
- Successful PT participation: 3.3%
- High Complexity LD qualifications: 1.5%
- PT enrollment: 1.4%
- Analytic System (QC): 1.0%

* Data from 17,873 surveys

CLIA data system 12/13
CMS Top Ten Deficiencies (Conditions) 
Cont’d.

- Mod Complexity test personnel 1.0%
- TC qualifications 0.8%
- Hematology 0.6%
- High Complexity test personnel 0.4%
- TS qualifications 0.3%
CMS Top Ten Deficiencies (All)

- Proper storage of reagents & specimens 5.4%
- Analytic systems QA 4.7%
- Alternative PT if no PT available 2X/yr. 4.6%
- Procedure manual 4.1%
- Test reports –patient ID 4.0%
CMS Top Ten Deficiencies (All) Cont’d.

- Manufacturer’s instructions 3.9%
- Mod Complexity LD qualifications 3.7%
- Expired reagents 3.5%
- Calibration verification 3.4%
- Successful PT participation 3.3%
CMS 2319-F: Patient Access Rule

• Final rule published 2/6/14.

• Centers for Disease Control and Prevention (CDC), Office of Civil Rights (OCR-administers HIPAA) & CMS collaborative effort.

• Revises CLIA regulations at 493.1291(f) and

• Adds new regulation at 493.1291(l)

• Removes exceptions for CLIA and CLIA exempt labs under Privacy rule.
CMS 2319-F: Patient Access Rule

• Requires all labs that are HIPAA covered entities to provide patients access to their test reports.

• Note: Except as provided in 493.1291(l), test results must only be released to authorized persons, the persons responsible for using them, and the lab that initially requested the test.

• CLIA Interpretive Guidelines will be revisited to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.
CMS 3271-P Fecal Occult Blood (FOB) Testing

- Proposed rule to amend CLIA regulations by
  - Specifying waived test categorization applies only to non-automated FOB tests
  - Removing copper sulfate method from waived list if comments confirm test no longer in use
- FDA rec’d. apps for automated FOB tests which use more complex, automated technology that doesn’t meet waived criteria.
This regulatory adjustment will permit FDA to categorize FOB tests appropriately.

Project is a CDC/CMS/FDA collaborative effort.

Proposed rule is in clearance; no ETA yet.
Updating PT Regulations

- CMS collaborating w/ CDC
- Received CLIAC recommendations, based on expert input
- Requires significant levels of data compilation & analysis
- CDC working w/ data from PT programs & statistician to determine better target values
- Reviewing current analyte list, grading criteria & target values, etc.
- Proposed rule in early development & will solicit comments on changes
- Final standards will be phased in to allow time for implementation
PT Referral in Burden Rule #2
CMS 3267-P

• NPRM published 2/7/13
• Proposes one-time exception carve-out for intentional PT referral regarding confirmatory & reflex testing; i.e., if PT sample goes to another lab for testing
• Comments received generally in support
• Final in clearance; 2014 publication planned
• Guidance will be provided to surveyors & labs
Taking Essential Steps for Testing Act of 2012
(TEST Act – HR 6118)

• Amendment to the CLIA statute signed by the President on 12/4/12.

• Clarifies that PT samples are to be tested in the same manner as patient specimens, EXCEPT that no PT samples shall be sent to another laboratory for analysis.
Taking Essential Steps for Testing Act of 2012
(TEST Act – HR 6118)

• Allows the Secretary enforcement discretion for:
  – Revocation of the CLIA certificate for PT referral; and
  – Imposition of the 2 year owner/operator ban when sanctioned for PT referral
Taking Essential Steps for Testing Act of 2012  
(TEST Act – HR 6118)

- Proposed rule is a rider included w/ FQHC rule (CMS 1443-P) details 3 hierarchical adverse actions for PT referrals by seriousness (defines when discretion will be applied & when revocation will be imposed).
- Public comments rec’d. & final rule in clearance
- ETA for rule is 2014
Individualized Quality Control Plan (IQCP) Topics

• Background & History of CLIA QC
  – In the beginning (1992)…
  – 2003 Quality System Regulations
  – Inception of EQC--2004

• 2005 ‘QC for the Future’ Meeting
  – Partnership w/ CLSI & development of EP-23
  – Publication of EP-23 in 2011

• CMS’ Development of & Plan for Individualized Quality Control Plan (IQCP)
  – Education & Transition Period
  – Implementation Status
IQCP Background & History

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity phase-in
    - Follow manufacturer’s instructions
    - All QC actions acceptable during phase-in
  - All QC requirements apply to high complexity
- Many expert meetings convened by CDC/CMS to find better QC, but to no avail
- Quality System (QS) Regulations pub.—2003
  - Updated all QC requirements
IQCP Background & History

- 2003 QS regulation--new provision for alternative QC in CMS’ Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as “equivalent quality testing” is provided--42 CFR 493.1250.

- Default: 2 levels external QC/day of testing
Inception of EQC

- Equivalent QC or ‘EQC’ developed in IG as a voluntary alternative QC--2004
  - Option employed depends on the extent internal QC monitors total testing process
  - Minimizes frequency of external QC required
  - Helps save costs/resources for labs
  - Acknowledges technological advances
  - Director responsible for choice of QC plan
  - Remaining quality systems must be acceptable
Inception of EQC

• Concerns expressed by industry, laboratories, experts, etc.
• Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
  – EQC limited in scope
• CMS reached out to CLSI to facilitate development of an scientific, objective consensus QC guideline
CMS-CLSI Partnership

- CLSI convened the well-attended ‘QC for the Future’ meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov’t. agencies
- Outcome:
  - Stakeholder concern that manufacturers don’t provide labs sufficient information
  - ‘One-size-fits-all’ QC doesn’t work w/ new technology
EP-23 Becomes IQCP

• CLSI meeting directed the development of Evaluation Protocol (EP)-23—*Laboratory Quality Control Based on Risk Management*
  – Chaired by James Nichols, PhD
  – Assembled expert group
  – Published October, 2011

• CMS incorporated key EP-23 concepts into CLIA IG as QC policy, called *Individualized Quality Control Plan -- IQCP*
IQCP Policies

- CMS S & C letter-link on CMS/CLIA website
- Applies to CMS-certified non-waived labs
- Covers all phases of the testing process
- May or may not reduce QC amt. or frequency
- IQCP is optional; default is regulation - 493.1256(d)
- Lab must define a QC number, type & frequency in its QCP
- Includes existing & new analytes/test systems & specialties, except cytology/histopathology
IQCP Pro’s

• Can be customized based on patient pop., environment, test system, personnel, test uses
• Offers flexibility & framework to achieve QC compliance for each test; broad in scope
• Adaptable to future technology advancements
• Permits labs to develop a QCP using their existing quality practices/information
  – E.g., test verification data is a start
• Considers known risks mitigated by mfgr. &
• Formalizes laboratories’ risk mgt. decisions
IQCP Facts

• Once effective, IQCP will supersede current EQC policy
• Includes Risk Assessment (RA), Quality Control Plan (QCP) & Quality Assessment (QA)
• Existing CLIA QC & QS concepts won’t change
• No regulations will change!
• CMS’ outcome oriented survey won’t change
• Minimally, labs must follow mfr’s. instructions
• Lab director has overall responsibility for QCP
IQCP Facts

- There is an education & transition period starting Jan. 1, 2014 to Jan. 1, 2016 for labs before IQCP is fully effective
  - Surveys will be educational
- At the end, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited
  - Surveyors will provide educational materials to labs
- National Surveyor Training on IQCP was conducted in Nov. 2013
- Ongoing educational info & guidance will be provided to labs

www.cms.hhs.gov/clia/
IQCP

In the interim, CMS certified labs should:

– Continue to follow existing QC protocols
– Learn about EP-23 concepts & IQCP
– Plan & complete their transition accordingly

• Phase out EQC (if using it)
• Decide to implement default QC or IQCP
IQCP & Accredited Labs

- CMS has solicited accrediting orgs (AO) to determine their interest in IQCP
- Accredited labs should continue to meet their accrediting org.’s current QC standards until they receive notice from their AO about any QC changes
- AOs need to:
  - select option
  - Revise standards accordingly
  - Obtain CMS approval
  - Educate their labs
IQCP Educational Period

• No control procedure regulatory citations will be issued during the education & transition (E/T) period, unless serious test quality problems are found.

• All questions regarding IQCP may be directed to the CMS electronic mailbox: IQCP@cms.hhs.gov

• Please stay tuned for more information.....
IQCP Surveyor Training Modules

- History & Rationale for IQCP
- CLIA IQCP Policies
- Overview of Risk Assessment
- Scope of IQCP
- Citations (D-tags) for IQCP
- Surveying for Compliance
- Sample Quality Control Plan (QCP) Evaluations
- Education & Transition Period
IQCP Educational Outreach

• **CLIA BROCHURES**
  – *First* in a series of IQCP brochures had its debut
  – Focus is introductory level Q&A addressing:
    • What is IQCP
    • Application
    • Participation
    • Manufacturer Instructions
    • Director Responsibility
  – Distribution
    • CLIA website
    • On-site survey of Certificate of Compliance (COC) labs
    • Booths, public venues, Partners
  – Anticipate the 2nd brochure release by early 2014
IQCP Educational Outreach

- COLLABORATION with CDC
  - CMS is collaborating w/ CDC on further educational material
  - Focus geared towards Physician Office Laboratories (POLs) & other smaller labs,
  - But can be used by all.
IQCP Communications

• CLIA website: two S&C letters w/ FAQs
  – Will be updated periodically
• Mailbox for inquiries: IQCP@cms.hhs.gov
• Educational Brochures: posted on CLIA website: www.cms.hhs.gov/clia/
• CMS media venues for IQCP press release
• IQCP information/materials will be shared w/ Partners & stakeholders
IQCP Planning

• IQCP Education & Transition (E/T) Period
  – Two years long—1/14 to 1/16
  – Learn about IQCP & ask questions
  – Determine QC option
  – Make transition plans
  – Begin to implement choice

• IQCP is optional for AO/ES Standards
IQCP AO/ES Planning

• During Education & Transition (E/T) Period
  – AO/ESs evaluate their standards
  – Ensure AO/ES standards contain acceptable QC options:
    1. CLIA QC regulations as written or
    2. IQCP

• End of E/T Period
  – EQC no longer acceptable

• Changes in AO/ES standards
  – Submit to CMS prior to implementation
  – CMS evaluation: must be equal to or more stringent than the CMS IQCP procedure
IQCP AO/ES Planning--Validation

- Validation Surveys for IQCP
  - Surveyors to be trained to follow the standard process of surveying w/ the CLIA requirements

- Validation Surveys: Education & Transition Period
  - Labs will be cited for not following CLIA QC requirements, only if a surveyor identifies quality testing problems; e.g.,
    - doing no QC at all
    - serious test quality concerns
    - immediate jeopardy (real or potential harm to patients)
Good Laboratory Practices for Waived Testing Sites

- Educational booklet with job aids
GPRA ‘Ready, Set, Test!’ Waived Project

Government Performance Review Act

- Goal – Improved compliance with CLIA standards as measured by increased percentage of Letters of Congratulations (no problems found) sent to waived (CW) laboratories based on onsite educational visits.
GPRA ‘Ready, Set, Test!’ Waived Project

• Pilot Study – 2 states in each CMS Region
  – Selected CW labs received copy of ‘Ready, Set, Test’ booklet prior to their CW survey
  – Post survey information collected regarding lab use of booklet to improve lab practices
GPRA ‘Ready, Set, Test!’ Waived Project

- 2010 Baseline – 18% received Letters of Congratulations
  - Results from 2011 – 32%
  - Results from 2012 – 44%
  - Results from 2013 – 45% (386/861 labs)

Conclusion – Educational materials like ‘Ready, Set, Test’ booklet are well-rec’d.; serve as excellent means to improve lab test quality.
GPRA ‘Ready, Set, Test’ Waived Project

- 97% - rec’d. the booklet
- 84% - reviewed the booklet
- 95% - found the booklet helpful
- 50% - changed current practices as a result of reading the booklet

Helpful sections of booklet:
- QC log instructions
- Record keeping
- QC testing
Where to Obtain Information

CMS/CLIA Web site:


CMS CLIA Central Office:
410-786-3531

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

IQCP Mailbox: IQCP@cms.hhs.gov
THE END!

THANK YOU!!

QUESTIONS??

CLIA

CMS