Annual Compliance Institute 2018

Laboratory Compliance: Maintaining Compliance in an Uncertain and Changing Environment

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..from the perspective of a Laboratory Accreditation Organization
COLA

- CMS approved lab accreditation organization since 1993
- Certified to ISO 9001:2015
- Accredits approximately 7,300 labs
  - All 50 states
- Two subsidiaries
  - COLA Resources, Inc. – Education
    - Offering educational surveys
    - Annual Laboratory symposium
  - NextLOGiK - IT

Most frequent citations

- Lack of complete competency assessments as required
- Lab Director not fulfilling the responsibilities of the position
- Lack of Proficiency Testing Documentation
- Lack of QC review
- Calibration or calibration verification not performed as required
The problem with competency assessment...

“It’s hard to see a problem clearly if you’ve already decided what to do about it.”

Levitt and Dubner

Lab Director responsibilities

- General
- Procedural
- Proficiency Testing
- Personnel
- Quality Control / Quality Assessment
PT documentation

- Attestations
- Raw data
- Review by LD or designee
- Review with staff and supervisory personnel
- Investigation of failures
- Corrective actions

What is PT referral?

Sending PT samples to another lab for testing and then reporting the other lab’s results as your own
Avoiding PT referral

Treat PT samples like patients…

UP UNTIL THE POINT that you would normally send to another lab for reflex, distributive, or confirmatory testing.

TEST act of 2012

Gave CMS the express authority to impose alternative sanctions in the event of a PT referral. Specifically, the word “will” would be replaced with “may” in the regulation that previously required revocation of a laboratory’s CLIA certificate if it refers a PT sample to another laboratory.
PT problems seen when

- More than one lab at the same location
- Testing personnel work multiple sites within the same health system
- Technical Consultants enter PT results for multiple sites

Overlap of CLIA requirements and laboratory billing...
**Food for thought**

If a laboratory test specimens that are beyond the specimen integrity limitations of the test, and bills for that testing....is this just a lab noncompliance or is it also a billing noncompliance?

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**Are the CLIA regulations outdated?**

Very few updates since 2004:

- PT
- Direct patient access to test results
Many common technologies seen in labs today were not around when CLIA was written

AOs need to continuously update and add standards. All must be approved by CMS.

2018 Request for information from CMS

- Personnel
  - Nursing degrees
  - Physical science degrees
  - Competency assessments – who can perform

- Proficiency Testing – waived labs
- CLIA fees
- Histocompatibility
How CMS and AOs work together

• Annual Partners in Laboratory Oversight meeting
• Survey and Certification Letters
• Validation surveys
• On-line training and joint participation in training
• Routine meetings between AO and CMS
• AOs must reapply for deeming authority

CMS Interpretive Guidance

• Available at www.cms.gov/clia

• Survey and Certification Letters are available to the public at the same site.

• Rule making process typically includes ability to submit comments
Questions

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