

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***



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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*



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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***



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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



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Lab Director responsibilities

- ***General***
- ***Procedural***
- ***Proficiency Testing***
- ***Personnel***
- ***Quality Control / Quality Assessment***



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PT documentation

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



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What is PT referral?

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



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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.**



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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.



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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*



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Overlap of CLIA requirements and laboratory billing...



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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



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***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.*



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2018 Request for information from CMS

- Personnel
 - Nursing degrees
 - Physical science degrees
 - Competency assessments – who can perform
- Proficiency Testing – waived labs
- CLIA fees
- Histocompatibility



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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



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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

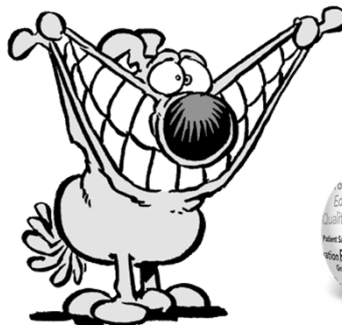


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Questions

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