CLIA Update 2014

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CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Current Statistics--Enrollment

Total Number of Laboratories	**244,564**
Total Non-Exempt	**236,882**
Compliance	18,959
Accredited	16,081
Waived	165,058
Provider Performed Microscopy	36,784
Exempt	**7,682**
NY	3,810
WA	3,872

CMS data base 1/2014

Top 10 Deficiencies

Condition Level Deficiencies
Moderate Complexity Lab Director qualifications
Successful Proficiency Testing Participation
High Complexity Lab Director qualifications
Proficiency Testing Enrollment
Analytic System (QC)
Moderate Complexity Testing Personnel
Technical Consultant qualifications
Hematology
High Complexity Testing Personnel
Technical Supervisor qualifications

Overall Deficiencies
Proper storage of reagents and specimens
Analytic Systems Quality Assurance
Alternative PT if no PT available
Procedure Manual
Test reports – patient ID
Manufacturer's instructions
Moderate Complexity Lab Director qualifications
Expired reagents
Calibration verification
Successful Proficiency Testing Participation

CMS 2319-P: Patient Access Rule

- Collaborative effort between CMS, CDC, and the Office of Civil Rights (OCR – administers HIPAA)
- Final rule publication date 2/6/14.
- Laboratories must be in compliance by 10/6/14

New CLIA regulation §493.1291(l):

Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Changes to HIPAA Privacy Rule

- Amended 45 CFR §164.524(a)(1)(i-iii).
- Removes exceptions that relate to CLIA and CLIA-exempt laboratories
- Aligns the Privacy Rule with the changes to the CLIA regulations

Key Points for Patient Access

- HIPAA preempts contrary state laws (laws that prohibit providing individuals with access).
- HIPAA covered laboratories must continue to abide by state law that provides "more stringent" access to protected health information (PHI).
  - "more stringent" means greater rights of access to PHI.

Key Points for Patient Access

- Laboratory is considered to be a “covered entity” (CE) under HIPAA if it performs one or more “covered transactions” electronically.

Key Points for Patient Access

- The CE laboratory is required to provide the individual with a copy of their test report in the form/format that the individual requests if a copy in that form/format is readily producible

- Must satisfy the verification requirements of §164.514(h) before providing an individual with access.

Fecal Occult Blood (FOB) Testing

- CMS 3271-P: 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
- This regulatory adjustment will permit FDA to categorize FOB tests appropriately.

Updating PT Regulations

- The final version of the revised list of analytes covered in Subpart I has been developed for the NPRM
- CDC has hired a statistician to work with the CDC for further decision making on target values for the new PT regulation.

Updating PT Regulations

- CDC and CMS are currently working jointly on drafting the regulation text and preamble for the NPRM
- Additional work is being done in preparation for drafting the regulatory impact analysis

TEST Act – HR 6118

- TEST Act - Taking Essential Steps for Testing Act of 2012
- 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.

TEST Act – HR 6118 (continued)

- 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

CLIA TEST Act : CMS-1443-FC

- Published 5/2/14, effective 7/1/14
- Final rule details hierarchical adverse actions for PT referrals by seriousness
- Defines when discretion will be applied & when revocation will be imposed
- Added definition to §493.2 for repeat PT referral

Repeat Proficiency Testing Referral

A 2nd instance in which a PT sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's PT program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization)

CMS 3267-F :Burden Rule #2

- Final rule published 5/12/14, effective 7/11/14
- One-time, narrow exception carve- out for intentional PT referral
- Clarifies intentional referral carve out with addition of the following terms/definitions:
  - Reflex testing
  - Confirmatory testing
  - Distributive testing

IQCP Facts

- National Surveyor Training on IQCP was conducted in Nov. 2013
- Education & transition period started Jan. 1, 2014.
- After Jan. 1, 2016, labs must be in compliance w/ their QC choice or deficiencies will be cited
- Ongoing educational info & guidance will be provided to labs

IQCP Policies

- Applies to CMS-certified non-waived labs, covering all phases of the testing process
- May or may not reduce QC amt. or frequency
- IQCP is optional; default is regulation - 493.1256(d)

IQCP Pro's

- Can be customized based on patient population, environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test; broad in scope
- Adaptable to future technology advancements

IQCP Pro's

- 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 manufacturer
- Formalizes laboratories' risk management decisions

IQCP Facts

- Once effective, IQCP will supersede current EQC policy
- No change in regulations, QC &QS concepts or outcome oriented survey process
- Includes Risk Assessment (RA), Quality Control Plan (QCP) & Quality Assessment (QA)
- Minimally, labs must follow mfr's. instructions and Lab director has overall responsibility for QCP

IQCP Education and Transition Period

CMS certified labs should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Decide to implement IQCP or default QC
- Plan & complete their transition accordingly
- Phase out EQC (if using it), implement default QC, or implement 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

IQCP Educational Outreach

- CMS is collaborating w/ CDC on further educational material
- Focus geared primarily towards Physician Office Laboratories (POLs) & other smaller labs

- All questions regarding IQCP may be directed to the CMS electronic mailbox:

IQCP@cms.hhs.gov

Ebola Virus Information

- Information for laboratories in regards to use of PPE, specimen processing, handling and transport being provided to ROs/SAs as it becomes available from CDC
- DLS is part of the CMS Ebola Internal Response Team

Where to Obtain Information

CMS/CLIAWebsite:

www.cms.hhs.gov/clia/

IQCP Mailbox: IQCP@cms.hhs.gov

CMS CLIA Central Office: 410-786-3531

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