What’s New in Quality and Regulatory Expectations for Laboratories
2018 Continual Improvement Forum

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Disclosures

Relevant Financial Relationship(s):
Nothing to Disclose

Off Label Usage:
Nothing to Disclose
Learning Objectives

• Recognize impact of the CMS 2018 “Request for Information” from the Clinical Laboratory Improvement Amendments (CLIA) program.

• Summarize trends in enforcement actions.

• Identify significant CLIA roles and responsibilities that may or may not be delegated.

CMS 2018 CLIA “Request For Information”

• RFI published January 5th announced in Federal Register on January 9th

• Seeking comments on personnel, PT, CLIA fees and histopathology requirements

• Have not been updated since 1992

• Comments were due by March 12, 2018
CMS 2018 CLIA RFI

Personnel

**Nursing degrees** for meeting educational requirements for **Technical Consultants** and **moderate** and **high** complexity testing personnel

Should regs be amended to expressly reflect that:

- A nursing degree is equivalent to a biological science degree or
- to add nursing degrees as a separate qualifying degree (as opposed to the equivalent of a biological science degree) to the current list of qualifying degrees?

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CMS 2018 CLIA RFI

Personnel

**Physical Science Degrees:**
What is considered a physical science degree and should any physical science degree(s) be considered as educational background(s) appropriate for qualifying to meet CLIA educational requirements?

**Non Traditional Degrees:**
What types of degrees should be considered to meet the requirements for a chemical, physical, biological, or clinical laboratory science, and/or medical technology degrees?
CMS 2018 CLIA RFI

Competency
CLIA be amended to allow general supervisors, with associates degrees, to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing?

Laboratory Training and Experience
What should be considered appropriate laboratory training, experience and skills when determining the qualifications necessary for all personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493 subpart M?
CMS 2018 CLIA RFI

PT Referral Discretion
Under what circumstances should discretion be applied in situations where CMS determines that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory’s PT results as its own (Category 1)?

PT Referral, COW
Should alternative sanctions instead of principal sanctions be an option in these cases in order to create parity for all certificate types for laboratories determined to have participated in PT referral?

CMS 2018 CLIA RFI

Histocompatibility
Should virtual crossmatching be an acceptable alternative to physical crossmatching, and under what criteria and decision-making algorithms would virtual crossmatching be an appropriate substitute for physical crossmatching? Suggestions for updating the histocompatibility regulations to align with current laboratory practice.
CMS 2018 CLIA RFI

CLIA Fees
Updating of fees for determination of program compliance and additional fees for laboratories established under the CLIA regulations as well as the collection of other fees we are authorized to collect such as fees for revised certificates, post survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.

PAMA
• Implemented January 1, 2018
• American Clinical Laboratory Association (ACLA) filed lawsuit December 11, 2017
  • ACLA vs. U.S. Health & Human Services
• Basis:
  • CMS ignored congressional intent
  • Labs prohibited from reporting private payer data
  • CMS failed to protect access
  • Financial harm
FDA

- Genetic Health Risks (GHR)
- DTC, Home Use Test Regulations
- New York State – 3rd party reviewer

Information Security

- Data Security and Breach Notification Act
  - Introduced late 2017
  - Would require companies to report data breaches within 30 days
  - If an individual knowingly conceals a data breach they could face up to five years in prison
Awareness- CAP and California

• CAP has deemed status as an accrediting organization with the California Department of Public Health.

Impact areas:

• Laboratories located in California
• Laboratories located outside of California that perform testing on specimens originating from California

Yates Memo

• Issued in 2015
• No new requirements, reinforces current DOJ policy

• Issued to:
  • Federal Attorney General of government enforcement agencies
  • Directors of Government agencies
  • United States attorneys
Yates Memo

• Criminal and civil corporate investigations should focus on individuals from the inception of the investigation

• To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.

• Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

• Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

Enforcement Actions

• Cancer Care Services- Radiology Oncology and Urologist Groups
  • $2.3 million
  • Paid in lieu of potential civil money penalties
  • Patient information illegally obtained by 3rd party
  • 2.2 million individuals affected
  • Names, social security numbers, physicians names, diagnoses, treatment and insurance information
  • Filed for bankruptcy
Enforcement Actions

- Urine Drug Testing Company
  - Free point of care urine cups
  - Prohibited referrals/Illegal Kickbacks
  - Numerous companies settled with OIG

Enforcement Actions

Recent Settlements

- Pain Management Center
  - $186,210 settlement with the OIG

- Addiction Medical Care
  - $79,880 settlement with the OIG

- Addiction Treatment Center
  - $64,200 settlement with the OIG
Enforcement Actions

- Michigan Lab
  - $55,000 liability
  - Violating Bioterrorism Preparedness Act
  - Allowing access to select agents or toxins maintained in registered laboratory space to an individual who lacked a security risk assessment approval, and who later identified as a restricted person.

Enforcement Actions

- North Carolina Physician and Practice
  - $60,000 settlement with OIG
  - Billed for services provided despite physician being absent
  - Routinely billed for services provided by unlicensed individuals
  - Received remuneration from lab companies in the form of process and handling payments in exchange for referring patients for laboratory testing services.
Enforcement Actions

• Detroit Area Physician
  • Prescribing medically unnecessary controlled substances
  • Requiring patient to undergo testing in lab that he had ownership
  • $19 million Medicare fraud
  • Medically unnecessary

Enforcement Actions

• Burbank Medical Clinic
  • Owner/Operator sentenced to 37 months in prison
  • $1,711,789 in restitution to CMS
  • Falsely billing Medicare medically unnecessary office visits/diagnostic tests

• Substance Abuse Clinic & CEO
  • $883,859
  • Improper billing for urine drug testing
  • Bundling tests and referring- double charging Medicaid
Enforcement Actions

- Blood Testing Laboratory
  - $6 million
  - False Claims Act
  - Kickback to physicians and patients
  - Medically unnecessary testing

Enforcement Actions

- South Carolina Family Medical Clinic, Co-owner and Lab Director
  - False Claims
  - $2 million
  - Illegal Medicare Referrals and Billing for unnecessary Medical Services
  - Custom panel & Standing Orders
Enforcement Actions

• Medical Center
  • Performance of flawed genetic diagnostic tests for 124 cancer patients
  • Failed to perform the testing per SOP
  • Sentenced to 15 months in prison

Enforcement Actions Trends

• Financial settlements for employing individuals excluded from participating in any Federal health care program.
• “Medically Necessary”
• Civil Cases - Individual Accountability
CLIA Roles

- CLIA Laboratory Director
  As laboratory director, you are responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel.
  Even though you have the option to delegate some of your responsibilities, you remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is your responsibility to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.

CLIA Laboratory Director

In the quality system approach, the laboratory focuses on comprehensive and coordinated efforts to achieve accurate, reliable, and timely testing services.
- It includes all of your laboratory’s policies, processes, procedures, and resources needed to achieve consistent, high quality testing services

- It also includes quality assessment which involves the following activities:
  - ongoing monitoring of each testing process used in your laboratory in order to identify errors or potential problems that could result in errors
  - taking corrective action and evaluating the corrective actions taken, to make sure that they were effective and will prevent recurrence.
CLIA Laboratory Director

As laboratory director, you must ensure that:

- Testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the preanalytic, analytic, and postanalytic phases of testing and are appropriate for your patient population
- Physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed
- The environment for employees is safe from physical, chemical, and biological hazards and safety and biohazard requirements are followed

CLIA Laboratory Director

- A general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing
- Sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you, are employed by the laboratory
CLIA Laboratory Director

• New test procedures are reviewed, included in the procedure manual and followed by personnel
• Each employee’s responsibilities and duties are specified in writing

The duties listed may **NOT** be delegated!!!!!
CLIA Roles

- Technical Supervisor (high complexity)/Technical Consultant (moderate complexity)
  - appropriate test method selection
  - adequate method verification in order to determine the accuracy and precision of the test
  - enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed
  - PT samples are tested in accordance with the CLIA requirements
  - PT results are returned within the time frames established by the PT program

CLIA Roles-Technical Supervisor

- PT reports are reviewed by the appropriate staff
- Corrective action plans are followed when PT results are found to be unacceptable or unsatisfactory
- Quality assessment and quality control programs are established and maintained
- Acceptable analytical test performance are established and maintained for each test system
- Remedial actions are taken and documented when significant deviations from the laboratory’s established performance characteristics are identified
CLIA Roles-Technical Supervisor

- Patient test results are reported only when the system is functioning properly
- Personnel have been appropriately trained and demonstrate competency prior to testing patient specimens
- Policies and procedures are established for monitoring personnel competency in all phases (preanalytic, analytic, and postanalytic) of testing to assure the ongoing competency of all individuals who perform testing
- Remedial training or continuing education needs are identified and training provided
- An approved procedure manual is available to all personnel

CLIA Roles-General Supervisor

- For high complexity testing, the director or technical supervisor may delegate to a general supervisor, in writing, the responsibilities for assuring:
  - Remedial actions are taken when test systems deviate from the laboratory’s established performance specifications
  - Patient test results are not reported until all corrective actions have been taken and the test system functions properly
  - Orientation is provided to all testing personnel
  - Annual personnel performance evaluations and documentation of testing personnel performance competency
**Now What?**

- Delegate in writing
  - It has become apparent that accrediting bodies prefer this to be performed using the responsible individual’s name, not title
  - Include what duties need to be delegated
  - Determine how delegated duties will be assessed
  - Remember that those who are being delegated must qualify for the CLIA role by education and experience

**Delegation of Duties**
Delegation of Duties

• Letters of Delegation
  • Outline what duties are being delegated
  • Signed by the delegator and the delegate
  • Reviewed annually for accuracy and completeness
  • Stored centrally
Delegation of Duties
Technical Supervisor/Laboratory Section Director to General Supervisor

As Technical Supervisor/Laboratory Section Director, I delegate to ___________________________ the following duties:

1. Daily supervision of the department, including the examination of the performance of the laboratory staff.
2. Monitoring the laboratory's performance and ensuring that it meets the recognized standards of the profession.
3. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.
4. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.
5. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.
6. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.

Signature:

Technical Supervisor/Laboratory Section Director

General Supervisor

No. Parent: Enrolled Staff's Name
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Delegation of Duties
General Supervisory and Laboratory Supervisor to Employee

As General Supervisor/PHS Laboratory Supervisor of ___________________________, I delegate the following duties:

1. Daily supervision of the laboratory staff.
2. Monitoring the laboratory's performance and ensuring that it meets the recognized standards of the profession.
3. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.
4. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.
5. Reviewing the laboratory's performance and ensuring that it meets the recognized standards of the profession.

Signature:

General Supervisor

Employee
Competency of Delegated Duties

- CLIA Laboratory Director, Technical Supervisors, Technical Consultants and Clinical Consultants are all enrolled in the Institutional Ongoing Professional Performance Evaluation (OPPE)
  - CLIA Laboratory Director has oversight of all MD's, Ph.D.'s in the department

Competency of Delegated Duties

- Competency is assessed for delegated duties that Laboratory Supervisors have and also any delegated duties the supervisor may have issued to other members of the laboratory staff
  - Competencies have been mapped to job descriptions
  - Competencies are performed annually, and are reviewed at the time of the delegates performance appraisal
**Competency Assessment for Delegated Duties**

**General Supervisor/VYS Supervisor**

**Employee Name:**

**Date Assessment Completed:**

Checked responsibilities have been delegated to working. Assessment must include job checklist below.

1. Daily/weekly evaluation of job performance by key personnel.
   - Performance
     - in
     - Excellent
     - Good
     - Fair
     - Poor

2. Monitoring the laboratory processes to ensure acceptable levels of performance are maintained, including review of quality control, calibration and equipment maintenance, and other quality assurance activities.
   - Performance
     - Document/GC/LSO evaluation to ensure accurate reporting of test results.
     - Methods/controls tests, verifying these are in place to ensure adherence and accuracy, as indicated.
     - Equipment maintained and calibrated according to manufacturer's instructions.
     - Testing, reporting, and validation of test results.

3. Verifying that testing personnel are evaluated semiannually during the 12th month of any contract or similar time frame, with comments on their performance.
   - Verifying
     - Performance
     - Evaluation
     - Comments

**Supervisory Comments:**

**Signature:**

**Employee Signature:**

**Supervisor Signature:**
Questions & Discussion