CLIA and Point of Care Testing

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Objectives

• General overview of CLIA
• Guidance on regulations regarding point of care testing
• CLIA updates
A mendments

Minimum federal standards laboratories must follow

Clinical Laboratory Improvement Amendments

What is CLIA?
CLIA History

• Public Law 100-578 CLIA ’88 signed by President on October 31, 1988
• CLIA final rules 42 CFR part 493 (administrative processes and quality standards) published on February 28, 1992
• CLIA final rules effective on September 1, 1992
• Uniform standards to ensure accuracy, reliability and timeliness
CLIA Program Responsibilities

CMS
Clinical Laboratory Oversight

DHHS

CDC
Scientific Consultation

FDA
Test Categorization
A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
That perform testing on patient specimens must:

• Apply for a CLIA certificate;
• Pay appropriate fees; and
• Follow applicable CLIA requirements
Test Complexity

- Waived
- Moderate (including PPM)
- High

Nonwaived
CLIA Certificate Types

• Certificate of Compliance (CoC)
• Certificate of Accreditation (CoA)
• Certificate for Provider-performed Microscopy (PPM) Procedures
• Certificate of Waiver (CoW)
Current Enrollment Statistics

CERTIFICATE TYPES

CoW 75%
CoA 6%
CoC 7%
PPM 12%

Source: CMS CLIA Database, April 2019
Continuous Laboratory Oversight

- CLIA (State Agencies/Regional Office)
- Accreditation Organizations (AO)
Certificate of Compliance

- Surveyed for compliance with the CLIA regulations
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by State Agencies
Certificate of Accreditation

- Laboratory selects Accrediting Organization at time of CLIA application
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by AO survey team
CMS Approved AOs

- AABB
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Association for Hospitals and Health Systems/ Healthcare Facilities Accreditation Program (AAHHS/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission
Certificate for Provider-performed Microscopy (PPM) Procedures

• Pay biennial certificate fees
• Not subject to routine surveys
• Can perform PPM procedures and waived testing
• Examples of PPM include:
  – KOH preparations
  – Fern tests
  – Urine sediment examinations
Which test is **not** a PPM procedure?

A. Semen analysis; presence and/or motility
B. Nasal smears for eosinophils
C. Tzanck smear
D. Fecal leukocyte examination
Certificate of Waiver

- Enroll in the CLIA program
- Pay biennial certificate fees
- Only perform tests categorized as waived
- Not subject to routine surveys
- Must follow manufacturer’s instructions
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Point of Care Testing

- Waived
- Moderate complexity
- PPM procedures
- High complexity

Nonwaived
Quality Control

Waived:
• Follow manufacturer’s instructions

Nonwaived:
• §493.1256(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must:
  – Follow additional specialty and subspecialty requirements
  – Perform control procedures using the number and frequency specified by the manufacturer or established by the lab when they meet or exceed performing two levels of QC each day of patient testing [§493.1256(d)(2)]
When Should You Consider an IQCP?

Waived:

• Not applicable

Nonwaived:

• If manufacturer’s instructions are less stringent than CLIA regulations, either follow CLIA control regulations at §493.1256-1278 or perform an IQCP
• Voluntary, tailored QC plan specific for your testing environment
• Entire testing process: preanalytic, analytic, postanalytic
• Includes:
  – Risk Assessment (RA)
  – Quality Control Plan (QCP)
  – Quality Assessment (QA)
  – LD signature
Personnel Requirements

• Waived testing
  – Laboratory Director (LD)
Personnel Requirements

• Moderate complexity testing
  – Laboratory Director (LD)
  – Technical Consultant (TC)
  – Clinical Consultant (CC)
  – Testing Personnel (TP)
Personnel Requirements

• PPM procedures
  – Laboratory Director (LD)
    • Physician (MD, DO, DPM), midlevel practitioner (nurse midwife, nurse practitioner, physician assistant), dentist
  – Testing Personnel (TP)
    • Physician (MD, DO, DPM), midlevel practitioner (nurse midwife, nurse practitioner, physician assistant), dentist
Personnel Requirements

• High complexity testing
  – Laboratory Director (LD)
  – Technical Supervisor (TS)
  – Clinical Consultant (CC)
  – General Supervisor (GS)
  – Testing Personnel (TP)
Laboratory Growth Nationwide

Non-Exempt Laboratories by Application Type

Source: CMS CLIA Database, April 2019
• CMS surveyed a percentage of CoW laboratories nationwide
• Announced surveys geared towards education
• Surveyors determined:
  – Patient safety
  – Regulatory compliance
  – Waived tests only
Findings from CoW Project

- Failed to have current manufacturer’s instructions
- Failed to perform quality control per manufacturer’s instructions
- Failed to follow manufacturer’s instructions
- Performed nonwaived testing
Why is this Important?

- Can lead to misdiagnosis
- Confirms complaints from the public
- Most important... PATIENT SAFETY
What Did We Do?

• Initiated test menu collection with CLIA application
• Created educational booklets in collaboration with the CDC
• Enlisted support of professional and patient advocacy organizations
Federal Register:


# Resources

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<td>FDA CLIA website</td>
<td><a href="https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia">https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia</a></td>
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Contacts

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QUESTIONS?