

# Electronic Health Records and CLIA

Karen Dyer MT(ASCP) DLM

Centers for Medicare and Medicaid Services

CLIA

September 1, 2010

**CLIA**

# Electronic Health Record (EHR)

- Electronic record of health–related information on an individual that:
  - conforms to nationally recognized interoperability standards
  - can be created, managed and consulted by authorized clinicians and staff across more than one health care organization

# Health Information Exchange (HIE)

- Electronic mobilization of Health Care information across multiple organizations within a community, state, or region

## Legislative Background

- Title IV of the Recovery and Reinvestment Act of 2009 (ARRA) established the Health Information Technology for Economic and Clinical Health Act (HITECH).

# Legislative Background

- HITECH created the Health Information Technology (HIT) Policy committee which reports directly to the Office of the National Coordinator for Health Information Technology (ONC)
- This committee included electronic exchange of laboratory information as one of the proposed “meaningful use” objectives for 2011.

# Potential Issues with EHR's

- Interoperability
- Safety
- Security
- System problems
- **CLIA**

# CLIA “Issues”

- Final report destination for laboratory results
- The accuracy, reliability, confidentiality and timeliness of laboratory test reports
- Ensuring Proper Laboratory Report Content
- Limitations on the Disclosure of Laboratory results to the “authorized person” and those persons responsible for using

- Key participants
  - Division of Laboratory Services
  - ONC
  - HIT Policy Committee
  - Office of General Council (OGC)
  - Office of E-Health Standards and Services (OEHS)
- Addressed CLIA “issues” thought to hinder the electronic exchange of laboratory information

# Steps Taken to Address CLIA “Issues”

- Revisions to specific Interpretive Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual.
- Survey and Certification Letter that introduces the revisions to Appendix C (S&C-10-12-CLIA)
- List of Frequently Asked Questions (FAQ’s)

# Revisions to Interpretive Guidelines

## Authorized individuals and others

Guidance for exchange of laboratory information by allowing laboratory results to be sent to the authorized individual and others designated by the authorized person to receive the information.

§493.1241 Standard: Test Request

§493.1291(f)(g) Standard: Test Report

# Issues Addressed

- Authorized person can designate an agent as one of the additional individuals/entities on the test requisition.
- Information necessary for the electronic transmission of laboratory results (e.g., electronic address) can be included on the test requisition by the authorized person.

# Issues Addressed

- Laboratory's CLIA responsibility ends when the authorized person or, if applicable, the individual(s) responsible for using the laboratory results receive the results

# Revisions to Interpretive Guidelines

## Electronic exchange of laboratory information

Additional guidance when surveying laboratories using Health Information Technology for the electronic exchange of laboratory information.

§493.1234

Standard: Communications

§493.1291(a)(e)

Standard: Test Report

§493.1291(k)(k1)(k2)

Standard: Test Report

# Issues Addressed

- Final report destination for CLIA purposes considered to be the authorized person or their designated agent
  - An agent is an individual or entity legally acting on behalf of the authorized person to receive test results

Laboratory can contract with another entity to assist with the delivery of laboratory test reports

# Frequently Asked Questions (FAQ)

- Address issues related to the electronic exchange of laboratory information and EHR use:
  - Use of transmission and vocabulary standards for laboratory results
  - Checking interfaces to verify accuracy of test result transmission to an EHR/Health Information Exchange (HIE)
  - Release of laboratory results to a patient
  - Clarification of the CLIA program's statutory authority

# CLIA regulations have not changed!

- Interpretive Guidance revised for specific regulations
- Survey Process remains the same
- Labs will still need to make sure that all the required data elements are in their test reports.
- Labs will still need to confirm the accuracy/timeliness of their data transmissions

# CLIA does not regulate EHR Systems or Vendors

- EHR companies are not required to develop products that are CLIA compliant
- The laboratory determines if the EHR product meets all applicable facility needs and regulatory requirements
- If a laboratory uses an EHR system, the laboratory (not the vendor) makes sure their staff are trained on EHR systems

## Next steps....

- Health care reform goals:
  - Patients in control of their personal health information and
  - Patients more actively involved in their own health care decisions.

# Future of CLIA and EHR

Discussions underway with ONC and OCR as to ways CLIA can help facilitate a patient's access to their personal laboratory results.

CLIA Interpretive Guidelines will be re-visited as needed to ensure that laboratories and relevant stakeholders have clear guidance on the best practices and resources for implementation of Health Information Technology.

# Helpful Links

- Health Information Technology
  - <http://healthit.gov/portal/server.pt>
  
- CLIA EHR S&C package
  - <http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopofPage>