

# CLIA and EHRs

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**CLIA**

**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

# CLIA and EHRs



## Topics for Discussion

- Applicable CLIA Regulations
- Misperceptions Regarding CLIA
- Clarifications of Misperceptions
- New CMS Interpretive Guidance for Laboratories & Surveyors

# CLIA and EHRs

## Regulations for Test Ordering & Result Reporting

- §493.1105 Standard: Retention Requirements (a)(6)  
Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, & corrected reports) at least 2 yrs. after reporting.
- §493.1241 Standard: Test request  
(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

# CLIA and EHRs

## Regulations for Test Ordering & Result Reporting

- §493.1241 Standard: Test request
- (c) The laboratory must ensure the test requisition solicits: (c)(1) The name & address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

# CLIA and EHRs

## Regulations for Test Ordering & Result Reporting

- (c)(2) The patient's name or unique patient identifier.
- (c)(3) The sex and age or date of birth of the patient.
- (c)(4) The test(s) to be performed.
- (c)(5) The source of the specimen, when appropriate.
- (c)(6) The date and, if appropriate, time of specimen collection.
- (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.
- (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

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## Regulations for Test Ordering & Result Reporting

- §493.1291 Standard: Test report
- (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

# CLIA and EHRs

## Regulations for Test Ordering & Result Reporting

- §493.1291 Standard: Test report.
- (a)(1) Results reported from calculated data.
- (a)(2) Results and patient-specific data electronically reported to network or interfaced systems.
- (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

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## Regulations for Test Ordering & Result Reporting

- §493.1291 Standard: Test report
- (f) Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

# CLIA and EHRs

## Regulations for Test Ordering & Result Reporting

- (k) when errors in the reported patient test results are detected, the laboratory must:
  - (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.
  - (k)(2) Issue corrected reports promptly to the authorized person(s) ordering the test and, if applicable, the individual using the test results.

# CLIA and EHRs

**Misperception:** Test results must be retrieved/saved in the identical format as the original report.

**Clarification:** No specific format is required, but all required elements must be transmitted accurately, reliably, confidentially & timely.

(493.1105)

# CLIA and EHRs

**Misperception:** CLIA requires both a paper & electronic copy of results.

**Clarification:** No, CLIA only specifies 1 copy & doesn't require a certain method of saving.

(493.1105)

# CLIA and EHRs

**Misperception:** CLIA doesn't permit patients to receive test results directly.

**Clarification:** Depending on State law, patients may be able to receive test results or the authorized person may request a copy for the patient when ordering the test. (493.1241 & 493.1291)

# CLIA and EHRs

**Misperception:** CLIA doesn't permit test results to go directly to an HIE.

**Clarification:** With the authorized person's designation or an order on the test request, they can. (493.1291(a) & (f))

# CLIA and EHRs

**Misperception:** The lab's responsibility is met when the 1<sup>st</sup> entity receives the results.

**Clarification:** The lab is responsible for getting the results to the authorized person who ordered the test. Once they reach the authorized person, the lab's CLIA responsibility is discharged.(493.1291(a)&(f))

# CLIA and EHRs

**Misperception:** CLIA requires visual verification of result transmission to the authorized person.

**Clarification:** CLIA doesn't specify the mechanism or frequency to check result transmission. (493.1291(a))

**Misperception:** If all EHR interface software is the same, it only needs to be verified once.

**Clarification:** ALL EHR interfaces & all locations must be checked. (493.1291(a))

# CLIA and EHRs

**Misperception:** CLIA should compile the list of LOINC codes & standard terminology, like HL-7 & oversee the accuracy of EHR vendor's transmissions.

**Clarification:** CLIA is user fee funded & doesn't have the authority to oversee these entities, but HHS supports the use of this standard terminology & transmission coding.

(493.1291(a))

# CLIA and EHRs

- **Newly clarified CMS CLIA Interpretive Guidance for EHRs is imminent!**
  - Contains expanded information, guidance & regulatory interpretations for test ordering, record retention & result reporting
  - As applicable to the present state of EHRs
  - Under the current regulations!
- **Will be accompanied by corresponding, explanatory FAQs.**

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# THE END!!



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# For More Information

CMS CLIA Web Site:

[www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/)

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# QUESTIONS??

