DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-12-CLIA

DATE: **March 1, 2010**

TO: State Survey Agency Directors

FROM: Thomas Hamilton, Director
Survey and Certification Group

SUBJECT: **Clinical Laboratory Improvement Amendments of 1988 (CLIA)** – Issuance of Revised Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual to Facilitate the Electronic Exchange of Laboratory Information

Memorandum Summary

- **Goal:** To support the commitment of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS) to create an environment in which most Americans will have access to health information exchange and Electronic Health Records (EHR) by 2014.
- **CLIA Role:** Laboratory information is an integral part of an EHR. CLIA requires accurate and reliable laboratory results be released to the authorized individual who ordered the tests, the individuals responsible for using the test results, and the laboratory that initially requested the tests.
- **Revised Guidance (Authorized individuals and others)** D5305, D5811, and D5813 are revised and offer guidance for the 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.
- **Revised Guidance (Electronic exchange of laboratory information):** D3041, D5207, D5301, D5659, D5801, D5809, and D5821 are revised to offer additional guidance when surveying laboratories using Health Information Technology (HIT) for the electronic exchange of laboratory information.

Background

Title IV of the Recovery and Reinvestment Act of 2009 (ARRA), which was enacted on February 17, 2009, established the Health Information Technology for Economic and Clinical Health (HITECH) Act.

The provisions in the HITECH Act authorized CMS to establish incentive programs for eligible Medicare and Medicaid providers who adopt, implement, upgrade or meaningfully use certified EHR technology. The HITECH Act creates a truly historic opportunity to transform our health system through unprecedented investments in the development of a nationwide electronic health information system. The focus on "meaningful use" is a recognition that better health care does not come solely from the adoption of technology itself but through the exchange and use of health information to best inform practitioners and support clinical decisions at the point of care.

HITECH created a Federal advisory committee, the HIT Policy Committee, with broad representation from major health care constituencies, to provide recommendations to The Office of the National Coordinator for Health Information Technology (ONC) and CMS on meaningful use. This committee included the electronic exchange of laboratory information in its proposed meaningful use objectives for 2011. As a result, Federal, State and other key stakeholders have been examining the current laboratory electronic exchange landscape to determine where there may be real or perceived barriers, and where opportunities exist to improve the current terrain.

On October 3, 2009 the Information Exchange Workgroup of the HIT Policy Committee held a hearing on issues surrounding the electronic exchange of laboratory information. The purpose of this hearing was to bring laboratories and EHR vendors together to discuss technological, business, operational, and regulatory issues that may impede the ability of stakeholders to exchange data. Stakeholder groups represented at the hearing included: CMS, large, medium sized, and public health laboratories, EHR vendors, providers, Health Information Exchanges (HIEs), and health policy experts. Materials from the hearing may be found at: http://healthit.hhs.gov/HITPolicyMeetings**.** The workgroup is currently formulating recommendations to ONC on the ways in which real and perceived barriers can be addressed to help increase the electronic exchange of laboratory data while protecting the safety and validity of specimen testing and result reporting.

CLIA Role

CLIA regulations may have limited scope over many aspects of the electronic exchange of laboratory information, particularly in light of State laws, and may be incorrectly perceived as a barrier by some stakeholder groups, but we strongly believe that CLIA can be one of several important levers to optimize health information exchange and realize the goals set by ARRA. This memorandum serves to communicate certain revised CLIA Interpretive Guidelines related to the transmission of laboratory results in the era of health information exchange and represents the beginning of what CMS expects to be a series of memoranda in support of the electronic

exchange of laboratory information. A list of frequently asked questions (FAQs) is also being included to dispel some misperceptions, provide facts, and assist States and laboratories in examining and developing their policies and processes to attain effective and efficient means to maintain their compliance with CLIA while implementing HIT in their practices.

CLIA Guideline Changes

CMS is revising certain Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual. We are:

- Revising Appendix C Subpart K, Interpretive Guidance for D5305, D5811, and D5813 to facilitate the electronic transmission of laboratory results to the authorized individual and others designated by the authorized person to receive the information;
- Revising Appendix C Subpart J, Interpretive Guidance for D3041 to include data from electronic health records under existing retention requirements;
- Revising Appendix C Subpart K, Interpretive Guidance for D5207, D5801, D5809, and D5821 to reflect additional considerations laboratories need to take into account when using HIT for the electronic exchange of laboratory information; and
- Adding new Interpretive Guidance under Subpart K, for D5659 to explain how to manage corrected laboratory reports for an electronic health record.

This set of revisions is effective immediately. A final copy of this new guidance will be available at http://www.cms.hhs.gov/Transmittals/ in the near future and ultimately incorporated into Appendix C of the State Operations Manual on the CMS Web site.

Future

We anticipate that when there is more maturity in standards and practices for the exchange of laboratory information, CMS will again revisit the CLIA Interpretive Guidelines as needed. Our objective is to provide clear guidance to laboratories and relevant stakeholders while identifying best practices and resources for implementing HIT as they become available on a national scale.

CMS will host an all-State call for CLIA surveyors, State Medicaid staff, and State HIT Leads in the near future to respond to questions about this memorandum. Additional information on this call will be forthcoming.

Attachments

- FAQ list for assistance with understanding CLIA's scope of authority and issues related to the electronic exchange of laboratory information and EHR use;
- Advance copy of revised surveyor guidance; and
- Transmittal sheet listing all changes.

For questions related to this memorandum, please contact Judith Yost at 410-786-3531 or via email at judith.yost@cms.hhs.gov.

Effective Date: The information contained in this memorandum is current policy and is in effect for all CLIA laboratories. The materials should be distributed immediately to all CLIA survey and certification staff, their managers, State Agencies, and State/RO training coordinators within 30 days.

cc: Survey and Certification Regional Office Management
State Medicaid Directors
State HIT Coordinators

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal - ADVANCE COPY **Date:**

SUBJECT: Revision to Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Subpart J and Subpart K.

I. SUMMARY OF CHANGES: Revisions have been made to reflect the transmission of laboratory results electronically to an Electronic Health Record (EHR) and/or to a Health Information Exchange (HIE)

NEW/REVISED MATERIAL - EFFECTIVE DATE*: UPON ISSUANCE
IMPLEMENTATION DATE: UPON ISSUANCE

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix C, Subpart J – Facility Administration for Nonwaived Testing, §493.1105 Standard: Record Retention requirements, Interpretive Guidelines §493.1105(a)(6)/D3041
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1234 Standard: Communications, Interpretive Guidelines §493.1234/D5207
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1241 Standard: Test request, Interpretive Guidelines §493.1241(a)
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1241 Standard: Test request, Interpretive Guidelines §493.1241(c)(1)-(c)(8)/D5305
N	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1274 Standard: Cytology, Interpretive Guidelines §493.1274(e)(6)/D5659
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(a)/D5801
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Probes §493.1291(a)

R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(e)/D5809
N	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(f)/D5811
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Probes §493.1291(f)/D5811
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(g)/D5813
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Probes §493.1291(g)/D5813
N	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(k)/D5821
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(k)(1)/D5821
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Probes §493.1291(k)(1)
R	Appendix C, Subpart K – Quality System for Nonwaived Testing, §493.1291 Standard: Test report, Interpretive Guidelines §493.1291(k)(2)/D5821

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

D3041

§493.1105 Standard: Retention Requirements

(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(6)
A copy, *either paper or electronic*, of the original report includes all information sent to the individual requesting the test or using the test result(s), and includes the name and address of the laboratory performing the test. The copy need not be paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information as sent to the individual ordering the test or utilizing the test results. *The laboratory copy of the report should contain information that provides an accurate, complete, and easily understood display of previously reported data retained or retrieved from the laboratory's record system.*

For test reports from histopathology, oral pathology, or cytology that require personnel identifiers or an authorized signature (which may be electronic), the copy must include evidence of the identifiers or signature(s).

A "preliminary report" means a test result that has been reported to the authorized person, laboratory, or entity such as an electronic health record or health information exchange that initially requested the test **before** the final test result is completed. Frequently, a preliminary report will contain significant, but not definitive information (e.g. a urine culture preliminary report of >100,000 Gram-negative bacilli after 24 hours incubation or a beta subunit preliminary report of >200 miu/ml). It should be noted on the report when the result is a preliminary result and that a final report will follow.

A "partial report" means multiple tests are ordered on the same specimen or patient. If partial reports are issued for only those tests that have been completed, then the report date will be the date when all tests have been completed. However, the laboratory should be able to identify the date that each new test is appended to the report. This also applies to electronic reports.

The laboratory must have a system for retaining copies of all reports including original, preliminary, corrected, and final reports. This includes computer-generated reports.

Probes §493.1105(a)(6):
How has the laboratory verified that its record retrieval system functions appropriately?

D5207

§493.1234 Standard: Communications

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

Interpretive Guidelines §493.1234
Communication may begin with the request *for* information concerning patient specimens. If the laboratory does not receive the appropriate specimen or patient information needed to perform the tests, the laboratory should assess the information concerning patient preparation and specimen handling requirements provided to the authorized individual*(s).*

The test report form should be easily understood and accurately portray patient test results and other information necessary for interpreting test results (e.g., *for Gentamicin drug test results, peak and trough levels should be identified).*

D5301

§493.1241 Standard: Test request

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

Interpretive Guidelines §493.1241(a)
An "authorized person" means an individual authorized under State law to order tests or receive test results, or both. *Some states expressly authorize patients to order tests or receive (or give them access to) test results regardless of who ordered the test. In these states a laboratory may release test results directly to a patient as an "authorized person" in accordance with state law.*

Patients may also be considered "individuals responsible for using test results" if state law does not expressly prohibit release of test results directly to patients. If the laboratory is requesting payment under Medicare, the laboratory must follow the requirements in the Social Security Act regarding test ordering *for Medicare reimbursement.*

See D5305 for specific guidance on the information necessary to maintain compliance during the test requisition process.

To assure that an authorized person is ordering the test, a laboratory using electronic test requests may issue passwords.

Use of standing orders should be clearly defined in written policy, describing which tests may be covered by standing orders and at what interval standing orders should be reconfirmed.

D5305

§493.1241 Standard: Test request

(c) The laboratory must ensure the test requisition solicits the following information:
(c)(1) The name and 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.

Interpretive Guidelines §493.1241(c)(1)-(c)(8)
The test requisition must provide the information necessary to identify and send test results to the individual who ordered the test (the authorized person), or, where applicable, to the authorized person's agent. An authorized person may also use the test requisition to designate additional individuals/entities who will be responsible for using the test results to provide care to the subject individual.

The address*(es)* *to which test results should be sent may include a postal address* (street, city or town, *state , and zip code), a fax number, and/or the information necessary for electronic transmission*. When appropriate, a telephone number or other mechanism to contact the individual responsible for using the test results should also be provided to the laboratory *on the requisition*.

Verify that test requisitions solicit all information necessary for the proper interpretation of results. This may include patient's age, sex, date, *fasting status,* and time of collection, specimen type (e.g., plasma, urine, spinal fluid), diagnosis, and date of last menstrual period (LMP) for Papanicolaou (PAP) smears. Verify that the instructions to clients are clear and specify the items requested.

If any information is missing from the test requisition or patient medical record or chart, the laboratory must *have a policy defining the criteria for specimen and/or requisition acceptability*. Laboratories must either obtain the missing information or report results and indicate on the test report, medical record or chart any limitations of test results due to the omission of patient information. If the missing information is essential (such as the family history for certain genetic tests) for accurate test results, it must be obtained prior to reporting patient test results.

(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.

Interpretive Guidelines §493.1241(c)(8)
This may include such items as preventative or therapeutic medications, or family history.

Probes §493.1241(c)(1)-(c)(8)
How does the laboratory uniquely identify patient specimens that share the same or similar name, birth date, address or sex?

How does the requisition provide for inclusion of additional information when necessary (e.g., specimen type or source)?

D5659

§493.1274 Standard: Cytology

(e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

Interpretive Guidelines §493.1274(e)(6)
Corrected reports, either hard copy or electronic, must clearly indicate both the corrected result(s), and the fact that the report is a corrected report. The corrected reports should be promptly sent to the authorized person and to all known recipients of the original incorrect report.

Probes §493.1274(e)(6)
How does the laboratory indicate that the report is a corrected report (to avoid confusion with the initial report)? Use D5821.

How does the laboratory include the cause or reason for the correction in the report?

D5801

§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:

Interpretive Guidelines §493.1291(a):
The regulations apply to manual as well as automated record systems *(e.g.,* a laboratory information system or LIS). *Regardless of the means used to transmit laboratory results, routine checks should be conducted to verify that transmissions are being accurately and*

reliably conveyed to the final report destination.

For CLIA purposes, the final report destination for test results is 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); additional individuals or entity(s) who are responsible for using the test results may also receive test results from the laboratory if they are designated by the authorized person on the test requisition; individuals may be able to receive their test results directly from the laboratory where there is no State law prohibiting it.

To ensure the accurate, timely, confidential, and easily understood reporting of patient test results to the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition, a laboratory may contract with another entity to assist in the delivery of patient reports in a manner that complies with all applicable laws, including the CLIA regulatory and statutory requirements.

Probes §493.1291(a):
How does the laboratory ensure that transmitted reports are legible and the information received at the final destination was the same data sent by the laboratory?

If the laboratory uses a LIS or facsimile, what security measures have been instituted to ensure that transmitted reports go directly from the device sending reports *to the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition?*

§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.

Interpretive Guidelines §493.1291(a)(3):
Manually transcribed or electronically transmitted results from an outside referral laboratory or from within the laboratory system (e.g., satellite or point-of-care testing locations) must be periodically verified for accurate and timely reporting.

D5809

§493.1291 Standard: Test report

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

Interpretive Guidelines §493.1291(e)
When the laboratory changes methods, establishes a new procedure, or refers tests to another laboratory, the laboratory *must make the* updated information concerning parameters such as patient preparation, preservation of specimens, specimen collection, or new "normal" ranges *or units of measure* available to its clients.

D5811

§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.

Interpretive Guidance §493.1291(f):
Test results must be released to the authorized person, or, if applicable, their agent. Test results must also be released to any additional individuals/entities designated on the test requisition. These entities are understood to be "responsible for using" the test results.

When the authorized person, and individual responsible for using the test results receives the results, the laboratory's CLIA responsibility ends.

See D5301 for the definition of an "authorized person."

Probes §493.1291(f):
What security measures have been instituted to ensure that reports go directly from the device sending reports (e.g., LIS, facsimile) to *the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition?*

D5813

§493.1291 Standard: Test report

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

Interpretive Guidelines §493.1291(g)
The laboratory records should document the date, time, test results, and person to whom the test results were reported.

*See **D5301,** for the definition of an "authorized person."*

Probes §493.1291(g)
What means does the laboratory use to ensure the *authorized* person is alerted in a timely manner to critical, *alert,* or panic test results?

D5821

§493.1291 Standard: Test report

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

Interpretive Guidelines §493.1291(k)
Errors in test results may include incorrect patient identification, test results, reference or normal ranges, interpretive information, or other significant information. See D5625 for specific guidance regarding certain amended cytology reports.

(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

Interpretive Guidelines §493.1291(k) (1)
When determining whether the laboratory gave prompt notification of test and/or reporting errors to the authorized person(s), *their agent (if applicable), and others who are identified as responsible for using the test results on the requisition,* consider *whether contact information was provided to the laboratory,* when the error was identified, when the authorized person was notified, and *the* extent of the error (e.g., clinically significant results reported on the wrong patient).

Probes §493.1291(k)(1)
What mechanism(s) does the laboratory use for notifying the authorized person(s) of the corrected values?

(k)(2) Issue corrected reports promptly to the authorized person(*s*) ordering the test and, if applicable, the individual using the test results.

Interpretive Guidelines §493.1291(k) (2)
Corrected reports*, either hard copy or electronic,* must clearly indicate *both the corrected result(s) and the fact that the report is a corrected report. The corrected reports should be promptly sent to the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition.*
For corrected reports in Cytology, use D5659.

Probes §493.1291(k)(2)
How does the laboratory ensure that incorrect original results are not reissued verbally, in writing or electronically?

Frequently Asked Questions
(CLIA, Health Information Exchange and Electronic Health Records)

1. Does CLIA require the use of Health Level 7 (HL7) 2.5.1 as the transmission standard for transmitting laboratory results electronically? Does CLIA require laboratories to use Logical Observation Identifiers, Names and Codes (LOINC) as the vocabulary standard to electronically transmit laboratory data?

Many laboratories are interested in ascertaining which transmission and vocabulary standards will work best for their electronic transmission of laboratory data. Health Level Seven 2.5.1 and LOINC are two standards recognized by the Department as transmission and vocabulary standards for the electronic exchange of laboratory data. These standards support the Department's Initial Set of Standards, Implementation Specifications and proposed certification criteria for electronic health record technology, and therefore CMS encourages laboratories to use these standards.

Additional information on HL7 2.5.1 can be found at http://www.hl7.org/.
Additional information on LOINC can be found at http://loinc.org/.

2. Does CLIA require test results received by an Electronic Health Record (EHR)/Health Information Exchange (HIE) to be identical in format to those generated by a laboratory information system (LIS) or to be reported in a specific format?

CLIA requires the inclusion of certain data elements in laboratory-issued test reports. While no specific format is required for these reports, they must accurately convey the required information in an easily understood manner. In addition, the Office of the National Coordinator for Health IT interim final rule (released on 12/30/2009) on EHR standards, implementation specifications, and certification criteria for EHR technology require that these data elements be displayed in all certified EHR technology.

As noted in the previous question, use of recognized vocabulary and transmission standards may facilitate accurate and reliable transmissions.

3. Does CLIA permit sending test results to an HIE and when does the laboratory's responsibility for delivery of results end?

An authorized person may contract with an EHR vendor or HIE to serve as their agent. That agent, as noted below, could then receive test reports from laboratories on behalf of that authorized person. To do so, authorized persons might designate these persons/entities as the final report destination on the test requisition. Based on that requisition, the laboratory would then be able to send the test results to the identified EHR vendors or HIEs.

CLIA regulations state that a laboratory must have an adequate system, either manual or electronic, to ensure that test results are transmitted accurately, reliably, and confidentially from the point of data entry to the final report destination in a timely manner. The final report destination has been interpreted to be the authorized person or their designated agent (the individual or entity legally acting on behalf of the authorized person to receive the test results). The authorized person's agent can be indicated by providing that person/entity's contact information in the place of the authorized person's where one would indicate the final report destination on the test requisition. The authorized person can also use the requisition to indicate additional individuals or entities who should also receive copies of the test report due to their responsibilities for using the test results in treating the patient.

We would note that laboratories may also hire agents to facilitate their obligations – for example, to ensure the accurate and timely transmission of test results. Whenever a laboratory or a laboratory's agent gets the test results to the individual(s) designated as recipients on the test requisition, the lab has generally met its CLIA obligations regarding the delivery of test results. "Panic results" may necessitate additional actions on the part of the laboratory. A laboratory has not met its CLIA obligations regarding final report destinations merely by transmitting the test report information to the laboratory's own agent. Its obligations would only be met after that agent successfully conveyed the test report to the final report destination.

4. When addressing record retention, does CLIA require a laboratory to maintain a paper and an electronic copy of the test results?

CLIA does not specify the form in which records are to be retained, rather, CLIA specifies that reports must be retrievable upon request for defined periods of time. Entities that elect to undergo State surveys are free to select the records retention method that meets their needs. Entities that elect to utilize an accreditation organization in lieu of State survey, however, may be subject to more stringent requirements. Accrediting organizations have requirements that meet or exceed those required under the CLIA regulations. As such, they may place additional restrictions on the CLIA laboratories they accredit, including record keeping requirements. For example, the College of American Pathology (CAP), a CMS approved accrediting organization, appears to require both paper and electronic copies in its LIS standards.

5. Must the laboratory <u>visually</u> verify the accuracy of the information transmitted to all intermediary systems until the report reaches the authorized person?

CLIA does not specify the method or frequency by which laboratories should confirm the accuracy and timeliness of their test report transmissions. Laboratories should establish protocols that are reasonable based on the transmission mechanisms they use.

We would anticipate that the use of standards would reduce the frequency with which laboratories would need to test interfaces. Furthermore, while we understand that some laboratories have interpreted the CLIA requirement to periodically check the success of

its test report transmissions as requiring a visual inspection of the terminal read-outs at each site, we would not anticipate a need to visually inspect each interface/terminal within an EHR installation in order to verify that all the CLIA required data elements were transmitted accurately and timely to the authorized person or their designated agent through the applicable systems and interfaces.

Ultimately, laboratories that are subject to CLIA must meet the requirements stated in 42 CFR §493.1291(a). CMS recommends that laboratories use Departmentally-recognized transmission and vocabulary standards, namely, Health Level Seven (HL7) 2.5.1 and Logical Observation Identifiers, Names and Codes (LOINC) to facilitate successful transmission of accurate and timely test reports. Federally-recognized specifications developed for use by the Nationwide Health Information Network (NHIN) also support this objective.

6. If all interfaces or electronic communication software used between a laboratory and an EHR system are identical, is verification of accuracy of test result transmission required at all sites which use this interface? If a laboratory has multiple sites interfaced to an EHR/HIE that utilize different interface software, do they all need to be checked?

CLIA does not prescribe the means by which a laboratory would test the accuracy and timeliness of their test report transmissions. Laboratories utilize varying test methods/devices for this testing, including manual and automated methodologies/devices.

Each laboratory, its test systems, and processes are unique; therefore, laboratories must devise their own methods to check for the accurate and timely transmission of test results. This may include identifying means of checking the accuracy and timeliness of intermediate systems through which test results travel to reach the authorized person or their designated agent.

Further, extensive laboratory oversight experience has demonstrated that devices do not always work properly in the field. This necessitates the testing of every interface to ensure that that interface is operating as it should. The protocol, method, and frequency for verifying the accuracy of an electronic test result transmission through an interface to an EHR/HIE to the authorized person are determined by the laboratory. Again, we would not anticipate the need for visual inspection of each interface/terminal within an EHR installation.

7. Does CLIA allow for laboratory results to be released to a patient?

Under 42 CFR § 493.1291(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. Depending on State law, individuals may be able to receive their test results from laboratories under one of these bases.

State laws define who is an "authorized person." Some States do afford patients with access to test results as an "authorized person." Currently sixteen (16) States prohibit the release of test results to patients as an "authorized person."

Patients may also be considered "individuals responsible for using test results" if state law does not expressly prohibit release of test results directly to patients.

8. Why doesn't CLIA require any patient contact information or clinician contact information?

Clinician contact information and certain information about the patient is required on the test requisition. See 42 C.F.R. §493.1241(c)(1). Laboratories do not, unless they are the authorized person who ordered the test, expect to be in contact with the patient.

9. Does CLIA require laboratories to verify if an EHR is federally certified? Are labs required to use national standardized results against which EHR vendors are certified?

No.

10. Does CLIA require the transmission of aggregate data for public health evaluation?

No.

11. Should the Clinical Laboratory Improvement Amendments Committee (CLIAC) make recommendations for CLIA improvements to facilitate EHRs?

CLIAC is well aware of the perceived need to clarify CLIA regulatory interpretations to enable laboratories' participation in health information exchange. This document aims to dispel misconceptions regarding perceived CLIA-based barriers to HIE. We understand that CLIAC also intends to work with stakeholders to facilitate their understanding of the CLIA requirements, thereby aiding their successful use of electronic technology to exchange data. We note, however, that CLIAC will not be able to address EHR implementation issues that are outside the scope of CLIA. For example, the use of standardized terminology and the lack of interoperability or State definitions of "authorized person."

12. When can other clinicians request test results directly from the laboratory?

CLIA permits laboratories to disclose test results to those who are "responsible for using" the results. This means that CLIA would not bar a laboratory from sending test results on file to another practitioner if it were to find that the requestor was treating the patient. Other laws or practical considerations, however, may limit the viability of this practice.