DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-05-CLIA EXPIRED

DATE: December 4, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Use of Direct for the Secure Transmission of Laboratory Test Results

Memo Information:
Memo expiration date: 2025-12-04
Original release date: 2013-11-08

Memorandum Summary

- **Direct:** A simple, secure, scalable, standards based way to send authenticated, encrypted health information directly to known, trusted recipients over the Internet.
- **Clinical Laboratory Improvement Amendments of 1988 (CLIA) Requirements:** 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 (42 CFR §493.1291(a)).
- **CLIA guidance:** The Centers for Medicare & Medicaid Services (CMS) considers that laboratories utilizing the Direct transport protocols and fully supporting the Direct Implementation Guide for Delivery Notification requirements would meet the CLIA regulations for an adequate electronic system for sending laboratory test results to the final report destination as specified in 42 CFR §493.1291(a).

On March 1, 2010, CMS issued revised Survey Procedures and Interpretive Guidance for Laboratories and Laboratory Services (see S&C-10-12-CLIA) to facilitate the electronic exchange of laboratory information using Health Information Technology (HIT) and Electronic Health Records (EHRs). Laboratory information is an integral part of an EHR and CLIA requires that this laboratory information be delivered accurately and reliably to the authorized individual who ordered the tests, the individuals responsible for using the test results, and the laboratory that initially requested the test.

The Office of the National Coordinator (ONC) created the Direct Project which was charged with creating a high level set of specifications and service descriptions for Simple Health Transport of content ranging from simple text messages to highly structured clinical messages and documents. This transport system is called “Direct”. Direct is a simple, secure, scalable,

standards based way to send authenticated, encrypted health information directly to a known, trusted recipient over the internet. Direct provides an alternative mechanism to legacy systems, such as mail or fax, and utilizes simple mail transport Protocol (SMTP). A workgroup, called the Direct Laboratory Reporting Workgroup, was created to specifically address the CLIA requirements for the reporting of clinical laboratory results, using Direct.

Direct will also provide acknowledgement that the laboratory test report was delivered successfully to the final report destination in order to meet certification and accreditation for CLIA purposes, and the operational needs of laboratories.

CMS staff, in addition to other laboratory and Health IT stakeholders, participated in the Direct Laboratory Reporting Workgroup to ensure that all applicable regulatory requirements would be met if a laboratory chose to use Direct to deliver laboratory test reports to the final report destination. The workgroup reviewed all relevant documents and CLIA requirements, along with subsequent guidance issued by HHS and the Direct Project. An Implementation Guide for Delivery Notification was created and approved by the workgroup for use by clinical laboratories and senders of healthcare information that require guaranteed notification of message delivery to the final report destination.

CMS considers that laboratories with electronic systems utilizing Direct Project transport that fully supports the Implementation Guide for Delivery Notification, and meeting all other relevant CLIA requirements, would meet the CLIA regulations for an adequate electronic system for sending laboratory test results to the final report destination as specified in §493.1291(a).

Additional information on Direct and the Direct Project can be found at:
http://wiki.directproject.org

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/

David R. Wright
Director, Quality, Safety & Oversight Group

Attachment: Frequently Asked Questions

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:
- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

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Frequently Asked Questions
(CLIA, the Direct Project)

1. **Does CLIA require laboratories to use specific data transmission standards and protocols for sending laboratory test results and reports to the final report destination?**

   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 recognized by the Department as two standards for the electronic exchange of laboratory data. The Direct Project is also recognized as an acceptable means of transporting laboratory data between trusted recipients via the Internet.

2. **If a provider uses a Health Information Service Provider (HISP) to enable the receipt of laboratory results via Direct, is there a need for an agent agreement?**

   The CLIA Interpretive Guidance issued on March 1, 2010 (see S&C-10-12-CLIA) indicated that the designated agent (for the authorized person) is an individual or entity legally acting on behalf of the authorized person to receive test results. The guidance did not specify what type of agreement should be in place, only that the agent must be legally acting on the authorized person's behalf.

   If a HISP is providing Direct Project services, has incorporated support for the Implementation Guide for Delivery Notification, and has a legal Business Associate arrangement with the authorized person, this would meet the CLIA interpretation of an agent agreement.

   The Implementation Guide for Delivery Notification can be found at the following link:

   http://wiki.directproject.org/file/view/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf