



Statement of The American Clinical Laboratory  
Association Before the HIT Policy Committee  
Information Exchange Workgroup

Donald E. Horton, Jr.  
Vice President, Public Policy & Advocacy  
Laboratory Corporation of America Holdings  
(LabCorp)

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Regulatory and Policy Issues Affecting the  
Electronic Exchange of Lab Data

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Ms. McGraw, Mr. Tripathi, and members of the Workgroup, thank you for the opportunity to testify today on behalf of both the American Clinical Laboratory Association (ACLA) and LabCorp regarding the regulatory and policy issues affecting the electronic exchange of lab data. ACLA represents national, regional and local laboratories, and its members, including LabCorp, have an extensive history of leveraging health information technology to enable the secure and reliable exchange of lab data between labs and stakeholders that need lab data for patient care and legitimate secondary uses. My testimony today will focus on two regulatory issues impeding the electronic exchange of lab data and their associated policy implications. The first relates to restrictions on the parties to whom a lab may transmit test results (which we refer to as the “authorized person” issue), and the second relates to the responsibility of the lab to ensure that test results reach the “final report destination” in a timely, accurate and reliable manner (which we refer to as the “interface issue”).

**The “Authorized Person” Issue**

Regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), in conjunction with applicable State law, govern the parties to whom a lab may transmit test results. CLIA provides that 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. 42 C.F.R. § 493.1291(f). Authorized person means an individual authorized under State law to order tests or receive test results or both. 42 C.F.R. § 493.2.

Most States either define “authorized person” narrowly, often including only the ordering provider, or fail to define authorized recipients of laboratory test results, in which case most labs default to the CLIA provision referencing “the individual responsible for using the test results”, which most interpret to mean the ordering provider. Many parties other than the ordering provider need lab result data for legitimate purposes, and request such data directly from the lab rather than from the provider who ordered it. Assuming the HIPAA Privacy Rule would otherwise permit the disclosure without patient authorization, most labs interpret CLIA and applicable State law to permit the lab to transmit test results to a non-ordering third party if either the recipient is defined as an authorized person under State law or the ordering provider authorizes the disclosure. The rationale for this interpretation is that it would be unreasonable to interpret CLIA and State law to prohibit the lab from making such a disclosure if authorized by the ordering provider, where the ordering provider could make the same disclosure to the same third party himself. However, while obtaining ordering provider authorization may not be difficult with respect to a single test result to be sent, for example, to a non-ordering treating

provider, it is far more difficult in the context of making millions of historical test results available for health information networks (e.g., for treatment purposes) or for peer-to-peer transmissions to entities who need large quantities of lab data for secondary uses (e.g., health plans who need lab data for quality improvement, disease or case management, patient safety, or pay-for-performance initiatives). Labs have attempted to address the issue of documenting ordering provider authorization through contractual representations and warranties from data recipients, but this “workaround” is extremely inefficient and is not always effective.

ACLA has developed proposed amendments of both the CLIA statute and regulations that would resolve this issue by simply expanding the list of “authorized persons” to whom labs can send test results to include covered entities and business associates as defined in the HIPAA Privacy Rule. Our proposal would operate as a targeted pre-emption of State authorized person laws; States would continue to be permitted to define “authorized person”, so long as they do not exclude covered entities and business associates. We would also clarify that these changes would not be construed to permit disclosure of any type of test result when disclosure of that type of test is otherwise prohibited (e.g., HIV). The intent here is only to expand the list of permissible recipients of test results in a responsible manner, not to expand the purposes for which test results may be used or disclosed, which are already governed by HIPAA. Uses and disclosures prohibited by HIPAA without patient authorization would still require patient authorization under these amendments; however, disclosures to covered entities and business associates that would otherwise be permitted by HIPAA without patient authorization, but that are currently prohibited under CLIA without ordering provider authorization, would be permitted without ordering provider authorization under these CLIA amendments.

### **The “Interface Issue”**

With respect to the interface issue, CLIA requires that 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 C.F.R. § 493.1291(a). Visual confirmation of receipt of the result at the interface user’s terminal is the typical method of validation.

Electronic health record (EHR) vendors often modify the test result report transmitted by a clinical laboratory to an ordering provider to customize the appearance of the report on the end user’s computer screen. Despite the fact that clinical laboratories have no control over such modifications, current CLIA regulations hold them responsible for ensuring that the required report elements reach the “final report destination” intact. Likewise, despite the fact that a clinical laboratory has no control over the data content of test results that are transmitted to a health information exchange once the results are transmitted, and despite the fact that such exchanges may modify the data content for purposes of meeting the needs of the exchange and the “final report destination” for any given report is necessarily unknown in such an exchange, the laboratory that transmitted the result is still held responsible for its ultimate data content under current CLIA regulations. In the current electronic health information exchange environment, “final report destination” has become a virtually meaningless term, and it is no

longer appropriate to use that term in policies governing the transmission of test results when intermediaries control the presentation of the final report to the ordering provider or authorized person. The clinical laboratory's regulatory responsibility for presentation of the the test results should end once the result is provided to the ordering provider's EHR, or to the system of another permitted intended recipient, or to an intermediary contractually obligated to send the results to the intended destination. ACLA has developed proposed legislative and regulatory amendments to address this issue.

Thank you again for the opportunity to testify, and I look forward to your questions.