



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

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October 20, 2009

Business Issues related to the Electronic Exchange  
of Laboratory 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 Quest Diagnostics regarding the business issues related to the electronic exchange of lab data. ACLA represents national, regional and local laboratories, and its members, including Quest Diagnostics. Although it is widely acknowledged that laboratory test data influence over 70% of clinical decisions, ensuring high quality laboratory data interoperability has not always received the necessary attention by industry stakeholders. My testimony today will highlight some of the business and operational dimensions that currently prevent wide-scale interoperability and exchange of lab data. I will conclude with my recommendations.

Let me first start with the financial dimension. EHR vendors and the growing number of Health Information Exchanges (HIEs) often expect laboratories to pay for the EHR interface license fees and the cost of implementation of each installation.

Second, with regard to quality, the CLIA Regulation section 42 CFR 493.1291 states, “*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 to final report destination in a timely manner.*” This requires laboratories to perform validation of every EHR lab interface.

For over a decade, major laboratories have invested significantly in electronic data interchange, offering their customers a broad range of laboratory transaction capabilities that enhance the quality and efficacy of the laboratory orders and results transactions. This process of adding to laboratory transaction capability has resulted in greater user satisfaction, improved efficiencies and reduced costs for the laboratories – reflecting the important goal of getting the data needed at the time it is needed. Duplicating these capabilities in HIE or EHR vendor systems is typically not a priority for the vendors; however, these capabilities must be considered an integral part of the minimum functionality set needed for HIE or EHR certification.

Some examples of lost or reduced functionality when a physician migrates from a laboratory based ordering and resulting system to a EHR or HIE may include

- Lack of robust electronic ordering capabilities including billing information
- Ability to prompt physicians to print the Advanced Beneficiary Notification (ABN) for Medicare patients with identification and lab specific pricing of the limited coverage tests

- Ability to split requisitions for different specimen types (e.g. frozen and room temperature)

In addition to these operational impacts, HIEs typically do not offer the technical capabilities that offer fault tolerant systems or fail-safe architecture necessary to guarantee the timely delivery (i.e., acceptable service levels) of the laboratory result transaction, therefore requiring laboratories to implement alternative delivery channels to ensure our compliance with the CLIA requirements for the laboratory “report of record.” Because of multiple handoffs between systems and stakeholders involved in lab transaction connectivity, it is often not obvious who “owns” a service issue when a failure occurs – which can result in overly long disruptions in service with potential ramifications for patient care.

Given these circumstances and the resulting cost and quality implications, there is not always a clear business justification for the laboratory to support this transaction integration and exchange. This circumstance is amplified for the smaller physician practices.

Additional challenges that impact either cost and/or quality that are worth highlighting are:

- Numerous versions of standards and even more interpretations of these standards by providers and EHR vendors
- Lack of a standard laboratory test compendium framework and implementation guides which leads to different technological and implementation approaches by vendors for receiving, maintaining and updating a laboratory’s test compendium. ACLA is working with its members to define a set of requirements for standard framework including formats, field definitions, and field lengths for an Electronic Delivery of the Test Compendium
- Given the absence of a standard patient identifier, EHR vendors and software systems are forced to use varying approaches and criteria for matching patients. This lack of automated matching is increased when a lab interface is only for results and/or the critical matching information is not provided within the lab order transaction.

**I’d like to close with my recommendations that would help create the environment for the desired high quality “meaningful” lab transaction interoperability and exchange.**

- Make bi-directional standardized lab interfaces part of the national certification criteria for EHR systems, including functionality pertinent to all the lab order data needed for proper testing, patient matching and billing. This will enforce the orientation of implementing a standard laboratory interface as a part of the initial EHR deployment and not an afterthought. Accordingly, this may also provide the environment to remove the current circumstance of lab interface fees being charged to laboratories.
- Either amend the CLIA regulations or clarify them through the CLIA Interpretative Guidelines that the laboratories are responsible only for insuring that the data transmitted to the initial receiving EHR or HIE systems is accurate and contains all of the required

CLIA information. This amendment should correspondingly include the requirement that EHR vendors and operators of HIEs be responsible for ensuring presentation of CLIA compliant reports / information display to the ordering physician / authorized person as transmitted by the performing laboratory.

- Require EHR vendors and HIEs adhere to a standard test compendium framework and format, which is fully integrated into the EHR system. This will improve integration speed and improve quality.
- Clarify the CLIA regulations to enable the performing laboratory to certify a vendor's laboratory interface by version and not for each individual practitioner installation.

Adopting these recommendations will be the key to achieving the industry's objective for wide scale and "meaningful" lab data interoperability.

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