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Good afternoon, my name is Jonah Frohlich. I am the Deputy Secretary of Health IT in the California Health & Human Services Agency and a member of the Health IT Policy Committee, Information Exchange Workgroup. It is an honor to be asked to testify before this Workgroup on issues related to the electronic exchange of laboratory data.

**The Lab Industry**

As you know, the lab market, like the healthcare industry, is highly fragmented. There are over 200,000 certified clinical labs in the US. Over half of these labs are physician office-based, yet they perform only 8 percent of all tests. Hospital-based labs and independent labs represent four percent and three percent of clinical labs respectively; yet together they perform the vast majority – over three-quarters of tests. While approximately one-quarter of physicians nationally have an electronic health record, (an EHR), many still receive faxed lab results that are either manually entered or scanned into the patient record. This is a limitation of both the lab and EHR industry, a limitation I would like to focus on for my testimony today within the context of independent and hospital-based labs.

**Technology Impediments and Standardization**

The lab industry's technical capability is highly variable; from large independent labs using modern service-oriented architecture, to small hospitals working on legacy systems that don't effectively support HL7 standards - standards most commonly used for reporting lab tests. Most labs fall under the latter category, and hospital-based labs have far fewer IT resources and less expertise to support electronic lab ordering and results reporting. Yet they provide a significant share of lab testing services.

There is virtually no standardization of lab messaging in the industry today. In my experience working on ELINCS projects – initiatives that use highly constrained HL7 messages or "implementation guides" to support electronic lab results delivery – all hospitals needed considerable outside technical assistance to comply with the standard. Labs required assistance to adopt the LOINC coding scheme; a standard naming system for lab tests, and labs were unprepared to adopt SNOMED or UCUM; standard coding schemes for results and units of measures. The lab information systems the hospitals operated had internal "proprietary" codes for test names, and they had little expertise to "map" these codes to LOINC. These labs relied heavily on external technical assistance to do the necessary mapping for the most frequent 95% of reported tests as required by ELINCS – approximately 150 of the thousands of reportable tests in their databases. Hospitals were unprepared to complete the

mapping for the many thousands of tests in their database. Even most of the largest labs in the country have yet to complete this mapping.

If providers are to meet meaningful use target starting in 2011 including accessing electronic lab results from these hospitals, a stepwise approach is needed. We recommend that a standard such as ELINCS with a predefined set of the most commonly used tests using LOINC be supported.

**A Manual Testing Process**

The current process for establishing an electronic lab interface between a lab and an EHR is labor intensive and expensive. The process requires testing of a virtual private network or web-based connection, planning and coding the interface, sending and verifying test messages, training and go-live. In all, we found that the process *typically* takes three months or more to complete – hardly the "plug-and-play" connectivity we have come to expect from our iPhones.

**Business Impediments**

The current process described above for establishing an electronic lab interface between a lab and an EHR is also expensive. These costs are passed on from the EHR vendor to the physician purchasing the product, typically with a $5,000 charge per lab interface. Hospitals and labs typically internalize their own costs; in some instances if the physician is a high volume customer, the labs may actually pay the EHR vendor charge for the physician. In some cases, if the physician is a low-volume customer, the lab may decide not to support an interface at all. The physician may be required to send a subset of her patients to that lab if the patient's payer has an exclusive contract with that lab. The physician may therefore be "stuck" with faxed lab results, impeding their workflow and decision support processes for those patients.

**Regulatory Impediments**

While some of the testing process described above can be shortened by standardizing the lab message, much of the three month implementation process occurs as a result of Clinical Laboratory Improvement Amendments or CLIA regulations. CLIA regulations put the burden on laboratories, and make them accountable for the way that EHRs display lab results to physicians. Under CLIA, labs must ensure that the right lab tests and results are sent to the right provider, for the right patient. This is appropriate. However, CLIA also puts the burden on labs to verify that the EHRs are configured to display lab results correctly. This may require on-site verification by lab personnel that the test is displayed correctly. Labs must therefore make a business decision whether to support physician

customers and must do so based on the arithmetic that they bear considerable costs for each interface. For this reason, labs may decide it does not make business sense for them to send electronic results to physicians who do not represent enough business.

**Recommendations**

Based on the above, we recommend the following course of action to amend CLIA and other proposed certification and meaningful use regulations to support more rapid and reliable implementation of lab interfaces:

(1) Under the federal EHR certification process, require that EHR systems adopt and use national lab standards such as ELINCS, and display the lab results in a CLIA compliant way,
(2) Under CLIA, require that labs verify whether or not the receiving EHR is federally certified
(3) Under CLIA, require labs to send results using the same national standards that EHR vendors are certified against
(4) Under meaningful use, require meaningful use eligible hospitals that provide outreach lab services to comply with (2) and (3) above as one of their meaningful use criterion.

Under the federal stimulus package, a national goal has been set that at least 90% of physicians are meaningful users of EHRs by 2015. This represents a massive expansion from the current adoption rate of EHRs in the US - approximately 25% in five years. To accomplish meaningful use, physicians must have working lab interfaces. The industry under the current regulatory framework cannot support demand today, and is completely unprepared for this expected explosion of demand. These issues need to be addressed immediately; and using the regulatory framework above would considerably help address these critical issues.

Thank you very much for allowing me to present this testimony before the workgroup today.