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Testimony

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On behalf of
The Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) is membership based, non-profit organization representing the interests of laboratories of public health significance. Our members include, but are not limited to central public health laboratories representing each of the 50 US States, all US possessions and territories, many local public health jurisdictions, environmental and food laboratories, and numerous related laboratories.

As an organization, APHL has been active in the development and deployment of various public health data standards and supporting technology projects for over 8 years. A small sample of APHL's involvement includes:

1. The Public Health Laboratory Interoperability Project (PHLIP),
    a. Participated in the refinement and constraint of the HL7 2.3.1 message standard
    b. Developed constrained implementable profiles for the deployment of the 2.3.1 message to report influenza test result data from public health laboratories to CDC.
    c. Currently reporting live flu data for 47 states.
    d. Seven additional laboratories in testing and validation
2. The Presidents Emergency Program for Aids Relief (PEPFAR), - established standards for selection and implementation of Laboratory Information Management Systems in numerous African countries.
3. The Electronic Laboratory Reporting Technical Assistance,
    a. Provided comment and input to the development of Stage 2 meaningful use standards and regulations
    b. Provided resources to drive the update of HL7 2.5.1 ORU Implementation Guide R2.
    c. Provides(ed) technical assistance to develop and deploy technical capabilities to send and/or receive HL7 2.5.1 ORU messages in compliance with MU requirements.
    d. Engaged and/or completed over 65 limited scope projects to date.
4. Vaccine Preventable Diseases,
    a. Built on success of PHLIP
    b. Expanded messaging to included Measles, mumps, rubella and pertussis.
    c. Successfully completed the pilot project of 4 jurisdictions and currently working on requirements for stage 2.
5. All projects involve(d) implementation, expansion and validation of LOINC and SNOMED coded standards.

APHL's comments will focus on data standards as related to laboratory reporting to and data exchange with public health agencies.

- **Current state of public health related standards;**

Laboratories reporting to public health may include hospital clinical labs; government sponsored public health labs, commercial labs, environmental labs, agricultural labs as well as individual providers. In most cases, the reportable laboratory result, and related public health reporting originates in a laboratory information management system (LIMS) and NOT in a traditional electronic health record. Many, if not most, such labs have long established and highly efficient LIMS implementations. Such systems are as varied as the type of entity, ranging from commercial off the shelf systems to customized and/or locally developed applications. These are often highly customized or focused on a specific laboratory type, function or area. In the interest of reporting efficiency, laboratories developed a variety of non-standardized approaches to electronic reporting and data exchange. While these data exchange methodologies were often highly efficient on an individual basis, they did not promote or facilitate true interoperable data exchange.

This is not to say that standards based ELR/ELSM implementations are non-existent in the public health laboratory domain. Beginning over 8 years ago, APHL worked with public health laboratories to implement a standardized HL7 2.3.1 message format with standardized LOINC coding for reporting of influenza test results to CDC. To date, 47 of the 56 ELC grantee laboratories are sending live flu surveillance data to CDC using the PHLIP program. In addition, under the Laboratory Technical Implementation Assistance for Public Health (LTIAPH), Electronic Laboratory Reporting Technical Assistance (ELRTA) and Vaccine Preventable Diseases (VPD) projects, APHL directly assisted at least 28 jurisdictions develop technical capability to support sending and/or receiving of HL7 2.5.1 message formats including standardized LOINC and SNOMED coding. However, in most jurisdictions, this capability does not extend to the full spectrum of reportable disease notifications, usually due to fragmentation and programmatic limitations of disease surveillance systems within the public health agency. Over the years, public health programs have implemented disease surveillance systems in multiple siloes. While the CDC sponsored NEDSS based systems were widely adopted to collect case report data, many programs, such as HIV, STD, etc. often elected to adopt unique and highly customized surveillance systems.

With the exception of hospital based laboratories, none of the aforementioned entities are incentivized under the HITECH or Meaningful Use (MU) regulations. As such, fiscal and operational challenges inhibit the motivation to upgrade or modify existing electronic reporting systems. In addition, many public health agencies are not yet prepared to fully accept and utilize ELR messages as specified under MU, and the drive to upgrade is even further hampered. However, it is very encouraging to recognize that most commercial LIMS vendors as well as any number of integration engine technologies have emerged to facilitate adoption of the newest and most progressive standardized messages and data sets.

As indicated in the preceding paragraphs, the experience of APHL would indicate the current state of public health related standards is highly fragmented. As evidenced by the wide adoption and utilization of PHLIP, those programs with the greatest longevity see the highest level of adoption and utilization. Those with less longevity, particularly those requiring large investments in technology upgrades see significantly smaller penetration in the public health community. However, it is encouraging to see the momentum towards adopting data standards is increasing across the board.

- **coordination of standards development activities;**

Over the last two years, the S&I Framework have been critical as a facilitator for standards development activities. Although federal funding has been minimal, the various associations and stakeholders have

contributed time, effort and money to support the ongoing efforts of S&I Framework. While these activities have driven unprecedented collaboration among wide ranging organizations and interests, they could have been far more effective with greater funding and coordination efforts.

A few key examples include the Laboratory Results Initiative which facilitated development of key definitions and guides for implementing ELR in compliance with Stage 1 MU. This workgroup also facilitated the update and balloting of release two of the IG to facilitate greater compliance and easier implementation of ELR in as we approach Stage 2 MU. Further, the Public Health Reporting Initiative gathered subject matter experts from across the multiple PH reporting focus groups to develop a consolidated approach to future public health reporting regulations and to harmonize specified data across the public health domain.

- **representation and participation by public health in standards activities;**

APHL believes current public health participation in standards development activities occurs largely through the respective associations. With a few, very notable exceptions, state and local public health officials have little or no ability to participate in standards development activities on a national level. With the highly constrained state and local government budgets, representative public health entities are experiencing significant funding cuts. In addition, the current fiscal climate at the federal level threatens continued funding for required programs and activities. The resulting staff limitations and time challenges force them to forego participation in these national work groups in order to accomplish work of higher urgency and/or priority. In addition, many state and local public health entities struggle with acquiring and/or developing employees with requisite skill sets to effectively work with the larger national initiatives. Finally, the requirement to support state and local regulations, which are often in conflict with national rules, impacts the ability and effectiveness of participation by state and local representatives.

- **Where is public health strongest and where is it weakest?**

By far the strongest element of public health is the dedicated and determined work force. Those who choose public health careers are truly dedicated to the enhancement of population health and the prevention of disease. Recognizing the limitations of existing technology as deployed and utilizing whatever tools at their disposal, public health practitioners effectively track, investigate and resolve outbreaks of disease and threats to the general population health.

Major weaknesses of public health, particularly with respect to data standards include the conflict between state and federal regulations and data needs, educational gaps with respect to federal data standard requirements and, limitations placed on public health by the move to centralized or shared IT services.

As evidenced on a recent nationwide call of MU participants, numerous local and state public health jurisdictions require reporting of individual data elements which are not required in the national standards. This conflict results in the certification of technology to meet federal standards, the adoption and utilization by reporting entities, and resistance on the part of jurisdictions to accept and certify compliance by those entities due to insufficient data. This is an ongoing conflict which public health is still working to resolve. Greater participation by local and state public health entities would help to facilitate the inclusion of additional required data elements into national standards, harmonize these data sets among multiple jurisdictions and educate the local and state entities with respect to Federal guidelines.

APHL recently published a paper on the effects of centralized IT services on the ability of public health to

deploy effective IT solutions. Among the major conclusions were: 1) health IT and public health reporting in particular are among the most rapidly changing of the various IT environments. 2) Centralized IT solutions generally decrease the overall IT budget and severely impact the ability of public health entities to keep pace with the evolution of reporting standards and 3) As a general rule, centralized IT departments have no effective knowledge of the public health function.

- **What are the incentives and drivers for adopting and using public health data standards;**

However, if the jurisdiction can overcome the hurdle and achieve an effective implementation, rewards are significant. In our experience, the most notable reward is that resources are deployed far more efficiently and effectively. In one local jurisdiction, we found a PhD level scientist functioning as a clerical analyst to resolve error messages on a non-standardized electronic laboratory reporting platform. Upon assisting the jurisdiction with an MU compliant ELR implementation, this scientist was able to return to his duties as an epidemiologist.

Major current drivers to implementation of national data standards include the movement of ELR from elective to core in stage 2 of MU. By October 1, of this year each state was required to publish their capability, or lack thereof to support MU compliant ELR.

  - **What are the barriers and challenges?**

Barriers to adoption of national data standards are many. As noted above, the public health community does not, in general receive targeted funding to support the adoption of standardized and harmonized data sets. With challenged budgets and already strapped resources, public health entities simply lack the manpower to initiate large implementation projects. Local and state jurisdictions are challenged to acquire and maintain deep knowledge and understanding of the constantly evolving national data standards landscape. In addition, long established and well ingrained business processes discourage the risk associated with moving to standardized electronic procedures.

- **What is the state of information exchanges of public health data from EHR systems; what are the standards being used?**

As previously noted, laboratory reporting does not utilize traditional EHR systems. As such, APHL is less qualified than other representatives to testify on that subject. However, we can state that LIMS systems achieving modular certification to the 2011 CMS standard were disappointingly unable to provide MU compliant ELR. Since ELR was elective for stage 1, most eligible hospitals simply elected to postpone ELR implementation. For those entities choosing ELR for stage 1, it was generally necessary to employ a modularly certified integration engine to develop MU compliant ELR messages. We are only beginning to see deployment of LIMS certified to the 2014 standard and the effectiveness of those LIMS systems remains to be seen.

  - **what are the drivers, and incentives;**

Major drivers and incentives are identical to those discussed above.

  - **what are the challenges and issues**

While the challenges and issues are as stipulated above, funding stands head and shoulders above all others. Achievement of truly interoperable laboratory reporting requires the upgrade of the LIMS and/or the implementation of very expensive public health reporting modules. At least one widely deployed LIMS system requires a complete re-implementation to deploy the latest version. Such a re-implementation requires a significant funding premium over a simple upgrade and many reporting entities, especially including public health laboratories have difficulty securing adequate funding. In addition, the rush to Stage 2 MU has challenged the ability of some commercial vendors to keep up with

the demand on experienced implementation consultants.

- **What are implementation challenges from the public health agency perspective; what are the needs (technical, resources, education, etc.) to advance adoption and use of standards by public health agencies**

Public health agency challenges are consistent with those outlined above, specifically:

1. Lack of ability to be involved in the development of national standards.
    a. Challenges the ability to know and understand the intricacies of national standards.
    b. Leads to conflict between local/state implementation requirements and national standards.
2. Inability to acquire and/or educate personnel on the applicability, requirements and interpretation of national data standards.
    a. Generates misunderstandings between reporting entities and public health entities.
    b. Causes delays in implementation of important initiatives and decreased ability to support private sector compliance.
    c. Requires significant and expensive rework to correct systematic errors.
3. Funding
    a. Unable to purchase required technology upgrades
    b. Unable to purchase required new technologies
    c. Unable to hire contractors for design, implementation and deployment of needed systems.
    d. Unable to retrain existing staff or hire new skill sets.

- **How is privacy and security covered in public health data standards? Are there privacy and security elements embedded in the standards? Is privacy and security under a different workflow process?**

Privacy and security processes are imbedded in the existing workflows and have been a primary concern of public health entities for many years.