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March 25, 2014

Dr. John Halamka
Chairman, Standards Task Force
Health Information Technology Standards Committee
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services

Dear Dr. Halamka:

HLN Consulting, LLC is a health information technology services company that has been working to promote standards in public health for many years. For immunization, HLN is concerned that recommendations being discussed by the Standards Task Force will undermine the rapid progress towards bidirectional interoperability between IIS and EHRs. We urge the Task Force to revisit preliminary discussions on Stage 3 use of immunization history to improve population and public health that took place during the Task Force's March 24th meeting. HLN strongly supports:

- Inclusion as Core the requirement for EPs, EHs, and CAHs to receive a patient's immunization history supplied by an immunization registry or immunization information system.
    - Inclusion as certification criteria the ability to receive and present a standard set of structured, externally-generated immunization history and capture the act and date of review within the EP/EH practice
- Inclusion as certification criteria the ability to receive results of external clinical decision support (CDS) pertaining to a patient's immunization
- For transport, continuation of SOAP web services requirements, specifically the Center for Disease Control and Prevention's (CDC) Transport Layer Expert Panel WSDL Specifications as these specifications are already used by IIS and meet the EHR to IIS use case better than Direct.

The remainder of this letter will be devoted to sharing our perspective and statistics demonstrating the argument for supporting the above recommendations.

Inclusion of a requirement for EPs, EHs and CAHs to receive a patient's immunization history from an IIS and to receive results of external clinical decision support (CDS) pertaining to a patient will provide critical support of the significant progress that has already been made. The Query/Response HL7 standard is mature enough to deal with both data retrieval and CDS, and

implementation is underway across the nation. This standard was supported by the recommendations of a workgroup convened by Public Health Informatics Institute in February 2013 to identify, define and document a standardized use case for bidirectional query and immunization information exchange. The expert workgroup included 24 subject matter experts with backgrounds in IIS, national policy and EHR systems. This workgroup recommended the HL7 QBP/RSP standard, as currently defined in the version 2.5.1 implementation guide, as the optimal message format to send back to an EHR system.[1] Initial data from the Quarterly IIS Meaningful Use survey administered by the CDC show that 22 IIS are engaged in some level of Query/Response (QBP/RSP) efforts as of December 2013. Of the 22, 14 are in production. These responses reflect IIS as of December 2013. Additionally the CDC WSDL being implemented in IIS supports both VXU submission and Query/Response. We also know that 100% of IIS can produce a clinical decision support via their IIS User Interface, so the functionality to produce decision support already exists. The functionality to interoperate may need to be built, but in the case of immunization-based CDS, the logic is more complicated than the population of the message, so the primary hurdle for implementation has already been overcome. As Stage 3 is several years in the future, HLN strongly believes that the vast majority of IIS will be prepared to support Query/Response and CDS in a standard way.

Public Health justification for inclusion of both data retrieval and CDS is strong. When a patient presents in a medical office, the clinician needs to know the current history of the patient for the immunization clinical decision support to be as accurate as possible. IIS have a long history of creating, maintaining and updating clinical decision support guidance for immunizations. IIS clinical decision support for immunizations includes recommendations for vaccines due on the date of each encounter and dates on which vaccines are due in the future. IIS take into account critical information such as age of the patient, minimum and maximum administration dates for each vaccine based on individual vaccine recommendations, dates of prior immunizations (including validation of prior doses), contraindications, history of disease, and substance refusal reasons. A great amount of time is spent on immunization clinical decision support; there is a unique expertise that is required as there are technical aspects and nuances of each vaccine that need to be understood, including the dynamic nature of the recommendations themselves which require on-going maintenance. The CDC has published guidelines for IIS clinical decision support, so there is one authoritative venue for ensuring that IIS CDS is correctly coded based upon ACIP recommendations.[2] Some states allow for flexibility or local variations in the schedule, and this flexibility is already supported by IIS.

It is worth noting that though IIS have been providing decision support guidance to provider EHRs for some time, today this is done primarily in the context of well-documented HL7 RSP messages from IIS in response to QBP queries from EHRs. We know of at least one major ambulatory EHR vendor that is accessing a CDS service for immunization in their latest production version which uses HeD standards (that would be HLN's ICE Open Source product used by eCW). The service they are using was developed cooperatively by a public-private partnership which included two public health agencies. HeD standards provide a more specialized way to enable this functionality, and

[1] Developing Nationwide Consensus on Bidirectional Query Immunization Information Exchange: http://www.phii.org/resources/view/5523/Developing%20Nationwide%20Consensus%20on%20Bidirectional%20Query%20Immunization%20Information%20Exchange

[2] http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html

likely IIS will move to supplement or replace their CDS capabilities to use these standards. Based on these facts, we suggest that the *standards* behind the CDS measure for immunization be loosened (but not eliminated) to include *either* HeD *or* the receipt of CDS information within an HL7 RSP message.

On the matter of transport of immunization data, HLN reiterates our long standing support for SOAP web services, specifically the CDC Transport Layer Expert Panel (TLEP) WSDL Specifications.[3] While there is a use case for Direct in other medical arenas, there is a strong argument against it and for SOAP web services for the immunization space. Direct was considered for an IIS use case by the CDC TLEP, but because Direct does not support synchronous response, which impedes the long term need for Query/Response to support bi-directional communication, SOAP was selected instead of Direct as the recommended transport layer. The December 2013 AIRA Quarterly IIS MU Survey referred to above also provides data on transport. Thirty-nine (39) of fifty-four (54) respondents are engaged in SOAP as their Transport. Of those thirty-nine, thirty-two (32) are in production, and twenty-four (24) are working directly with the CDC WSDL. By supporting web services as a Stage 3 standard, the Task Force will support better positioning both IIS and EHRs for Query/Response. We understand that the committee is strongly recommending the use of Direct, but this is only after the committee concluded that Query/Response was not something IIS could support in the time frame necessary for Stage 3. Since we do believe that Query/Response is feasible in this time frame, we feel (for the reasons stated) that web services continues to be the right strategy and investment for supporting both data submission and query/response between and EHR and an IIS.

We sincerely appreciate the opportunity to provide comments on the Standards Task Force of the HITSC Stage 3 recommendations and hope that our comments are helpful. If you have any questions regarding our comments or need additional information, please contact me at arzt@hln.com or 858-538-2220.

Sincerely,

Noam H. Arzt, PhD, FHIMSS
President

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Charlie Ishigawa, Executive Secretary, JPHIT Secretariat
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[3] http://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/ehr-interop-trans-layer-tech-recs.pdf