Health IT Standards Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

February 12, 2015

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo,

In response to the recommendations from the Data Provenance Task Force, the Health Information Technology Standards Committee (HITSC) was asked to provide your office with recommendations around the next steps and focus areas for the Data Provenance Standards and Interoperability (S&I) Initiative. This transmittal offers these recommendations.

These recommendations are informed by the Final Consented Use Case[1] and an Executive Summary[2] of the Use Case from the Data Provenance S&I Initiative; deliberations among the Data Provenance Task Force subject matter experts, and presentations from relevant stakeholders.[3]

Background:

In April 2014, the Office of the National Coordinator for Health Information Technology (ONC) launched the Data Provenance S&I Initiative to identify the standards necessary to capture and exchange provenance data, including provenance at time of creation, modification, and exchange.

At the November 18, 2014 HITSC meeting, ONC proposed the time bound interdisciplinary Task Force Model as part of the HITSC Efficiency presentation[4]. During that meeting, the Data Provenance Initiative ("Initiative") provided an update and asked the HITSC for feedback and advice[5]. The HITSC recommended that a Data Provenance Task Force ("Task Force") be formed to address the specific question (charge) and three supporting questions from ONC below:

> *Given the community-developed S&I Data Provenance Use Case, what first step in the area of data provenance standardization would be the most broadly applicable and immediately useful to the industry?*

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[1] http://wiki.siframework.org/file/view/DPROV%20Use%20Case%20_%20Final%20Consented%20Use%20Case_10.16.2014.pdf/527056914/DPROV%20Use%20Case%20_%20Final%20Consented%20Use%20Case_10.16.2014.pdf
[2] http://healthit.gov/FACAS/sites/faca/files/HITSC_DPROV_Use_Case_Exec_Summary_2014-11-18.pdf
[3] Speakers included: Robert Deiterle, CMS, esMD; Reed Gelzer, HL7 Records Management-Evidentiary Support Workgroup; Gary Dickenson, CentriHealth; and Adrian Groper, Patient Privacy Rights
[4] http://healthit.gov/facas/sites/faca/files/HITSC_Efficiencies_Final_2014-11-18.pdf
[5] The HITSC has expressed the need to be involved earlier in the S&I process to provide feedback and advice, instead of hearing a report out towards the end or at the end of an initiative.

Supporting Questions:

1. *Do the 3 scenarios in the Use Case, and the Use Case's identified scope, address key data provenance areas, or is something missing?*
2. *The Use Case is broad and spans a lot of challenges. Where in the Use Case should the Initiative start in terms of evaluating standards to meet Use Case requirements?*
3. *Are there any architecture or technology specific issues for the community to consider?*

In January 2015, the Task Force[6] convened three meetings to review and discuss the Initiative Use Case and Executive Summary, listen to stakeholder presentations, and produce recommendations to address the Task Force Charge given by ONC. During these meetings, the Task Force heard from different stakeholder perspectives including CMS and the Electronic Submission of Medical Documentation (esMD) S&I Initiative, records management, patient privacy rights, and the HL7 EHR Functional Model project.

The Data Provenance Task Force presented its recommendations to the HITSC on January 27, 2015[7].

The recommendations presented herein respond to the Task Force Charge and the three supporting questions asked of the Task Force.

The Task Force's highest level recommendation comes from its conclusion that the Initiative Use Case may be over specified and recommended that the Initiative focus on the following priority areas:

- Where did the data come from? ("source provenance")
- Has it been changed?
- Can I trust it (the data)?

Recommendations:

To address the priority areas recommended by the Task Force, the HITSC recommends the following:

1. The Initiative should begin its focus from the perspective of an EHR, including provenance for information created in the EHR ("source provenance") and when it is exchanged between two parties. Provenance of the intermediaries is only important if the source data is changed.

   The notion of "who viewed/used/conveyed without modification along the way" is not important for provenance, as long as the information was not changed.

2. Clearly differentiate between Communication/Information Interchange Requirements and System Requirements. The HITSC acknowledges that both are important. For the purposes of the Initiative Use Case, start with the assumption that at the point of information interchange, the "source provenance" is good, complete, and trusted.

[6] For Task Force Members and Charge, see: http://healthit.gov/FACAS/sites/faca/files/DPROV_HITSC_TF_2015_01_06_FINAL_0.pptx
[7] http://healthit.gov/FACAS/sites/faca/files/HITSC_DPROVTF_Final_Recommendations_2015-01-27_Final_0.pptx

a. Address Communication/Information Interchange Requirements
   - As a basic requirement, converting between different transport protocols should retain the integrity of the provenance data relating to the payload/content.

b. Address System Requirements for provenance (including "source provenance") by looking at provenance data at time of import, creation, maintenance, and export.
   - This should be agnostic of transport technologies
   - The Initiative should also consider the FDA Project, Guidance and Regulations. (There are 12 requirements and use cases for the use of EHRs and eSource applications (e.g. patient reported information/eDiaries) requiring provenance described in an *eSource Data Interchange Document*[8], which includes a definition for "the source" and regulation for Electronic Records.

3. Consider the definition of "change" to data (for example, transformation with no intent to change the meaning of the data such as content format, terminology, or feature extraction, versus substantive changes such as amend, update, append, etc.) and the implications for provenance. If the content changes, the change should be considered a "provenance event".

4. Consider the security aspects such as traceability, audit, etc., and the impact on the trust decision.

5. If applicable, capture policy considerations and request further guidance from the HITPC.

6. Clearly differentiate a set of basic/core requirements for provenance and address the Initiative Use Case in the following priority order:
   a. With exchange of data between EHRs
   b. At the point of origin/data creation in an EHR or HIE
   c. With the transfer of data from a Patient Controlled Device (PCD)/PHR to an EHR system
   d. At the point of data creation in a PCD or PHR

7. Add CDISC Operational Data Model (ODM)[9] to the candidate standards list

8. Consider if there are related requirements that may have implications for provenance (i.e., regulatory, program specific), for example:
   a. Medical Record retention
   b. Data receipts
   c. esMD (digital signatures)

[8] http://www.cdisc.org/system/files/all/reference_material_category/application/pdf/esdi.pdf
[9] http://www.cdisc.org/odm

9. With regards to architecture or technology specific issues, the HITSC recommends that the Initiative:
    a. For Content: Consider related work in HL7 projects (for refining provenance capabilities for CDA/C-CDA while supporting FHIR), such as:
        - CDA/C-CDA provenance
        - FHIR Provence Project
        - Privacy on FHIR Projects

    b. For Information Interchange: The integrity of the provenance data for clinical content should remain intact during transport.

We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/	/s/
P. Jon White	John D. Halamka
Chair, Health IT Standards Committee	Vice Chair, Health IT Standards Committee