

**National Council on Vital and Health Statistics
Work Group on Computer Based Patient Records**

**Testimony on Data Quality, Accountability and Integrity
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Good Morning, Mr. Chairman and Members of the Working Group. My name is Gary Dickinson and I am Manager of Healthcare Standards for Per-Se Technologies, Incorporated.

Per-Se Technologies is a global leader in delivering integrated financial and clinical software solutions, comprehensive business management services, and Internet-enabled connectivity. Per-Se Technologies enables healthcare provider organizations, integrated delivery systems and physician practices to simultaneously optimize the quality of care delivered and profitability of business operations. Ranked the third largest HIT and services company worldwide, Per-Se Technologies employs 6,400 and supports more than 18,000 physicians and 2,000 healthcare organizations. Per-Se Technologies processes more than 80 million healthcare claims annually and its solutions manage over 20 million patient lives online.

I co-chair the HL7 Special Interest Group on Accountability, Quality and Performance. I also lead the Architecture Sub Group of ISO Technical Committee 215 on Healthcare Informatics, Working Group 2 on Messaging and Communications. As Per-Se's representative, I am active in a wide variety of standards development activities in the U.S. and internationally, focusing primarily on healthcare informatics standards.

Question 1A: How would you define or describe PMRI?

[Last March, Alfred S. Buck, MD, of the JCAHO offered the following description of PMRI in his written NCVHS testimony. Since Dr. Buck and I collaborated on this specific description I have taken the liberty to paraphrase it again here.]

For each individual patient or health plan member, PMRI forms an essential chronicle of health status and interventions. It can include demographics, orders, schedules, clinical pathways (e.g., care plans and protocols), observations, diagnoses/problems, allergies, medications, etc. For clinical service events, PMRI describes the clinical and operational context and ascribes accountability: who, what, when, where and, as applicable, why, how and under what conditions.

PMRI is encompassed in a personal health record for individual patients and health plan members. PMRI is also a foundation to the operations (business) record for health care providers and to the service record for individual healthcare professionals.

PMRI forms a longitudinal chronology with essential views:

- .1 Prospective (future view) - pending, scheduled events (including preventive and wellness);
- .2 Concurrent ("now" view) - events currently "in progress";
- .3 Retrospective (past or historical view) - completed events.

Question 1B: Why is comparable PMRI required, what functions does it serve?

- It ensures trust, confidence.
- It ensures validity of assessment, e.g.:

| To the Assessor, e.g.: | To the Assessed, e.g.: |
|--------------------------------------|----------------------------------|
| Healthcare Professional | Patient, Subject of Care |
| Accreditation Agency (e.g., JCAHO) | Health Plan, Healthcare Provider |
| Reporting Agency (e.g., NCQA) | Health Plan, Healthcare Provider |
| Regulatory Agency (e.g., DHHS, HCFA) | Health Plan, Healthcare Provider |

- It ensures the value of health services: to consumers, to purchasers.
- It allows clinical findings and trends to be validated and/or contrasted: e.g., health status indicators, vital signs, diagnostic results.
- It allows population measures and trends to be validated and/or contrasted: e.g., epidemiological surveillance, public health indicators, immunizations;
- It allows measures of clinical operation to be validated and/or contrasted: e.g., quality indicators, performance and outcome measures, costs, allocations/deployments.
- It highlights areas in need of improvement. It validates the results of improvement programs.

Question 1C: How comparable does PMRI information need to be for these purposes (i.e., how precise, how accurate)? What are the consequences if the PMRI is not accurate?

Comparability, accuracy, precision (and consistency, continuity, completeness and persistence) are essential characteristics of data integrity/quality. There is a direct trust correlation between these issues. The greater the assurance of data integrity/quality, the greater the level of trust.

The healthcare industry is awash with many examples where conclusions are suspect and/or cannot be fully validated due to issues of underlying data integrity/quality. This problem is pervasive and seriously compromises many clinical, claims/payment, reporting and measurement programs. The most impaired are often those furthest downstream from the point of data origination.

Consider particularly where data:

- Is managed (stewarded) by multiple systems, from its point of origination (e.g., point of service/care) to its ultimate point of use (e.g., point of report).
- Has traversed one or more points of interchange between systems, via interfaces and/or mediators (e.g., interface engines, hubs);
- Has passed through one or more points of translation or remapping: e.g., translations from one coding/classification scheme to another, clearinghouse remapping of source to target datasets;
- Is converged from multiple highly disparate sources.

Question 2. What is the role of data quality, accountability, and integrity to achieve comparable PMRI?

To ensure the utmost degree of confidence and trust, they are imperative characteristics (requirements) which must be both measurable and verifiable. They form crucial requirements for information management practices (both manual and automated), system architectures and healthcare informatics standards, particularly data interchange and vocabulary standards.

Question 2A: Is the current state of data quality, accountability, and integrity impairing our ability to measure outcomes, quality, or performance? If so, please describe?

As suggested previously, the impairment is profound and pervasive. The impairments are manifest in the disparities introduced by, and inherent in, the industry's continuing reliance on:

- Multiple disparate systems, data and functional architectures;
- Lowest common denominator data interchange standards;
- Mediation between applications: e.g., interface engines, hubs;
- Data translation from original to a transmuted form;
- Remapping to alternate data structures;
- Data type conversion.
- Data aggregation, summarization and derivation.

The response to the next question identifies additional areas of impairment.

Question 2B: What are the specific problems or limitations impacting data capture, encoding, translation, transformation, auditability, decoding, or presentation processes?

In the HL7 SIG on Accountability, Quality and Performance, we have focused on specific data integrity and quality issues. Our findings are as follows:

Accountability:

Designation of accountable healthcare parties is often inconsistent or incomplete, including:

- Individuals: e.g., healthcare professionals, authors/scribes/verifiers of data content, stewards and users of data content;
- Organizations: e.g., healthcare providers, health plans, payers;
- Business units: e.g., departments, services, specialties.

Designation of accountable healthcare agents is often inconsistent or incomplete: e.g., software, devices.

Designation of healthcare parties with ascribed accountability for the provision, performance and completion of health services is often inconsistent or incomplete.

Designation of healthcare parties/agents with ascribed accountability for data origination, amendment, verification, translation, stewardship, access and use, disclosure, transmission and receipt, is often inconsistent and incomplete.

Designation of accountable actions is often inconsistent and incomplete. [See following examples.]

Persistent evidence of accountability for data origination is often missing or difficult to track: who, what, when, where, how, under what conditions, in what context.

Persistent evidence of accountability for data amendment is often missing or difficult to track: who, what, when, where, how, why, previous data state, new data state.

Persistent evidence of accountability for data verification is often missing or difficult to track: who, what, when, where, data originator (e.g., other healthcare professional, an automated device, instrument/monitor).

Persistent evidence of accountability for data stewardship, access, use and chain of custody is often missing or difficult to track, from point of origination to point of use: who, what, when, where.

Persistent evidence of accountability for data translation is often missing or difficult to track: who, what, when, where, by what convention/method, by what authority, from/to coding and classification scheme, original (unaltered) data state, new translated data state.

Persistent evidence of accountability for data remapping, including data type conversion, is often missing or difficult to track: who, what, when, where, by what convention/method, by what authority, from/to dataset, original (unaltered) data state, new remapped data state.

Persistent evidence of accountability for data duplication, disclosure, transmission and receipt is often missing or difficult to track: who, what, when, where, by what authority or permission, for what purpose.

Complete auditability of data content is often impossible or difficult at best: e.g., tracking end-to-end information flow and accountable actions by accountable parties along that path, across multiple points of interchange, among and between multiple disparate systems; original and successive data states; forward (downstream) and backward (upstream) audit trails.

Data Definition:

Common and uniform data definitions are often lacking, both for atomic data elements and data aggregations (e.g., core/minimum/reference datasets).

Persistent evidence of accountability for data definition is often missing or difficult to track: who, what, when, where, by what convention/method, by what authority, previous data definition, new data definition.

Data definitions often change over time.

Coding and Classification:

Use of coding and classification schemes is often inaccurate, inconsistent or incomplete.

Coding and classification schemes are deployed unevenly, with some organizations encoding virtually all data, some a more limited set, some almost none at all.

Some organizations extensively deploy recognized national/international coding and classification schemes, some rely mostly on local or proprietary schemes, many use some combination thereof.

National/international coding and classification schemes are often supplemented with local or proprietary codes and classifications.

Coding and classification schemes, both national/international and local, are often supplemented with data in the form of free text strings.

Some organizations deploy national/international encoding at the clinical front-end (e.g., healthcare professionals are prompted to encode data directly at the point of service/care), some encode as an automated back-end function after the fact, some use a manual back-end encoding method, some encode as a function of downstream data interchange (e.g., via mediators/interface engines).

Data Translation:

Data translation is often inaccurate, inconsistent or incomplete: e.g., translation from one coding and classification scheme to another; translation of human language.

Data translation is often conveyed downstream with the newly translated data content but not the original unaltered data.

Such lapses:

- Breach data authentication and validation conventions; and

- Expose data content to repudiation of authorship.

Data translation is often accomplished without specific notation, and/or without persistent evidence, of:

- Translation to identical term(s);

- Translation to presumed equivalent, but not identical, term(s);

- Translation to term(s) with greater precision or granularity;

- Translation to term(s) with lesser precision or granularity;

- Translation to arbitrary, non-equivalent term(s);

- Translation to null term(s).

Data Aggregation, Summaries and Derivations

Data is often aggregated, summarized and/or derived incorrectly or inconsistently.

Sampling methods are often incorrect or inconsistent.

Data is often reported in inconsistent units of analysis (e.g., inconsistent time span/bounds, dissimilar populations).

Specifications for functions of data aggregation, summarization and derivation are often interpreted incorrectly.

Defaults are often incorrect.

Cohorts are inconsistent over time.

Additional Data Quality Issues:

For both data elements and datasets, persistent evidence of data integrity/quality checks is often missing or difficult to track, from point of origination to point of use: e.g., checks for accuracy, consistency, context, comparability, continuity, completeness.

Data integrity/quality edits and reviews are often lacking or inadequate: data is inaccurate but unrecognized as such, data is inaccurate but within accepted limits.

Data is often embedded in text strings, not as discrete data elements. Subsequent data extraction functions (from free-form text strings) are invariably impaired.

Clinical data is often subject to origination, amendment, verification, translation or interpretation by individuals who lack sufficient clinical knowledge and/or mastery of clinical terminology.

Medical judgment often leads healthcare professionals to varied interpretations and conclusions from the same data.

Question 2C: What techniques, methods, standards, or technologies are needed to address these problems or limitations?

In response to this and as a lead-in to the next several questions, I would like to describe several initiatives in which I am currently engaged, each focused on key aspects of accountability and data integrity/quality.

HL7 SIG on Accountability, Quality and Performance

First is the HL7 SIG on Accountability, Quality and Performance which I co-chair with Carla Robelli of the JCAHO. The SIG itself does not craft standards but rather acts in an advisory capacity to the HL7 Technical Steering Committee and Technical Committees. We have charted a careful and deliberate approach to ensure that industry needs are properly identified and that recommendations and requirements statements are properly founded. In its brief tenure, a number of SIG work activities have progressed:

- Top Data Quality Issues. As referenced in response to a previous question, the SIG has developed a brief identifying top data quality issues. These provide a major focus for the SIG agenda and work plan.

- Points of Authority, Points of Reference. The SIG has drafted a list of key points of authority and points of reference on which to base SIG principles, objectives and work plan. Sources for these references include JCAHO, NCQA, DHHS, HCFA, the GCPR project, IOM, NRC, NIST, ISO and others.

Principles and Objectives. The SIG has drafted a white paper outlining key principles, objectives and areas of focus, including:

- Ensured trust
- Trust and accountability constituency
- Health information rights, including privacy and confidentiality of individually identifiable data
- Health information obligations, including accountability
- Health information components and composition
- Health care parties and their accountable actions
- Health care agents and their accountable actions
- Scope of accountability, unit of accountability
- Trusted end-to-end information flows
- Authentication, attestation, non-repudiation, digital signature
- Auditability
- Chain of custody
- Faithfulness, persistence, non-alterability
- Data definition, data registration
- Data integrity/quality

Trust and Accountability Constituency. The SIG has drafted a roster of healthcare parties who make up the trust and accountability constituency for health data and information.

As subjects of health information: e.g.,

- Individual patients, health plan members
- Individual healthcare professionals, caregivers
- Individual originators of health information, as authors, scribes, verifiers
- Organizations: healthcare providers, integrated delivery networks, health plans...
- Business units: departments, services, specialties...
- Others: next of kin, employers, guarantors...

As accountable parties participating in the provision, performance and completion of healthcare services and whose accountable actions are (or should be) ascribed in health data and information: e.g.,

- Individual healthcare professionals, caregivers
- Organizations
- Business units

As accountable parties participating in the origination, amendment, verification, translation, stewardship, use, transmittal and receipt of health data and information and whose accountable actions are (or should be) ascribed therein:

- Individual healthcare professionals, caregivers
- Organizations
- Business units

Privacy and Confidentiality Protections. The SIG has noted that various parties have inherent rights and expectations regarding privacy and confidentiality protections for their individually identifiable information. The SIG has agreed that these protections are a primary overriding objective for the SIG agenda and work plan.

Accountable Parties. As noted above, the SIG has drafted a description of accountable healthcare parties: individuals, organizations, business units.

Accountable Agents. The SIG has drafted a description of accountable healthcare agents: software, medical devices (e.g., instruments, monitors).

Accountable Actions. Also as noted above, the SIG has drafted a description of accountable actions (significant to the SIGs domain of interest):

- Provision, performance and completion of health service events (and the capture of data relevant thereto);
- Origination or amendment of data content: as author, scribe or verifier;
- Accuracy and completion of data content;
- Translation or remapping of data content;
- Access to, or use of, data content;
- Stewardship of data content;
- Duplication of data content;
- Disclosure, transmission or receipt of data content;
- Aggregation, summary or derivation of data content.

Data Definition, Data Registration. The SIG has identified data definition and data registration as a key foundation to the assurance of data integrity/quality. The registry should include both data elements and datasets.

For HL7 v2.x and v3 data and datasets, the SIG is drafting a recommendation for HL7 to become a registration authority in the U.S. Health Information Knowledgebase (U.S. HIK), a data registry project now proceeding under the auspices of the ANSI HISB and underwritten by HCFA (in the first year).

The SIG also intends to be proactive with other SDOs, vocabulary (i.e., coding and classification) developers, regulatory, accreditation and reporting agencies to encourage broad industry participation in the U.S. HIK. Each organization can be granted its own standing as a registration authority (for its data and dataset definitions).

Data Registration and the HL7 v3 Message Development Framework (MDF). The SIG is drafting a recommendation for the U.S. HIK to be engaged in formal steps in the HL7 v3 message development process and is suggesting corresponding revisions to the MDF, as follows:

As new data elements and datasets are contemplated for inclusion in HL7 Standards, HL7 Technical Committees and Special Interest Groups should consult the U.S. HIK for similar and existing data constructs and usage. Any standing precedents should be seriously considered prior to creating new HL7 data elements or datasets.

As the ballot process is completed for each successive version of HL7 Standard(s), newly introduced and revised data elements and datasets should be formally registered in the U.S. HIK.

Data Registry - Data Elements. For atomic data elements, the SIG is recommending data definition/registration to include:

Naming, identifiers;
Precise usage;
Data type, format, unit of measure;
Range, if applicable;
Domain, if applicable: e.g., coding or classification scheme; AND
Measures and rules to ascertain, for a given data element instance: accuracy, consistency, comparability, continuity, completeness.

Data Registry - Datasets. For datasets, the SIG is recommending data definition/registration to include:

Naming, identifier(s);
Precise usage;
Data element aggregation and structure (e.g., hierarchies, repeating elements or groups); AND
Measures and rules to ascertain, for a given dataset instance: contextual data relationships; data inter-dependencies; consistency, comparability, continuity, completeness.

Data Registry - "Observation" Data Elements. The SIG is drafting a recommendation regarding use of the open "observation" data construct (known in HL7 v2.x as the OBX Segment). The "observation" data construct allows repeating data name/value pairs in an interface message sequence. As an open interchange construct, HL7 has not defined specific data elements or datasets, although this space is neatly filled by vocabulary developers such as LOINC. In terms of the "observation" construct, it is the SIG's recommendation that interface implementers use common, uniform data definitions from open, public data registries (such as the U.S.HIK) to the greatest extent possible - and particularly in preference to creating their own new data elements, datasets and related definitions.

Persistent Context Templates. The SIG has followed the lead of the HL7 Vocabulary TC in recommending a series of persistent context templates, which are intended to track data and information flow from point of origination to ultimate point of use:

Accountability Context.

Evidence of the provision, performance and completion of healthcare services: who, what, when, where, why, how, under what conditions, in what role (as applicable).

Evidence of data source or authorship, transcription, verification, translation, stewardship, access, use, duplication, disclosure, transmittal and receipt: who, what, when, where.

Data Integrity/Quality Context. Evidence that specific data integrity/quality rules and measures were engaged to ensure data and dataset accuracy, context, consistency, continuity, completeness, persistence (as applicable).

Clinical Context. Evidence of corresponding clinical context which may include data regarding:

Rationale;
Clinical parameters;
Clinical context, conditions;
Rules/measures to ensure continuity and completeness (of healthcare services);
Rules/measures to ensure compliance with standards of care/practice;
Measures/indicators for performance, quality and outcomes.

Operational Context. Evidence of corresponding operational context which may include data regarding:

Allocations, deployments;
Assigned responsibility;
Resource utilization: staff, time, facilities, equipment, supplies;
Measures/indicators of cost, productivity.

Trusted End-to-End Information Flows. The SIG has developed series of conceptual diagrams and a white paper on trusted end-to-end information flows. This exercise has:

Staged information flow from point of data origination (point of service/care) to point of use; from data source to data consumer; from clinical front-end to back-end repository to third party;

Traversing multiple points of interchange (interfaces);

Traversing multiple points of translation or remapping;

Concluding, in one case, at a point of use or point of report;

Concluding, in an alternate case, at a point of convergence, where data from multiple sources is aggregated, summarized or derived, then reported;

Included privacy and confidentiality protections for individually identifiable information;

Designated accountable parties, agents;

Designated accountable actions;

Demonstrated auditability, including: accountable actions by accountable parties or agents; data states (from original through each amendment); forward (downstream) and backward (upstream) audit trails;

Ensured faithfulness, persistence and non-alterability of data and information;

Demonstrated assigned responsibility;

Demonstrated chain of custody;
Ensured measurable and verifiable data integrity/quality: accuracy, consistency, context, comparability, continuity, completeness;
Demonstrated persistent contexts: accountability, data integrity/quality, clinical, operational.

Information Flow Modeling. The SIG is drafting a recommendation that HL7 regard end-to-end information flow models as integral to the suite of v3 foundational constructs. HL7's current v3 repertoire includes the Message Development Framework which describes the RIM and the progression therefrom to interface messages via use cases, stateful classes, state/transition models, application interaction models (pairing each set of transmitters and receivers), discrete application profiles (as the basis for conformance claims), high level message descriptions, implementable message specifications and ultimately encoded XML messages. The current MDF primarily focuses on the interchange space, point to point, between an arbitrary pair of application systems. From the SIG's perspective each point to point interface cannot be described only as an isolated instance but rather must also be considered in terms of its staging, sequence and data state in an end-to-end information flow.

Reference Information Model Supplements. The SIG is drafting a recommendation that HL7 consider various classes and subject areas for inclusion in the RIM. These include:

Data definition, data registration.
Accountability: for provision, performance and completion of healthcare services;
Accountability: as data source, author, scribe, verifier, translator, steward, user, transmitter or receiver;
Auditability: accountable actions by accountable parties; initial and successive data states; forward and backward audit trails;
Chain of custody;
Assigned responsibility;
Persistent contexts: accountability, data integrity/quality, clinical, operational;
Data aggregation, summaries and derivations.

The introduction of these classes and subject areas into the RIM forces a substantive shift in the HL7 modeling paradigm, in that the proposed additions have legitimate relationships with virtually all existing RIM classes. Think of how all/many RIM classes (and their attributes) may be subject to data definition, accountability, auditability, chain of custody, assigned responsibility and persistent contexts, etc. Think also in terms where any/all RIM classes (and their attributes) may be subject to data aggregation, summaries and derivations.

Use Cases. To illustrate specific needs for accountability and data quality, the SIG is working on several use cases, including:
Information flow for lab HEDIS reporting;
Immunization information flow;
Information flow for performance measurement.

Additional detail on the SIG agenda, work plan and current work products is available at this URL: <http://www.hl7.org>

[International Standards Organization, Technical Committee 215 on Healthcare Informatics \(ISO TC215\) Working Group 2 on Messaging and Communications](#)

As lead of the Architecture Sub-Group of ISO TC215/WG2, I have collaborated with a number of international experts in drafting a New ISO Work Item Proposal (NWIP), "Essential Characteristics Required to Enable Precise Messaging and Communication Standards". This ISO Technical Report establishes a series of requirements statements to guide developers of messaging and communications standards and to guide implementers of such standards. As a forward guidepost, it establishes a benchmark of achievement well beyond of the current state of the industry and the messaging and communication standards on which we depend.

This report draws on many of the same principles and objectives focused by the HL7 SIG but introduces them formally to the international standards arena. In July, this NWIP was affirmed by WG2 on a vote of 25-0-0, with 8 countries participating. In August, it was affirmed by the U.S. Technical Advisory Group (to ISO TC215) on a vote of 19-0-0.

[Health Level Seven Data Interchange Standard, Chapter 1, Section 7, Versions 2.3 and 2.3.1](#)
Published 1997 and 1999 respectively

In the Fall of 1996, I collaborated with Dr. Al Buck (JCAHO) and John Quinn (Ernst & Young and Chair, HL7 Technical Steering Committee), to declare the problem space/domain of the HL7 Standard, essentially what it is, what it isn't. This declaration appears in Chapter 1, Section 7 of the two most recent revisions of the HL7 Standard and includes many of the topics now on the SIG agenda. This is another example of requirements statements serving as a forward guidepost for standards development efforts.

Question 2D: Is the private sector making satisfactory progress to address these problems or limitations?

Progress is painfully slow and it is unclear as to whether the private sector has the appropriate incentives to act and/or commit necessary resources.

Question 2E: Is there a role that the government should play in this area that would yield results within the next four years? (For example, provide incentives, support for JCAHO or NCQA quality initiatives, support for quality standards development, etc.)

Four years is optimistic but anything is possible. Support for existing initiatives is crucial. Incentives provide an excellent boost - but should be reserved for serious partners in these endeavors.

Question 2F: Is there a role that the government should play in this area that would yield results within the next ten years?

Continue as described in the response to Question 2E.

Question 3: Is there a need to facilitate the inclusion of data quality, accountability, and integrity issues within standards development activities?

Yes. As previously described.

Question 3A: Can the private sector address this need satisfactorily?

There is little reason to believe that the private sector can shoulder this without government involvement and the inducement of substantial incentives.

Question 3B: Is there a role that the government should play to address this need?

The government should champion a coalition of healthcare industry organizations including key government, regulatory and accreditation agencies, standards developing organizations, providers, payers, vendors, consumers, employers and others. Prime participants should include:

U.S. government, regulatory agencies: DHHS, HCFA, CDC, FDA, the GCPR Group (DoD, VA, IHS);

U.S. accreditation and reporting agencies: JCAHO, NCQA;

Informatics standards coordination and developing organizations: ANSI HISB, ASC X12N, DICOM, HL7, NCPDP;

Vocabulary, coding and classification developers: LOINC, SNOMED, READ, ICD, CPT and others;

The government can offer support and incentives to those standards based initiatives currently underway, especially those focused on accountability and data integrity/quality. From our perspective, there is a substantial bias to follow the lead of the HL7 SIG on Accountability, Quality and Performance.

The government can engage its own agencies and offer incentives to non-government organizations (especially JCAHO, NCQA and the U.S. based SDOs). A basic strategy is to:

Characterize the problem space: e.g., data integrity/quality deficiencies, lack of trusted end-to-end information flows, disparate systems and architectures.

Establish objectives and rationale; then

Forge specific requirements statements; then

Set measurable milestones and benchmarks for achievement; and

Develop implementable technical specifications as open, consensus standards.

Specific areas of focus:

Facilitate common, uniform data definitions: register data elements and datasets in open data registries: U.S. HIK.

Describe "best practices" for data integrity/quality in cases where:

Data is forwarded from multiple disparate sources;

Data is translated, remapped or subject to data type conversion;

Data is aggregated, summarized or derived.

Encourage the use of recognized national and international vocabularies, coding and classification schemes. Preferably:

In place of free text entries;

In place of local or proprietary coding and classification schemes;

Without supplement by local/proprietary schemes or free text;

Via encoding at the point of data origination: point of service/care;

By individuals knowledgeable in clinical practice and terminology.

Designate the trust constituency for health data and information.

For members of the trust constituency, designate rights and obligations with regard to health data and information.

Designate subjects of health data and information.

For subjects, designate required privacy and confidentiality protections for individually identifiable information.

Designate accountable parties with regard to the provision, performance and completion of healthcare services.

Designate accountable parties and agents with regard to data source, authorship, transcription, verification, stewardship, access and use, duplication, disclosure, transmission and receipt of health data and information.

Designate accountable actions.

Establish auditability requirements: e.g., accountable actions by accountable parties, initial and successive data states, forward (downstream) and backward (upstream) audit trails.

Designate requirements for trusted end-to-end information flows.

Establish requirements for authentication, attestation, non-repudiation, digital signature.

Establish requirements for chain of custody tracking.

Establish requirements for data faithfulness, persistence, non-alterability.

From point of origination to point of use, establish requirements for persistent contexts (i.e., persistent evidence of): accountability, data integrity/quality, clinical, operational.

Open, consensus industry standards have to be motivated by strong leadership, driven to produce results. The HIPAA legislation has served to focus much energy around specific standards, serving particular purposes. As an industry, the HIPAA momentum needs to carry us forward into many new areas. Accountability and data integrity/quality are prime candidates for this continuing initiative and the long term benefits of this strategy will prove to be enormous!

Thank you.