Standardization of Information for
Burden Reduction and Post-Pandemic America
("Convergence 2.0")
June 21, 2021

Background/Problem Statement:

The framers of the Health Insurance and Portability Act of 1996 (HIPAA) had a vision for harmonized federal information and technology standards to achieve efficiency, simplicity and burden reduction in the U.S. health care system. This was groundbreaking at the time the HIPAA law was enacted. In certain areas like health care billing and payment, and a national identifier for providers, the law and its first implementing regulations succeeded. However, for other functions like prior authorization and health care attachments, it has yet to offer industry sufficient efficiencies to adopt at scale. In clinical systems, the American Recovery and Reinvestment Act of 2009 (ARRA) significantly advanced the standardization of common clinical data flows from provider to provider. These trends were augmented and accelerated by provisions of the 21st Century Cures Act and the Cares Act.

In the 25 years since passage of HIPAA, industry business models, data flows, and technologies have changed such that:

- Administrative and clinical data flows are frequently co-mingled and used in both the same and different systems or by the same entities – data can no longer be considered separate and distinct, or in silos;
- The electronic exchange of both administrative and clinical data has in some cases exceeded the uses envisioned by the HIPAA framers for health plans, providers and patients; for example, aligning components of clinical data with administrative processes (e.g., patient name and demographics) is critical for patient care in any setting, from acute care to public health to mobile apps;
- There are new kinds of actors involved in health data exchange that did not exist in 1996, and the scope of data sharing now encompasses social and behavioral services, public health, cost and quality assessment and research, in addition to HIPAA's original administrative uses;
- Transaction processing technology has migrated away from mainframe computing and batch processing (for which the basic X12 transactions like the 837 Claim were designed) and data sharing increasingly is accomplished with new technologies such as Application Program Interfaces (APIs) based on HL7's Fast Healthcare Interoperability Resources (FHIR) data standard and the use of mobile devices.

The **regulatory structures** established under HIPAA are less relevant to business needs in the 2020s. NCVHS has determined that there is broad industry need to **modernize the standards adoption** framework to support current needs, including **harmonizing clinical, public health, and other standards**

with HIPAA standards. The NCVHS Predictability Roadmap hearings identified a need to increase the timeliness of adoption and updating of the HIPAA standards.[1]

Furthermore, the recognition of Social Determinants of Health (SDoH) as a key factor in **patient wellness** and the fragility of the state-operated public health and vital statistics systems exposed by the pandemic (public health emergency) is affirmation of our assessment that there is a need to **revisit the HIPAA framework.**

Finally, the rise of the internet and empowerment of patients in the **bidirectional flow of their data** between and among providers, health plans and others, demands rigorous reflection on the **Privacy and Security** of data in general, and HIPAA specifically. Data flows common today did not exist at the time the HIPAA privacy and security frameworks were adopted by regulation, e.g., how HIPAA is statutorily limited to Covered Entities, but patient data now flows routinely to other parties who are not Covered Entities and are thus outside the safeguards of HIPAA.

Therefore, the National Committee on Vital and Health Statistics (NCVHS), in consultation with industry and other governmental affected agencies (e.g., ONC[2], CMS[3] and NIST[4]) proposes to embark on an expanded convergence project.

End Product: Actionable recommendations for specific federal agencies, states, localities and industry groups to collaborate in support of convergence goals specific to:

- *Regulatory framework*

- *Standards adoption and implementation*

- *Harmonization of clinical, public health, and other standards*

- *Bidirectional flow of data*

- *Privacy and security*

Project Timeline: 2 years overall, including Phase 1 (year 1) and Phase 2 (year 2)

Benefit to Patients, Providers, Payers, and the System-as-a-Whole:
Standardized data capture and improved availability of data to support individual health care and wellness, health equity, public health, health policy, price transparency, coordination of care, burden reduction, privacy, and the usability of personal health information.

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[1] NCVHS Letter to HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," specifically recommendations #1 and #2. (February 13, 2019): https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf
[2] The Office of the National Coordinator
[3] The Centers for Medicare & Medicaid Services
[4] The National Institute for Standards and Technology

Scope of Data:

This project will consider a broad spectrum of data requirements including HIPAA administrative transactions, clinical data, public health, privacy, and social services use cases, examples of which are provided in the Appendix.

Overall Project Plan Summary:

This project, **"Standardization of Information for Burden Reduction and Post-Pandemic America," ("Convergence 2.0"),** builds on previous work with the Predictability Roadmap and the Intersection of Clinical and Administrative Data (ICAD) Task Force HITAC recommendations[5] and will be carried out in two phases:

Phase I will gather information from health sector stakeholders, intentionally starting with a broad approach in order to identify key system-wide priorities. This information may lay the groundwork for an updated framework for standards adoption that takes into consideration newer technologies, health-related and social services information beyond medical claims, and interoperable data exchange.

Phase II will refine the project focus and define a plan for potential deliverables, informed by Phase I input and in consideration of the Federal Health IT Strategic Plan.

The Phase II project plan will evolve to reflect findings in Phase I and consideration of expanded use cases. This project recognizes the rapid evolution of use cases and information needs, and the need for cross-system, cross-sector data that integrates clinical, public health, and social service data and information across the health care ecosystem.

Plan Domains:

Activities under this project include activities and opportunities in the following domains:

- Standards Assessment, including but not limited to functional suitability for purpose, implementability, manageability over life cycle, and conformity assessment
- Convergence of data, e.g., interoperability across use cases and across health industry sectors
- Semantic Harmonization among Terminologies, Vocabularies, and Code Sets
- Privacy, Confidentiality, and Security.

Phased Plan Approach

Implementation, of Phase I includes the initial activities that assess standards landscape and identify potential deliverables. Phase II activities are based on the outcome of Phase I.

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[5] At its November 10, 2020, meeting, the HITAC approved the Intersection of Clinical and Administrative Data Task Force (ICAD) report, "A Path Toward Further Clinical and Administrative Data Integration," to the National Coordinator, identifying recommendations to support the convergence of clinical and administrative data: https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it

Phase I:

- **Assess Standards Landscape**

Activities will be conducted to assess the current standards landscape in light of federal priorities for interoperability, capabilities of the new technologies (e.g., FHIR) and need to more effectively exchange or share medical documentation (Standards Landscape Assessment). In order to identify opportunities and priority needs around coordination of standards development and implementation, conformity of standards across data systems, and workforce readiness, a listening session will be convened with additional input obtained through a Request for Information. Other means of soliciting input will be considered to flesh out a plan for potential deliverables in the key areas of standards. Phase I activities:
1. Hold Listening Session to solicit stakeholder input to identify gaps or opportunities for improving the adoption, implementation, and use of standards to accommodate the changing health information ecosystem (3rd Quarter 2021).
2. Conduct a Request for Information (RFI), similar to those used by other FACAs, to obtain information on priority needs in standards development and adoption (3rd Quarter).
3. Make recommendations to HHS as needed based on findings (some of which may potentially impact numerous agencies).
4. Develop a work plan for Phase II deliverable(s) once its scope can be clarified.

- **Specify In-Scope Convergence Opportunities**

Activities in this domain will include coordination with ONC and HITAC/ICAD to advance and harmonize common standards development and use across clinical, administrative, and social services data (ICAD Collaboration), and additional coordination that may go beyond the scope of ICAD. Building on the ICAD Future State and Recommendations and recognizing ongoing HITAC developments and ONC and other federal standards-related projects in the health and wellness data flow ecosystem:
1. Coordinate between NCVHS, ONC, and other federal agencies as appropriate (ongoing). Establish communication channels to assure consistency of standards across electronic clinical and public health data systems, including community services and behavioral health services.
2. Assess and define Semantic Harmonization scope among Terminologies, Vocabularies, and Code Sets (Quarters 3 and 4).
3. Revisit and assess updates to the NCVHS ICD-11 research project and determine recommendations in light of new findings and developments.

- **Privacy, Confidentiality, and Security**

Recognizing the importance of privacy, confidentiality, and security around the data flows of the health and wellness ecosystems:
1. Establish regular liaison with the NCVHS PCS Subcommittee (ongoing). This coordination will identify and refer privacy/security related issues that arise in Phase I and Phase II Convergence activities.

Phase II Potential Project Activities:
As stated above, the following are **potential activities** that Phase I could inform. Examples are listed, but these are subject to change and other activities may be identified in Phase I.

- **Standards Assessment Plan Refinement (Quarters 3-4, 2021)**
  1. Recommend activities TBD to improve coordination and conformity of standards development and adoption, including workforce capacity-building opportunities.

- **Convergence**
  1. Maintain HITAC/ONC coordination (ongoing).
  2. Identify opportunities for coordination of the All-Payer Claims Database (APCD) Common Data Layout (Department of Labor) for consistency with HIPAA and other national standards.
  3. Analyze and consider recommendations for a common framework and harmonization of data across statistical, vital records, and clinical data systems including population health-related data developments (gender, race/ethnicity and Social Determinants of Health (SDoH)).

- **Semantic Harmonization among Terminologies, Vocabularies, and Code Sets**
  1. Maintain continued coordination and analysis leading to recommendations for the development, possible adoption and implementation of ICD-11 (ongoing).
  2. Identify business workflows that have requirements for additional harmonization and standardization of clinical and administrative code sets.
  3. Identify code sets, terminologies, vocabularies, or value sets that are used in multiple use case scenarios across the national health and human services ecosystem, including public health, social services, clinical, and administrative terminologies outside of the HIPAA transaction scope.
  4. Building on previous NCVHS Terminology and Vocabulary activities, suggest approaches for ensuring semantic interoperability across multiple stakeholders for the in-scope use cases.

Potential Phase II recommendations to HHS might include:
- Improved coordination of standards development projects in SDOs to meet convergence goals for expanded uses of claims and administrative data, or for the expanded scope of semantic harmonization
- Toolkits and resources to assist standards convergence such as expanded coordination on the use of shared value sets for administrative transactions and quality assessments, or to promote broader stakeholder engagement in voluntary consensus standardization activities
- Consideration of ways to minimize inconsistencies in the way individual organizations implement adopted standards. Consideration of ways to effect a smooth transition to adoption of new standards. Explore the potential for national conformity assessment.
- Evaluation of opportunities to obtain more learning-oriented value from enforcement efforts.
- An assessment of workforce needs for developing, implementing, and maintaining health and human/social services information standardization.

Anticipated Partners:

- ANSI and SDO publishers of adopted health information standards, HL7 accelerators (DaVinci and Gravity), and other standards organizations for standards coordination, standards conformity assessment, and workforce assessments.
- Industry groups, e.g., ADA, AHA, AHIMA, AHIP, AMA, MGMA, WEDI and others.
- HHS and other federal agencies, e.g., CDC, CMS, DoD, FDA, FTC, NIH/NCI, NIH/NLM, NIST, ONC, SAMHSA, VA, Census.
- Others as they become identified, i.e., state, local and private sector partners.

Quick Wins?

Potential interim deliverables with 2-year project timeline:

1. Findings on standards maturity, cost and workforce capacity, industry consensus/readiness for implementing new/emergent versions that may inform HHS on standards that accommodate new technologies and possible alternative standards under HIPAA.
2. A population health social determinants initiative to complement work already underway, such as through the Gravity Project and with ONC,[6] which seeks to identify data elements and associated value sets to represent SDoH information documented in EHRs and other systems across clinical activities (including screening, diagnosis, planning and intervention) – focusing initially on food insecurity, housing, and transportation access. Consider opportunities for collaboration with other existing initiatives.
3. Collaboration with CDC, ONC, and others on a population health public health data guidance initiative to support recommendations for public health data for reportable and surveillance data standards, harmonized with applicable clinical, social, and administrative standards:
   - For example, consider recommendations on a compendium of common formats or requirements to guide State public health agencies (minimum standards as guide for all states to adopt).

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[6] ONC 2/23/21 Special Emphasis Notice (SEN) Interest in Applications to Advance Health IT Standards and Tools to Improve Social Determinants of Health Data Exchange, and to Develop Tools for Making Electronic Health Records Data Research and Artificial Intelligence-Ready NOTICE NUMBER: NAP-AX-18-003. (https://www.grants.gov/web/grants/view-opportunity.html?oppId=306704)

APPENDIX

Examples of Use Cases:

Potential scope of use cases and topics of interest the Subcommittee identified for further exploration to be considered in Phase 2, depending on input and considerations from Phase 1:

- APIs and FHIR used for:
    - consumer access and data sharing (May 2020 Interoperability and Patient Access final rule)
    - provider data sharing and transactions
    - payer data sharing and transactions
    - data exchange with public health agencies
- Existing administrative and clinical data exchange standards, e.g., X12, NCPDP, IHE, and HL7.
- Administrative data capture requirements and data reporting requirements for the X12 claims and encounters (837) for the All-Payer Claims Databases (APCD) Common Data Layout (CDL).
- Data required for value-based care (VBC) coordination, risk sharing arrangements, and price/cost transparency.
- Public health laboratory and encounter reporting including syndromic surveillance and reportable condition data.
- Electronic clinical quality measures [eCQMs].
- Integrating social determinants of health data and social/community services data standards, behavioral/mental health:
    - Integrating SDoH standards into EHRs and other appropriate systems
- Nationally standardized cross-maps of clinical semantics (SNOMED CT, LOINC, and RxNorm), to administrative semantics (ICD-10 CM and PCS, HCPCS, and CPT).
- National compendium of harmonized value sets and semantic sub-sets for all purposes encompassed in this effort. (remove "MSU" syndrome).
- Interoperability between EHRs and vital record systems – including national vital record systems.
- Privacy and security within and beyond HIPAA related to the above scenarios and use cases.
- Expansion of covered entities under HIPAA.