Subcommittee on Standards Listening Session on Healthcare Standards Development, Adoption, and Implementation

Meeting Summary

August 25, 2021

National Committee on Vital and Health Statistics (NCVHS)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This report was written by NCVHS consultant Bethany Stokes, MS, and colleagues at Rose Li and Associates, Inc., in collaboration with NCVHS members and staff.

NCVHS Members and Staff in Attendance

Nicholas L. Coussoule, NCVHS Chair
Richard W. Landen, MPH, MBA, Subcommittee Co-chair*
Denise Love, BSN, MBA, Subcommittee Co-chair*
Tammy Banks, MBA*
Denise Chrysler, JD
James (Jim) Cimino, MD*
Jamie Ferguson*
Vickie M. Mays, PhD, MSPH
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Valerie J.M. Watzlaf, PhD, MPH, RHIA, FAHIMA
Wu Xu, PhD

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Rebecca Hines, MHS, NCVHS Executive Secretary/Designated Federal Officer
Health Scientist
National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

Lorraine Tunis Doo, MPH, Lead Staff to the Subcommittee on Standards
Senior Policy Advisor
Health Informatics and Interoperability Group, Office of Burden Reduction and Health Informatics
Centers for Medicare & Medicaid Services, HHS

See Appendix B and C for complete lists of meeting participants.

NCVHS—The National Committee on Vital and Health Statistics

NCVHS serves as the public advisory committee to the Secretary of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. 242k[k]). The Committee also serves as a forum for interaction with interested private-sector groups on important health data issues. Its membership includes experts in health statistics, electronic interchange of health care information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. The HHS Secretary appoints 16 of the 18 committee members to 4-year terms. Two additional members are selected by Congress. The NCVHS website provides additional information at ncvhs.hhs.gov.

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Welcome, Call to Order, and Opening Remarks

To open the meeting on Wednesday, August 25, 2021, Executive Secretary Rebecca Hines welcomed the participants and called roll. Participants and invited speakers introduced themselves and NCVHS members disclosed any potential conflicts of interest. Mr. Ferguson recused himself from any conversations that pertained to Kaiser Permanente.

The goal of this meeting was for the Standards Subcommittee to learn about status, including barriers and opportunities, related to development, adoption, and implementation of health care standards. Based on what it learned, the Subcommittee may generate recommendations for the HHS Secretary.

NCVHS Subcommittee on Standards Charge

The Standards Subcommittee monitors and makes recommendations to the HHS Secretary. Mr. Landen presented the Subcommittee's charge, summarized below:

- Identify issues and opportunities in health data standards
- Provide outreach, liaison, and consultation with, and serve as a public forum on health information technology (HIT) standards for the health care industry and federal, state, and local governments
- Recommend electronic standards, operating rules, and code sets under HIPAA administrative simplification, make recommendations for HIPAA privacy and security standards, and address standards for health terminologies and vocabularies
- Recommend strategies to promote a continuing process of developing, coordinating, adopting, implementing, and maintaining standards
- Participate in development and publication of periodic reports to Congress on HIPAA Administrative Simplification
- Collaborate with other Federal Advisory Committees on cross-cutting issues as appropriate and when delegated by the full committee

Current Subcommittee Project: Standardization of Information for Burden Reduction and Post-Pandemic America ("Convergence 2.0")

The Standards Subcommittee focuses on immediate and long-term needs identified by industry and within the Subcommittee's charter, including its Predictability Roadmap project. The Subcommittee's objectives related to Convergence 2.0are to (1) build on prior Predictability Roadmap recommendations, (2) improve availability and/or access to updated versions of standards, (3) address clinical, administrative, and other data intersections, (4) support interoperability, (5) improve regulatory processes to enable access to updated or new standards, (6) improve the standards update and adoption processes, and (6) reduce administrative burdens.

The Subcommittee's current work plan aims to identify existing industry innovative activities, priorities, and burdens. This work plan includes two phases: (1) assessing the current health data standards landscape (which largely occurred during this meeting) and (2) developing and refining recommendations based on the assessment of the standards landscape, as well as on industry consultations and NCVHS input. The Subcommittee released a Request for Comment related to the current health standards landscape during June 2021 and over received 30 submissions to date.

Overview of Federal Health Information Standards Convergence Landscape

Current NCVHS activities include refining the Predictability Roadmap (described in the previous section); supporting the harmonization development of terminologies and vocabularies; advocating for research of issues related to the *International Classification of Diseases, 11th Revision* (ICD-11); and collaborating with the Office of the National Coordinator for Health Information Technology (ONC), the HIT Advisory Committee (HITAC), and others to facilitate convergence of standards to move the nation to cross-sector interoperability.

HITAC was launched as a result of the 21st Century Cures Act to streamline the HIT standards development processes and support ONC with recommendations. HITAC is governed by the Federal Advisory Committee Act

(FACA). HITAC includes an Interoperability Task Force, which aims to identify gaps in the HIT standards field and policies that could help fill those gaps, and an Electronic Health Record Reporting Task Force, which assesses multiple outputs of the health care sector to investigate dimensions of quality and measure the health care sector's performance. HITAC is currently considering approaches for optimizing standards aimed at reducing inequities of care.

Panel 1: Lessons Learned from National Standards Coordination (Functions and Processes)

The purpose of this panel was to explore successful development and implementation models for harmonized sector-wide data standardization for the health care and other sectors.

Fran Schrotter

American National Standards Institute

The U.S. standards and conformity assessment system is designed like a public-private partnership so that no single government agency has control over standards and each agency determines the standards that meet its needs. The National Technology Transfer and Advancement Act (NTTAA; Public Law 104-113) directs federal government agencies to adopt voluntary consensus standards that are broadly applicable wherever possible in lieu of developing government agency–specific standards. The Office of Management and Budget (OMB) Circular A-119 policy dictates the government's strategy for standards development and adoption per the NTTAA.

The American National Standards Institute (ANSI) was founded in 1918 as a private, nonprofit membership organization with the mission to enhance U.S. global competitiveness and American quality of life by promoting, facilitating, and safeguarding the integrity of the U.S. voluntary standardization system. ANSI represents the interests of more than 270,000 companies and organizations, as well as 30 million professionals worldwide, and serves as the U.S. representative to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

ANSI's goals are to (1) serve as the national coordinating institution for voluntary standards, conformity assessments, and related activities in the United States, (2) provide the means for determining the need for new standards and conformity assessment programs, and (3) cooperate with federal, state, and local governments to achieve optimum compatibility between government laws and regulations. To achieve these goals, ANSI coordinates and supports the standardization system through collaboratives and workshops that convene public- and private-sector representatives in a neutral forum; identifies current and in-development standards, gaps, and solutions; and determines which organizations can perform the work needed to move the standards field forward. For example, a 2017 workshop on the Unmanned Aircraft Systems Standardization Collaborative generated a comprehensive roadmap describing the current and desired future standardization landscape for unmanned aircraft systems, as well as a document containing critical gaps and solutions. Most workshops are successful through broad stakeholder support, clearly defined objectives, timelines, and deliverables, committee leadership and participants, and stable funding mechanisms.

Ms. Schrotter encouraged NCVHS and its Subcommittees to view ANSI as a resource for assessing the current standardization landscape related to federal priorities for interoperability and for identifying opportunities to improve the adoption, implementation, and use of standards to accommodate the changing health information ecosystem.

Lane Hallenbeck, MS

American National Standards Institute Accreditation Board

Conformity assessments demonstrate whether or not an object complies with the requirements of a standard. These assessments must balance the value derived by sellers with the confidence felt by buyers that the object will perform as expected, and this balance is influenced by many other stakeholders. The conformity assessment

framework directly involves the object (e.g., software, system, or project), the requirement (e.g., regulation, guide, or code), and the method (e.g., audit, inspection, or certification). Other elements include the party (e.g., acceptance authority, consumer, or regulator), issues (e.g., inputs/outputs, risks, cybersecurity, or cost), and the relevant tools and technology (e.g., blockchain, Cloud, or artificial intelligence).

The ANSI Accreditation Board (ANAB) accreditation third-party hierarchy scheme dictates that accreditation bodies assess competence, whereas conformity assessment bodies certify, audit, test, and verify conformity of a given product, service, process, person, or system. ANAB also uses the ISO Committee on Conformity Assessment toolbox that provides specific standards and guides for each conformity assessment activity, including testing inspection, certification, accreditation, mutual recognition/peer assessment, and supplier declaration of conformity. Customer requirements, product risks, and regulatory requirements can influence which methods are used during conformity assessments. Mr. Hallenbeck presented a list of current conformity assessment programs and their relevant standard (e.g., laboratories use the ISO/IEC 17025 standard).

Another critical piece of the accreditation process is cross-checking accreditations, which occurs via international collaborations between ANAB, the International Laboratory Accreditation Cooperation, Asia-Pacific Accreditation Cooperation, the International Accreditation Forum (IAF), the Inter-American Accreditation Cooperation, and the European Accreditation Cooperation.

CAPT Scott Colburn, MS

U.S. Food and Drug Administration

The U.S. Food and Drug Administration's (FDA's) Standards and Conformity Assessment Program (S-CAP) in the Center for Devices and Radiological Health (CDRH) seeks to promote patient safety, advance regulatory science, and support the least burdensome regulatory framework. S-CAP supports FDA's mission by facilitating the development, recognition, and appropriate use of voluntary consensus standards and conformity assessments for medical devices, radiation-emitting products, and emerging technologies. Standards are a key element and driver of product quality and consistency, and thus play a large role in patient safety in the context of medical devices. Standards help to ensure that emerging and innovative products entering the medical market are safe and efficient.

The NTTAA and OMB Circular policies inform federal agencies' use of voluntary consensus standards. Language in the FDA Food and Drug Modernization Act reinforces the importance of recognizing and conforming to standards as a pre-market requirement; this Act enabled FDA to begin promoting existing standards instead of requiring the creation of new standards, which can delay the integration of new products into the market.

S-CAP actively collaborates with other FDA programs to ensure sharing of best practices to advance the health standards field, as well as coordinates with other federal agencies through the National Institute of Standards and Technology's Standards Coordination Office and Interagency Committee on Standards Policy.

Dan Vreeman, DPT, MSc

RTI International

Launched in 2008, the Health Standards Collaborative (HSC) aims to develop an executive forum and process for leadership of the health standards development community to have strategic dialogue, planning, and collaboration across organizations, and to harmonize standards to address interoperability. HSC membership includes approximately 22 Standards Development Organizations (SDOs), SDO-related entities, and official observers. Members do not develop standards through HSC; rather, they share best practices and guidance so that partnering organizations can develop optimal health standards and reduce potential health standard overlap. HSC operates on a voluntary basis; organizations attend meetings, when available, to discuss the status of the health standards field, share guidance, and update members on relevant activities and policies.

Question and Answer Session

How should NCVHS measure success of standards development and conformity assessment coordination across the health care sector?

Ms. Schrotter emphasized that success criteria are traditionally difficult to identify, but could include a measure of (1) the number of organizations participating in the coordinated effort and (2) the responsiveness of the SDO community. CAPT Colburn echoed Ms. Schrotter's recommendation to use participation as a measure of success, adding that involvement of the necessary stakeholders in the coordination effort is critical to success. Mr. Hallenbeck emphasized that the optimal metric of success is compliance with the developed standard.

How should NCVHS manage transitions to new standards?

CAPT Colburn emphasized the importance of identifying the need for transitioning to new standards in a timely manner and to understand the requirements associated with the standard transition (e.g., challenges, content, timelines, and laboratory requirements) in order to achieve successful transition. Dr. Vreeman noted that the transition process likely depends on the standard being updated and that the process should be dictated by all critical stakeholders involved.

Panel 2: Information Exchange and HIPAA—Present Day Challenges and Future Opportunities

The purpose of this panel was to (1) obtain input on how the HIPAA-regulated transactions, code sets, and operating rules fit within current business needs and use cases, (2) discuss whether any unmet business needs could be fulfilled with alternative electronic exchanges, and (3) identify opportunities to adopt new and emerging standards that could reduce end-user burden, improve timeliness of updates, and mitigate update implementation costs.

Dan Kalwa

Centers for Medicare & Medicaid Services

The National Standards Group (NSG) of the Centers for Medicare & Medicaid Services (CMS) Office of Burden Reduction and Health Informatics is charged with adopting national standards and operating rules under the Administrative Simplification provisions of HIPAA. Implementation specifications are necessary for every HIPAA transaction because they contain the data and format conformance requirements for the transaction. Without the specifications, adoption will not occur. In addition, operating rules add additional business requirements to standard transactions in order to ease implementation and standardization of transactions with covered entities. Operating rules can explain how to use an implementation specification when the specification itself does not.

The standards adoption process relies on NCVHS recommendations to the Secretary and rulemaking. Covered entities can request exceptions from the Secretary if they wish to modify and then test an existing standard. All covered entities involved in the exception must participate in testing, whose purpose is to assess whether the modification improves the efficiency and effectiveness of the health care system by reducing costs or improving benefits from electronic transactions. The primary goal of exceptions is to develop financial and administrative transactions that improve the operation of, and reduce to costs of, health care administration. In addition, the exceptions process enables covered entities to conduct full testing of new specifications without compliance complications.

Heather McComas, PharmD, MA

American Medical Association

The American Medical Association recommends that NCVHS consider certain steps when assessing the standards: (1) recognize successful transaction/code set standards to preserve, (2) identify unmet industry business needs, and (3) rigorously evaluate new transaction standards for adoption. Given the limited resources available to

provider organizations to invest in technological changes and upgrades, Dr. McComas urged NCVHS to prioritize advancing standards that improve workflow efficiencies and address unmet industry needs. Current successful electronic transaction standards, operating rules, and code set standards include the Council for Affordable Quality Healthcare (CAQH) index (which should be maintained) and the Automated Clearing House (ACH) and Electronic Funds Transfers (EFT) standards (which are successful, but could be improved through CMS enforcements because of the fees). Dr. McComas emphasized that before testing or adopting new standards, NCVHS and the Standards Subcommittee must assess whether these standards are ready for widespread deployment, will be implementable across the health care sector, and advance the Administrative Simplification provisions and purpose.

From the provider perspective, high-priority unmet business needs include automated prior authorization (PA) and clinical data exchange, real-time pharmacy benefit (RTPB) transactions, and both good faith estimates (GFEs) and advanced explanations of benefits (AEOBs). Each of these unmet needs directly impacts patients, particularly PA (which is associated with delays in patient care, subsequent adverse events, and wasted resources). The lack of transaction standards supporting clinical documentation exchange in medical PA automation is a rate-limiting factor to progress.

Dr. McComas encouraged NCHVS to recommend adoption of the National Council for Prescription Drug Programs electronic PA standards for all types of prescription drug plans to eliminate industry confusion and to identify methods to support widespread use of these standards by incorporating them into the ONC electronic health record (EHR) certification program. Dr. McComas also encouraged NCHVS to recommend adoption of transaction standards for RTPB technology that integrates with all EHRs and provides accurate information for all drug plans and patients. Given the recent delays in GRE enforcement, NCHVS should also prioritize the development of standards and operating rules for GFEs and AEOBs. Dr. McComas emphasized the importance of requesting comments from all stakeholders on any NCVHS proposed recommendations to the Secretary.

Chuck Jaffee, MD, PhD

Health Level 7 International

Dr. Jaffee recommended that NCVHS (1) support elevating and formalizing the adoption of Health Level 7 International (HL7) Fast Healthcare Interoperability Resources (FHIR) standards to the same level as existing HIPAA standards and (2) use implementation guides to address any unsolved common data exchange challenges across all health care stakeholders. To improve data exchange and remove administrative burden, the health care industry must embrace modern technology, increase automation, allocate limited resources to their best use, improve the patient experience and engagement, promote privacy and security capabilities that underpin trust and transparency, and garner consensus on methods to support the intersection of clinical and administrative data to a modern framework. As the health care sector moves toward increased use of Application Programming Interfaces (APIs), more real-time, discrete data exchange and modern security standards will test the ability to use the FHIR's existing framework and the capabilities to advance the industry. The FHIR community has grown substantially in recent years, as evidenced by the 1,200 registrants for a recent CMS FHIR-based connect-a-thon. CMS and ONC have provided a consistent message to the standards community that FHIR should be implemented as much as possible.

Jocelyn Keegan

HL7 Da Vinci Project

Founded in 2019, the HL7 Da Vinci Project involves 55 committed founding members and a growing community of hundreds of organizations that help to define, build, test, and deploy project outputs. Its goal is to help payers and health care providers positively impact clinical, quality, cost, and care management outcomes. The Project has led to the development of 14 implementation guides across five core focus areas: quality improvement, member access, clinical data exchange, coverage/burden reduction, and process improvement. Project members and partners select the use cases outlined in each implementation guide. In addition, the Project developed the Health Record Exchange framework, which includes implementation guides for specific business challenges that detail how a provider can share specific health information with another provider or payer.

To reduce burdens across the industry, HL7 and the Da Vinci Project prioritized PA reduction support and automation. The work the Da Vinci Project has initiated to redefine PA was recognized in the 2020 HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force Report; this work includes developing a detailed implementation guide related to PA and new methods to reduce waste for all stakeholders involved in PA. The HITAC ICAD report concluded with the recommendation that NCVHS follow a holistic approach toward PA.

Kirk Anderson

Cambia Health Solutions

Cambia Health Solutions is an active supporter and implementer of FHIR-based solutions because of FHIR's use of secure, open, and scalable standard APIs and the belief that these types of APIs are critical to creating a person-focused, economically sustainable health care ecosystem. In working with other health care providers and EHR vendors, Cambia Health Solutions has helped deliver multiple Da Vinci Project FHIR-based use cases into production to support clinical data exchange for quality measures and risk-based member identification. These use cases have demonstrated the value of FHIR-based automation. As a result of implementing these use cases, Cambia Health Solutions' provider partners have identified a 40 percent improvement in quality measure compliance and a 40 percent reduction in burdensome, resource-intensive chart chases. These benefits are directly attributed to the automation benefits of FHIR and removing the need to share spreadsheets between providers and payers. These benefits can be scalable across all Cambia Health Solutions partners; however, this scalability depends on the development of standard APIs.

The field has benefited from the use of conformance standards such as X12 standards, but to continue to advance and innovate, the field needs to complement X12 with API standardization via FHIR-based solutions. Cambia Health Solutions aims to implement more FHIR-based solutions to reduce the burden of the PA process while allowing providers to remain within their native EHR Portals. The PA process is also burdensome for patients, and thus Cambia Health Solutions in collaboration with the Da Vinci Project aims to standardize the PA process to enable the patient to gain ownership over their health care data and process.

Cathy Sheppard

X12

X12 is an ANSI-accredited, consensus-based nonprofit organization focused on development, implementation, and ongoing use of interoperable electronic data interchange (EDI) standards. Many organizations have adopted X12 EDI infrastructure. X12 acknowledges that health care stakeholders need access to complementary administrative and clinical information. Standardized metadata is the foundation for successful interoperability between syntaxes and delivery systems. X12, as well as the Da Vinci Project, have been working to align administrative and clinical data to enable easy translation between X12 and FHIR transactions. Pairing emerging and existing technologies in innovative ways can help to leverage technological investments and standardize data content while supporting transmission syntaxes.

X12 recently performed a health care industry survey to understand industry stakeholder perspectives and identified a set of recommendations for advancing mandated standards. These recommendations will include adopting additional EDI standards that align with currently mandated standards in order to provide more robust information exchange. X12's recommendations will provide implementers with compliant options for meeting emerging federal mandates in a way that enables them to (1) take advantage of existing trading partner endpoints and significant investments in EDI infrastructure and (2) incorporate emerging technologies and syntaxes that are based on the same data requirements that include guidance describing instructions for consistent use. SDOs are currently asked to provide return-on-investment data related to proposed standards, which can be challenging because most SDOs are already overwhelmed with federal and state requirements and are reticent to invest sparse resources in upgrading or implementing transactions that may or may not be mandated in the future. X12 has identified several policy opportunities for NCVHS, including reducing overlapping federal requirements and releasing publications of new and enhanced standards and implementation guides on a predictable schedule.

Gail Kocher, MPA

Blue Cross Blue Shield Association

Blue Cross Blue Shield Association (BCBSA) is a national federation of 35 independent, community-based, and locally operated BCBS companies that provide health care coverage for 1 in 3 Americans. Ms. Kocher emphasized that discussions and review of new standards must occur in the context of whether current infrastructure meets the current business needs, and whether gaps exist. Creating new standards that do not dramatically improve business values are not worth the diversion of time and resources, whereas updating standards may provide the necessary added benefit while retaining the benefits of the previous version. Upon identifying a critical gap in infrastructure, standards organizations must review relevant use cases to assess how current standards could be applied and how to use those standards to fill the gap or expand the standard to add necessary value.

Ms. Kocher emphasized the need for the standards field to understand the complexity of underlying business processes (e.g., what payers and providers need when exchanging data), as well as the maturity of standards in relation to new technology. Ms. Kocher recommended that pilot studies of standards should be undertaken, if possible but especially when the technology underlying the standard is not widely implemented, in order to assess potential barriers in a real-world setting. Also important are gap analyses to estimate the resources needed for implementation; these analyses should also involve pilot testing. Providers can rely on vendors that are not HIPAA-covered entities, which can impact smaller providers because they lack the resources needed to implement a new standard as quickly as those with more resources. Ms. Kocher recommended implementing and then aligning FHIR standards with HIPAA to enhance provider ability to use third-party applications. Ms. Kocher also emphasized the need for increased access to standards, as well as increased engagement with all stakeholders during the standards development process.

Crystal Ewing, MBA

Cooperative Exchange and Waystar

The Cooperative Exchange of the National Clearinghouse Association has 22 clearinghouse organization members that represent greater than 90 percent of the clearinghouse industry. The Cooperative Exchange processes more than 6 billion health care claims, representing $2 trillion annually and providing national connectivity for 800,000 provider organizations, more than 7,000 payer connections, 1,000 HIT vendors, and the EDI commerce system.

Ms. Ewing noted that NCVHS could improve data sharing throughout the health care sector by reducing ambiguity in health care regulation implementation, solving existing business processes and technical workflow inefficiencies, executing solutions identified in pilot programs, incorporating additional key stakeholder participation, and increasing stakeholder accountability, ownership, and transparency of the decision-making process. Barriers to these improvements include a lack of HHS response to NCVHS recommendations, inadequate stakeholder regulatory guidance, and ineffective liaison processes between NCVHS, HHS, and industry stakeholders.

Ms. Ewing recommended that NCVHS adopt X12 acknowledgment and attachment standard, approve HIPAA exemptions to test HL7 coverage requirements discovery and PA support implementation guides, and help facilitate the EDI standards risk assessment. Ms. Ewing identified the following short- and long-term actions for NCHVS to prioritize: (1) address the lack of response or action from HHS to NCHVS stakeholders related to administrative simplification, (2) instate immediate efforts focused on stakeholder-vetted NCVHS recommendations (e.g., PA), (3) provide concise and timely stakeholder guidance on the No Surprises Act, and (4) publish and communicate a regulatory roadmap with realistic implementation timelines.

Nancy Spector, MSc

Workgroup for Electronic Data Interchange (WEDI)

The Workgroup for Electronic Data Interchange (WEDI) is the leading authority on the use of HIT to improve information exchange in order to enhance quality of care and efficiency and reduce health care system costs. In the context of industry, WEDI aims to provide multi-stakeholder leadership and guidance to the U.S. health care

system on ways to leverage the industry's collective technology, knowledge, and expertise to improve administrative efficiency, quality, and cost-effectiveness.

Current challenges associated with health care standards include the lack of broad stakeholder involvement in standards development, protracted release of regulations, lack of standards adoption flexibility, insufficient trust between providers and health plans, lack of covered entity status for vendors, insufficient testing and piloting, and lack of federal funding for standards development. The ability to overcome these challenges is hindered by a lack of clearly defined return-on-investment (ROI) documentation, high implementation costs, low stakeholder inertia, and variation in application of standards.

WEDI recommends that NCVHS (1) prioritize missing transactions by advocating for the adoption of X12's 275 Electronic Attachments, X12 999 Acknowledgement Transaction, and X12 277 Health Care Status Notification Transaction, (2) adopt individual HIPAA transaction standards, and (3) advance administrative automation (particularly for prior authorization (PA)). WEDI acknowledges that FHIR-based API standards could increase administrative automation, and thus WEDI endorses inclusion of FHIR standards adoption in the CMS PA rule. WEDI also recommends that NCVHS explore how FHIR and API standards can augment current data exchange processes. Finally, WEDI recommends real-world testing and piloting to ensure that new standards work in current business environments; performing cost-benefit analyses of ROI before mandate implementation; facilitating economic and clinical impact testing on a period basis; and expanding the HIPAA waiver process.

WEDI acknowledges the need to expand collaborations, particularly to fix the broken knowledge supply chain and create an advantageous environment for all stakeholders. Opportunities such as "connect-a-thons" and federal financial awards for innovators could enhance collaboration. WEDI can serve as an industry convener and facilitator to instate positive change in the data exchange process.

Question and Answer Session

With HL7 FHIR API solutions, are both the practice management system and electronic medical record divisions within the participating vendors in the Da Vinci Project working to solve use cases?

Ms. Keegan noted that the Da Vinci Project ensures that each participating vendor, as well as all stakeholders, are sufficiently involved in the development of API solution implementation guides. Dr. Jaffe agreed with Ms. Keegan, noting that HL7 encourages a diverse group of individuals to participate in implementation guide development, as well as connect-a-thons to pilot those guides. Ms. Sheppard added that active communication and convening of stakeholders by HL7 ensures that vendors receive adequate exposure to best practices for a variety of solutions and share back pertinent information with HL7.

What are your thoughts on ROI?

Dr. Jaffe noted that some important solutions that benefit patients may decrease ROI, which is acceptable when patients are helped. Ms. Sheppard emphasized that ROI includes more than monetary returns and recommended documentation of other forms of ROI to assist SDOs. Dr. McComas recommended viewing ROI in terms of human cost and whether patients are receiving the care needed and avoiding adverse events, adding that new transactions related to ROI must undergo real-world testing. Mr. Kalwa emphasized that CMS requests information related to ROI to address legislative mandates, noting that free sharing of this information with CMS is imperative to its actions and that any barriers to this information sharing must be overcome. Ms. Keegan noted that Cambia Grove performed a pilot study on whether a common framework could be developed for ROIs related to APIs, and the Da Vinci Project recently expanded this effort to understand better how stakeholders view ROI models. Ms. Spector noted that collecting ROI data is difficult and recommended convening a large multi-stakeholder group to identify important ROI measures and methods of measurement.

Panel 3: Semantic Harmonization of Standards

The purpose of this panel was to learn about opportunities for improving interoperability between clinical and administrative standards and code sets.

Jeff Swanson, MD

Kaiser Permanente

Kaiser Permanente (KP) is a health care consortium with approximately 12.5 million members, 40 hospitals, 727 medical offices, and 213,791 employees across eight major regions in the United States. Each of these eight regions uses a different version of the EHR, causing a patient moving from one region to another to appear as a new patient. KP staff must then perform clinical discovery processes and reconciliation for this *new* patient. KP's Convergent Medical Terminology (CMT) program sets standards for terminologies that are used in all eight regions to ensure the best possible care across the KP enterprise. The more than 100,000 KP physicians, clinicians, and other providers use the same diagnoses and procedures in all eight regions, which allows for quick reconciliations of issues when patients visit from another region. However, the situation is more complex for new patients or patients that received care outside of the KP system and are now reentering the system. Automated mapping for these patients can be incomplete and incorrect, which requires staff to reconcile issues manually.

In 2020, KP performed more than 165 million electronic medical record exchanges with external providers, with approximately half of those exchanges inbound. KP is dedicated to providing the best care to all of its patients, new and existing, as well as patients at non-KP facilities. KP is committed to (1) ensuring that its CMT program aligns with other major standards and (2) semantic interoperability by contributing to those major standards (e.g., KP is a formal partner with Systemized Nomenclature of Medicine [SNOMED] and the National Library of Medicine [NLM]). To date, KP has submitted more than 25,000 concepts to the SNOMED Core and has donated CMT products to international entities. KP recommends adopting shared standards for all health care systems and encouraging a 1:1 mapping for critical terminology to provide the best care to all patients.

Matthew Rahn

Office of the National Coordinator for Health Information Technology (ONC)

The ONC mission is to improve the health and wellbeing of individuals and communities through the use of technology and health information. ONC's strategic goals are to (1) advance person-centered and self-managed health, (2) transform health care delivery and community health, (3) foster research, scientific knowledge, and innovation, and (4) enhance national HIT infrastructure.

The U.S. Core Data for Interoperability (USCDI) is a ONC-defined set of structured and unstructured health data needed to support patient care (e.g., information related to medications, allergies, procedures, or health concerns) and facilitate patient access using FHIR or Consolidated Clinical Document Architecture (C-CDA) exchanges. Some USCDI data elements require the use of specific HIT vocabulary standards, such as SNOMED. USCDI establishes a consistent baseline of harmonized data elements that can be broadly reused across use cases. USCDI datasets will expand over time in a predictable, transparent, and collaborative manner, with new versions released annually during July. ONC has developed a first and second version of the USCDI datasets; the second dataset includes more components related to pandemic-specific health inequities.

ONC asserts that coordination with industry can drive interoperability across the health care system. ONC collaborates with HL7 to facilitate FHIR connect-a-thons and implementation-a-thons, as well as to provide terminology support. ONC has also executed the Regenstrief Cooperative Agreement with Logical Observation Identifiers Names and Codes (LOINC) and the Integrating the Healthcare Enterprise Cooperative agreement.

Wayne Kubick, MBA

Health Level Seven International

HL7 is an ANSI-accredited nonprofit SDO founded in 1987. The mission of HL7 is to provide standards that empower semantic global health data interoperability. To date, HL7 has produced more than 250 specification products and developed FHIR. Currently, FHIR has a global community of more than 17,000 active members across hundreds of servers, applications, and testing environments. FHIR is a platform standard that aims to address interoperability by using multiple flexible outputs and functional components (e.g., coding systems related to

different types of content). FHIR leverages HL7 Terminology, which includes approximately 1,050 code system resources, more than 2,200 value sets, and more than 15,000 terms (with some from SNOMED). FHIR can be tailored to the many different contexts in health care, and semantic consistency can be enforced through the use of FHIR implementation guides, which consist of information related to terminology bindings, extensions, and constraints. HL7's vision and mission focus on achieving semantic interoperability through the use of the FHIR platform and conformance with FHIR implementation guides.

HL7 has also launched the Clinical Information Modeling Initiative, which aims to improve interoperability of health care systems through shared implementable clinical information models (including models of laboratory tests and family history information).

Clem McDonald, MD

National Library of Medicine

The NLM has provided funding and guidance for the development of multiple health data vocabularies and standards, including SNOMED, dbSNP, and ClinVar. NLM has also been involved in supporting implementation of multiple FHIR-based resources and capabilities, including the FHIR questionnaire and the Research Data Finder query too; NLM has also helped to convert nearly 5 billion database of Genotypes and Phenotypes (dbGaP) records into FHIR resources. National Institutes of Health (NIH) as a whole has also promoted health data standards, for example, by releasing a 2018 and 2020 guide notices encouraging researcher to use FHIR to adopt USCDI resources for semantic coding, respectively. NIH has sought to help improve data interoperability since 2003; however, this goal has been difficult because the field lacked an accepted framework until the emergence of FHIR. NIH launched the NIH Cloud Platform Interoperability committee to help improve adoption of FHIR and thus enhance data interoperability across NIH as well as the broader research community.

Semantic interoperability is only part of the answer to the many challenges in the health standards field. Early developers in the health standards field built systems that construct narrative reports using codes of semantic terminologies; multiple companies adopted this system, but most of these systems failed because the system did not have sufficient structure. Semantics and structure are highly dependent, and semantic interoperability is impossible without standardized structure. However, many standardized data structures have emerged, including FHIR and CDA, with the former being the most advanced existing framework. Nevertheless, semantic interoperability will only be possible when the field has agreed on a single coding system and vocabulary.

Jay Ahlman

American Medical Association

Semantic harmonization and interoperability enable clinicians to coordinate care across teams and institutions and therefore act on current information, and help provide individuals with access to and ownership of their health data. Interoperability is also critical to safe, responsible, and transparent public health reporting and monitoring. Functional interoperability remains lacking within the health care sector; however, this interoperability can be accomplished through enhanced technical capabilities, trust, and data consistency, which together support care teams have the right information at the right time for the right patient.

The health standards field has created many medical vocabularies, and thus novel vocabularies are not needed for semantic harmonization. Rather, the field should focus on harmonizing the available vocabularies. Support for semantic harmonization can occur when the field recognizes the value of foundational, evidence-based standards and the role they play in the health care sector. The field must also rely on terminology standards that are fit for a specific purpose and build on foundations that are universally trusted within the health care sector. Mr. Ahlman recommended that NCHVS focus on implementing incremental changes that improve overall clinical data exchange and identifying consensus-driven and evidence-based standards to overcome existing barriers. Many semantic harmonization efforts are under way, including those of the Gravity Project—the American Medical Association's (AMA's) standardization of self-measured blood pressure monitoring data using HL7 implementation guides and terminology mapping by multiple institutions.

Mr. Ahlman emphasized that physicians rely on the Current Procedural Terminology (CPT) code sets, which provide a common language across health care stakeholder domains. The COVID-19 pandemic highlighted the need for better public health infrastructure that enabled rapid responses across the nation. The CPT Editorial Panel developed new CPT codes related to COVID-19 vaccines and vaccine administration, and AMA developed, produced, and distributed educational materials for physicians on the use of these new codes. Mr. Ahlman recommended that NCVHS recognize, enhance, and expand foundational code sets and prioritize work based on high-impact use cases that address unmet industry needs. In addition, NCVHS must promote consumer-friendly descriptors that enable patients to take ownership of their care using plain language and consumable descriptors of health care procedures and claims data. Mr. Ahlman also recommended that NCVHS enforce standardizing rules related to data submissions and ensure that semantic harmonization frameworks reuse standard code sets.

Jim Case, DVM, PhD, MS

SNOMED International

Semantic harmonization involves the maintenance of data meaning fidelity throughout its lifecycle, which may include multiple mappings or translations. Dr. Case emphasized that the greatest opportunities for harmonizing terminology standards are (1) identifying a subset of high-priority fit-for-purpose standards, such as USCDI, (2) facilitating collaboration among SDOs, and (3) aiding efforts of the Joint Initiative Council for Global Health Informatics Standardization. The biggest barriers to semantic harmonization are the extensive use of local code sets, different underlying terminology models, and resistance to change. The health standards field could overcome these barriers by leveraging experiences of other countries, developing a national strategic plan with all necessary stakeholders, and demonstrating the benefits through real-world examples.

SNOMED International actively integrates terminologies and maintains clinical cross-maps to other terminologies, as well as participates in multiple collaborations to ensure that the health standard field has ample resources to guide its practices. Dr. Case emphasized the need to identify relevant, comprehensive, and interoperable clinical standards driven by common information models to reduce the need for extensive cross-maps. Agreeing on specific maps can help reduce the significant costs of creating and maintaining new maps. Standard harmonization is impeded by technical limitations, implementation and maintenance costs, and lack of perceived benefit across the field. Dr. Case recommended educating the field about the benefits of terminology standards, developing common ontologies for clinical terminology, creating focused terminology subontologies, and encouraging a staged implementation strategy for standards adoption.

Question and Answer Session

What elements are needed to convert data documentation into billing-related information?

Dr. McDonald noted that these conversions typically use CPT codes and keywords for additional descriptors. Mr. Kubick noted that ONC is funding a project through HL7 at Boston's Children's Hospital, whereby researchers will survey clinical notes to identify COVID-19 symptoms and perform a public health analysis, adding that such a project could be repurposed to identify adaptable billing information.

How can NCVHS help better combine administrative and clinical data?

Dr. McDonald noted that ONC is now requiring submission of diagnostic notes from physicians (and added that receipt of surgical notes would also be helpful). Mr. Kubick noted that the field is in a state of rapid adoption and development of new standards and, within the next 2 years, will experience significant advances in combining administrative and clinical datasets. Mr. Rahn added that ONC's Electronic Health Information Export program will soon collect additional population health information and that a paired implementation guide will also be available.

How can NCVHS increase coding consistency?

Mr. Ahlman noted that AMA aims to enhance the meaning behind many codes and convenes a regular meeting of more than 1,000 coders to identify gaps in consistency. Mr. Rahn added that ONC's certification program includes tools that test the consistency of codes.

Panel 4: Update on National and HHS Initiatives on Public Health Data Systems and Social Determinants of Health

The purpose of this panel was to hear insight regarding the exchange of health information for public health, vital statistics, social determinants of health (SDOH), social services, and APIs, recognizing that federal, state, and private sector administrative systems are a backbone to our research, policy, and health care delivery system.

Vickie Mays, PhD, MSPH

University of California, Los Angeles

The development of conceptual frameworks of health systems interventions requires an understanding of the distinctions between structural determinants of health and social determinants of health (SDOH), as well as differences between social risk and social need. Structural determinants include governing processes and economic and social policies that can affect everything from sick leave policies to housing and education, each of which are intermediate steps leading toward unequal distribution of power, prestige, and resources. Structural determinant–related interventions are often characterized by the ability to intervene during events that alter the course of specific events, not at the individual level. Structural determinants create and maintain social hierarchies, which in turn create SDOH and eventually differential health outcomes and disparities. Social risk is the manifestation of SDOH at the individual level (e.g., food insecurity, transportation, intimate partner violence, or utility needs), whereas social needs relate to quality of life (e.g., finances, access to healthy food, or housing).

Recent structural interventions include Medicare Advantage, which provides chronically ill individuals with non-medical benefits (e.g., transportation to doctor's visits or home improvements); the Social Determinants Accelerator Act of 2019, which helps to identify opportunities for state and local governments to coordinate with federal agencies, build more community partnerships, and increase intervention uptake; and the Improving Medicare Post-Acute Care Transformation Act of 2014, which requires the facilitation of research on issues related to social risk in Medicare's value-based payment programs.

LaShawn McIver, MD, MPH

Centers for Medicare & Medicaid Services

The mission of the CMS Office of Minority Health (OMH) is to lead the advancement and integration of health equity in the development, evaluation, and implementation of CMS policies, programs, and partnerships with the goal to provide all individuals served by CMS with the highest level of health and wellbeing. The OMH serves as the principal advisor and coordinator of all minority health issues at CMS by (1) leading the development of CMS-wide data collection infrastructure for minority health activities, (2) participating in the formulation of CMS goals, policies, priorities, and legislative proposals as they affect the delivery of culturally appropriate health services to minorities and disadvantaged populations, (3) consulting with the HHS Operating Divisions and other public- and private-sector agencies to collaborate in addressing health equity, and (4) coordinating the implementation of health equity–related Executive Orders issued by the President.

Executive Order 13985, titled "Advancing Racial Equity and Support for Underserved Communities through the Federal Government," details a systematic approach to address inequities in federal policies and programs that serve as barriers to equal opportunity and to embed fairness in the decision-making process within executive departments and agencies of the federal government. This Executive Order has multiple CMS-relevant sections, including those that establish implementation policies across the federal government; provide definitions of equity, underserved, and specific populations and methods to assess equity; and mandate the need for federal agencies to increase coordination, community, and engagement with community-based and civil rights organizations.

In addition, OMH aims to better incorporate definitions of SDOH within CMS practices, as defined by *Healthy People 2030*, in order to ensure that health care delivery is tailored to the millions of individuals served by CMS. SDOH are important because they affect 70 to 90 percent of patient health. Thus, strengthening collection,

reporting, and analysis of demographic and SDOH data is imperative to the mission of CMS OMH. OMH aims to collaborate across federal agencies to standardize data elements, increase collection of these elements, perform additional analyses using these data elements, and support clinical teams and coders with training on how to use SDOH information to improve care.

Janet Hamilton, MPH

Council of State and Territorial Epidemiologists

Ms. Hamilton served as Co-Chair for the Public Health Data Systems Task Force convened by ONC and HITAC to inform HHS' response to President Biden's Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. The focus of the Task Force was to address bi-directional data exchange between clinical data sources and information systems. The Task Force developed 52 recommendations, including the following: (1) a recommendation emphasizing the need to envision public health contributions and alignment with innovative health care, (2) a recommendation that ONC create a health data ecosystem that supports public health during responses to high-consequence health threats, (3) a recommendation that ONC and CDC advocate to the U.S. Congress for robust, sustained, and consistent funding of CDC's Data Modernization Initiative, (4) a recommendation that CDC collaborate with health departments to collect multiple health equity measures (e.g., race, ethnicity, disability, sexual orientation, and preferred language), (5) a recommendation to develop national standards describing disability and that those standards encompass the physical, sensory, and intellectual components of disability, (6) a recommendation that ONC support the development for technology for patient use, and (7) a recommendation to standardize the collection of address information to facilitate geolocation interoperability and merging with census data.

The Council of State and Territorial Epidemiologists (CSTE) launched the Data: Elemental to Health campaign in collaboration with multiple other stakeholders in the health standards field to support data modernization. This campaign identified five core data systems that support public health surveillance and are essential to protecting the health security of all Americans: (1) the National Notifiable Disease Surveillance System, (2) electronic case reporting, (3) syndromic surveillance, (4) the electronic vital records system (particularly death certificate data), and (5) laboratory information systems. These data systems must be interoperable, particularly between death records and case management systems in state, local, and tribal health departments.

Shawna Webster

National Association for Public Health Statistics and Information Systems

The National Association for Public Health Statistics and Information Systems (NAPHSIS) is the nonprofit member organization representing the nation's 57 vital records jurisdictions (50 states, New York City, Washington, DC, and 5 territories). Vital records are imperative to health care reporting and overall health reporting and are the bedrock of population health and identity. Thus, vital records are critical to data modernization efforts, as outlined by Ms. Hamilton in the previous presentation. The standard birth certificate contains approximately 58 fields, and standard death certificates contain approximately 55 fields; however, some jurisdictions contain additional fields to those provided by NCHVS. Timely and accurate death certificate data enable organizations and government agencies to respond in real-time to disease outbreaks or other high-mortality disasters. Ms. Webster emphasized that vital records infrastructure must be improved and made to increase the health care system's ability to respond to these types of disasters in real time with the necessary data. Sustained and coordinated investments are needed to update legacy systems that are now between 5 and 15 years old.

Vital records are not always easily accessible or easy to link with other datasets. Legal barriers that vary across states are only one of the challenges to making these records accessible and linkable. Through the "Data: Elemental to Health" campaign, CDC funded vital record collection to help implement FHIR within death certificate registration systems in each NAPHSIS jurisdiction (approximately $1 million funded to each); however, the majority of NAPHSIS jurisdictions have indicated a lack of readiness to collect such data. Additional time will be needed to build infrastructure and a workforce to implement many of the data standards recommended by CDC. Ms. Webster recommended that NCVHS emphasize the value of vital records broadly across CDC and other federal agencies that rely on these data and advocate that these agencies pay commensurate with their use of these data.

In 2015, the Social Security Administration (SSA) testified that the receipt of state death data saved the SSA approximately $50 million per month by preventing the allocation of improper payments, leading the SSA to allocate less than $10 million to all 50 states each year since then. The SSA shares these death data with multiple other agencies, including CMS, likely further reducing improper health care payments by hundreds of billions of dollars. Unfortunately, these saved dollars do not reach the states that provided these data in the first place. Recent legislation has set a 3-year timeline to expand SSA's authority to share death certificate data with other agencies, likely leading to near-time negotiation of many state contracts. Ms. Webster recommended that NCVHS advocate a funding structure so that the states receive adequate reimbursements in exchange for these critical death certificate datasets provided to SSA each year. These revenues are needed to sustain and improve state vital statistics data infrastructure. Ms. Webster noted that SSA has also engaged with NAPHSIS to begin collecting race and ethnicity data within their death certificate collections. Higher reimbursements to the states would help NAPHSIS expand the data fields collected during death certificate collection.

Evelyn Gallego

EMI Advisors and HL7 Gravity Project

The HL7 Gravity Project aims to foster equitable health and social care using consensus-driven data standards to support the use and exchange of SDOH data and minimize current challenges in SDOH data capture and exchange. The Gravity Project was launched in 2019 as a multi-stakeholder collaborative with the scope of developing data standards to represent patient-level SDOH data documented across four clinical activities: screening, assessments, goal-setting, and interventions.

The Gravity Project's roadmap involves two major workstreams: the terminology workstream and the technical workstream. The Gravity Project has developed several terminologies, including those for stress, social connection, and intimate partner violence, as well as several implementation guides. The terminology workstream is focused on data element and coding gap analysis across four domains: (1) LOINC screening/assessment, (2) ICD-10 diagnoses, (3) LOINC/SNOMED goals setting, and (4) SNOMED interventions. Through this workstream, the Gravity Project has submitted new and updated ICD-10 CM codes for release in 2022. The technical workstream focuses on implementation guide and domain dataset development to support FHIR use. The Gravity Project helped to develop a SDOH Clinical Care FHIR Implementation Guide, which serves as a framework to support clinical activities related to assessments, health concerns, goals, interventions, consent, and aggregation of reports.

The Gravity Project is also involved in policy integration and formally submitted information for inclusion in the USCDI Version 2; this submission has been approved by HITAC and ONC as of July 2021. Further, CMS has started to encourage states to participate in the Gravity Project. Gravity Project-derived resources have also been incorporated into grants released by the Administration of Community Living and the ONC Leading Edge Acceleration Projects in HIT.

Ms. Gallego emphasized the need for NCVHS to promote interoperability in public health by incorporating terminology and data exchange standards in public health reporting requirements, providing specific technical guidance for public health agencies to use in procurement specifications, embedding incentives for adopting technology capable of sharing standards based on SDOH information, and finance testing and piloting of terminology and data exchange standards with data sharing partners.

Question and Answer Session

How can NCVHS increase the amount of state-collected information?

Ms. Gallego emphasized that including USCDI in current processes can help to increase the volume of information collected and that embedding easy solutions into the broader workflow can help overall. Ms. Mays added the lack of standardization across states challenges data collection. Dr. McIver commented that CMS is actively investigating strategies to collect the best and most data from states.

Ms. Hamilton noted that additional granularity in the demographic and clinical data collected would greatly improve the types of data collected across states because some current fields may not encompass how patients view themselves (e.g., race or gender fields), adding that the field should also determine a minimum set of clinical

information that enables patient matching. Ms. Hamilton added that many states are required to share race and ethnicity information in the context of COVID-19, but these data are not reaching the public health sector, leading to an information gap. Ms. Mays emphasized that these gaps are not a provider issue, but a public health regulatory issue that must be solved.

NCVHS Standards Subcommittee Discussion

Need for Change and Improved Communication

Mr. Landen reflected on the common recommendation for NCVHS to review the HIPAA transaction and code set processes in order to align them with the emergence of APIs and FHIR. Currently, the health standards field depends on voluntary consensus standards, but the implementation of those standards must be supported by policy decisions. Ms. Love added that the presentations and discussions highlighted the need for improved messaging and broad change throughout the industry and that NCHVS can be the impetus for identifying where that change must occur and the processes forward.

Content Standards from a Point of Origin

Mr. Ferguson recommended developing a roadmap to achieve consistent implementation and compliance with content standards from a point of origin. The best method to collect SDOH data, as well as converge clinical and administrative data and achieve semantic harmonization, requires the use of a consistent content standard at a point of origin, including different standards for different purposes. Mr. Landen added that there can be multiple points of origin.

Scope

Ms. Love noted that many speakers discussed the need for expanded HIPAA regulations for covered entities. Mr. Landen noted that NCVHS will continue to prioritize assessment of this topic for its applicability to the Subcommittee's scope. Ms. Bernstein noted that the Subcommittee's scope can include any necessary recommendations, including whether to expand HIPAA for covered entities, and that the Secretary has the ability to promote legislation, as needed.

Public Comment

The Standards Subcommittee received two comments during the Public Comment session, summarized below:

- Obtaining mortality data is challenging, particularly because most pricing models cause mortality data to be overly expensive, causing projects involving mortality data to be infeasible (Isabella Chu).
- Mortality data is a high-priority for many research studies and increasing the accessibility of these data would benefit such work (Sam Roosz).

Closing Remarks and Adjournment

Mr. Landen thanked all speakers, moderators, and attendees for their participation and adjourned the listening session.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/	10/28/2021
Nicholas Coussoule Chair, NCVHS	Date

Appendix A: Agenda

National Committee on Vital and Health Statistics (NCVHS)

Subcommittee on Standards Listening Session on
Healthcare Standards Development, Adoption, and Implementation

Wednesday, August 25, 2021

Time	Panel	Participants
10:00 a.m.	**Welcome, Call to Order**	Rebecca Hines Executive Secretary/Designated Federal Officer
10:10 a.m.	**Opening Remarks/Agenda Review**	Rich Landen and Denise Love, Co-Chairs Subcommittee on Standards
10:20 a.m.	**Overview of Federal Health Information Standards Convergence Landscape**	Rich Landen, Project Lead for Convergence Project Aaron Miri, Co-Chair, ONC HITAC
10:40 a.m.	**Panel 1: Lessons Learned from National Standards Coordination (Functions and Processes**	Moderator: Jamie Ferguson, Subcommittee on Standards, NCVHS ANSI: Fran Schrotter ANAB: Lane Hallenbeck FDA: Scott Colburn RTI: Dan Vreeman
11:30 a.m.	**Panel 2: Information Exchange and HIPAA—Present Day Challenges and Future Opportunities**	Moderator: Tammy Banks, Subcommittee on Standards, NCVHS CMS/National Standards Group: Dan Kalwa AMA: Health McComas HL7: Chuck Jaffe Da Vinci: Jocelyn Keegan Cambia: Kirk Anderson X12: Cathy Sheppard BCBSA: Gail Kocher Cooperative Exchange: Crystal Ewing WEDI: Nancy Spector
1:00 p.m.	**Break**	
1:45 p.m.	**Panel 3: Semantic Harmonization of Standards**	Moderator: Jim Cimino, Subcommittee on Standards, NCVHS Kaiser Permanente: Jeff Swanson HHS/ONC: Matthew Rahn HL7: Wayne Kubick NIH/NLM: Clem McDonald AMA: Jay Ahlman SNOMED: Jim Case
3:00 p.m.	**Break**	

Time	Panel	Participants
3:15 p.m.	**Panel 4: Update on National and HHS Initiatives on Public Health Data Systems and Social Determinants of Health**	Moderators: Denise Love, Subcommittee on Standards, NCVHS, and Denise Chrysler, Subcommittee on Privacy, Confidentiality, and Security, NCVHS UCLA/NCVHS Member: Vickie Mays CMS: LaShawn McIver CSTE and ONC PHDS Task Force Co-Chair: Janet Hamilton NAPHSIS: Shawna Webster Gravity Project: Evelyn Gallego
4:30 p.m.	**NCVHS Standards Subcommittee Discussion**	Subcommittee and NCHVS Members
5:00 p.m.	**Public Comment**	Rebecca Hines Executive Secretary/DFO
5:15 p.m.	**Closing Remarks and Adjournment**	Rich Landen and Denise Love Co-chairs, Subcommittee on Standards

Appendix B: Invited Speakers

Jay Ahlman, Vice President, Coding and Reimbursement, American Medical Association

Kirk Anderson, Vice President and Chief Technology Officer, Cambia Health Solutions

Jim Case, Head of Terminology, SNOMED International

Scott Colburn, Director, Center for Devices and Radiological Health Standards and Conformity Assessment Program, U.S. Food and Drug Administration

Crystal Ewing, Board Chair, Cooperative Exchange, and Director of Product, Waystar

Evelyn Gallego, Chief Executive Officer, EMI Advisors, and Program Manager, HL7 Gravity Project

Lane Hallenbeck, Executive Director, American National Standards Institute Accreditation Board

Janet Hamilton, Executive Director at Council of State and Territorial Epidemiologists, and Co-Chair of Public Health Data Systems Task Force, Office of the National Coordinator for Health Information Technology

Chuck Jaffe, Chief Executive Officer, HL7

Daniel Kalwa, Policy Analyst, Centers for Medicare & Medicaid Services

Jocelyn Keegan, Program Manager, HL7 Da Vinci Project

Gail Kocher, Director of National Standards, Blue Cross and Blue Shield Association

Wayne Kubick, Chief Technology Officer, HL7

Vickie Mays, Professor and Director, Department of Psychology and Health Services, University of California, Los Angeles

Heather McComas, Director of Administrative Simplification Policy, American Medical Association

Clem McDonald, Senior Investigator, Office of the Director, National Library of Medicine, National Institutes of Health

LaShawn McIver, Director, Office of Minority Health, Centers for Medicaid and Medicare Services

Aaron Miri, Chief Information Officer, Dell Medical School at the University of Texas at Austin

Matthew Rahn, Deputy Director, Standards Division at Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

Fran Schrotter, Senior Vice President and Chief Operating Officer, American National Standards Institute

Cathy Sheppard, Executive Director, X12

Nancy Spector, WEDI Chair and Coding and Health Advocacy Director, American Medical Association

Jeff Swanson, Physician, Kaiser Permanente

Dan Vreeman, Senior Clinical Data Standards Lead, RTI International

Shawna Webster, Executive Director, National Association for Public Health Statistics and Information Systems

Appendix C: Virtual Meeting Attendees

Name	Organization
Marietta Squire	HHS/CDC, NCVHS
Maya Bernstein	HHS/ASPE, NCVHS
Geneva Cashaw	HHS/CDC, NCVHS
Rachel Seeger	HHS/OCR, NCVHS
Oluwarantimi Adetunji	HHS
Leslie Amoros	Imprado/DynaVet Solutions/HL7 Da Vinci Project
Liz Amos	National Library of Medicine
Kelly Anderson	
Dennis Anderson-Villaluz	HHS-ODPHP
Hallie Andrews	CDC/NCHS
Ebunola Aniyikaiye	American Medical Association
Sara Armson	RTI International
Vivian Auld	National Library of Medicine/NIH/HHS
Victoria Aysola	HHS/ASPE
Pooja Babbrah	POCP
Kelly Baker	OSDH VR
Alison Barr	ODM
Michelle Barry	Availity, LLC
Rita Barsoum	Kaiser Permanente
Fred Bazzoli	Health Data Management
Regina Beach	Enterprise Resource Planning International, LLC
Gary Beatty	ASC X12
Guy Beaudoin	Wyoming Vital Statistics Services
Tony Benson	Blue Cross and Blue Shield of Alabama
Michelle Benz	Edifecs
Melissa Bird	Iowa
David Bissell	Philadelphia Public Health Dept - Medical Examiner's Office - Fatality Review
Angie Bleibaum	UHG
Meryl Bloomrosen	Premier healthcare alliance
Alexis Boaz	
Peter Boersma	CDC
Sue Bowman	American Health Information Management Association
June Bronnert	IMO
Benjamin Brooks	Whitman-Walker Health
Susan Brousseau	BCBSMN
Denae Brown	Oklahoma
Djibril Camara	AHRQ
Katie Campanale	Accel Solutions LLC
Vanessa Candelora	POCP
Verbit Captions	
Yulia Carroll	Division for Env Health Science and Practice, CDC
Lynn Chapple	Optum
Flavia Chen	UCSF

Chanda Chhay	Caset Associates
Kristol Chism	Change Healthcare
In Hye Cho	NIH/NLM
Isabella Chu	Stanford Center for Population Health Sciences
Jim Cimino	UAB
Joseph Cody	American College of Cardiology
David Cohen	Vesta Inc
Beth Connor	CMS
Amanda Cooney	PA Government
Amy Costello	UNH
Sara Couture	
Caleb Cox	SCDHEC
Lindsey Crandle	HHS
Corina Davis	Wyoming Vital Statistics
Beth Davis	Allscripts
Durwin Day	Health Care Service Corporation
Michelle Deane	ANSI
Mike Denison	Change Healthcare
Chad Denlinger	Genesis Systems, Inc.
TUYET DESJEAN	AMA
Anne Deutsch	RTI International
Kim Diehl-Boyd	CoverMyMeds
John Donnelly	IntePro Solutions Inc
Michelle Dougherty	RTI International
Dawn Duchek	Trizetto Provider Solutions a Cognizant Company
Dionne Evans-Dean	Office of Statewide Health Planning and Development
Stephanie Fiore	Anthem, Inc.
Deanna Flores	The Permanente Federation
Rachel Foerster	RFA-EDI
Evert Ford	UnitedHealth Group
Catherine French	American Society of Plastic Surgeons
Brad Frome	UnitedHealth Group
Elizabeth Frugale	Connecticut Department of Public Health
Diana Fuller	State of Michigan Medicaid
Charles Gabrial	Federal Electronic Health Record Modernization (FEHRM)
Christine Gerhardt	CMS
Zabrina Gonzaga	Lantana Consulting Group
Ana Goold	NAPHSIS
Alix Goss	Imprado
Christopher Gracon	Independent Health
Becky Gradl	Academy of Nutrition and Dietetics
Catherine Graeff	Sonora Advisory Group, LLC
Tina Greene	Mitchell
Maribeth Greenway	
Violanda Grigorescu	HHS/ASPE
Eric Grindstaff	Allscripts
Mary Griskewicz	Cigna

Pam Grosze	PNC Bank Healthcare
Philo Hall	Epstein Becker & Green, PC
Kuki Hansen	APHL
Patrick Haren	Evernorth
Chris Harrison	Georgia Department of Public Health - Vital Records
David Haugen	MN Dept. of Health
Lauren Hovey	NORC at the University of Chicago
Susan Hull	MITRE
Bernadette Inskeep	UnitedHealthcare
Katherine Isbell	LexiCode
Christine Jackson	Medtronic
Merri-Ellen James	CMS
Miranda Jarnot	National Library of Medicine
Karah Jarvis	RELI Group Inc
Jennifer Jentsch	National Library of Medicine
Tim Jones	Joint Commission
Denise Joseph	HHS
MJ Karimi	HHS-ASPE
Janice Karin	Massachusetts Health Data Consortium
Beth Karpiak	CMS
Matt Kerschner	AHIMA
John Klimek	NCPDP
Patrice Kuppe	Surescripts
Ramona Lainhart	TDH
Rikki Lam	Sirona Strategies
Lisa Lang	NLM/NIH/HHS
Susan Langford	BlueCross BlueShield of Tennessee
Desirae Leaphart	NORC at the University of Chicago
Euny Lee	HHS
Jason Lee	The Open Group
Celine Lefebvre	AMA
Heidi Lengdorfer	NAPHSIS
Betty Lengyel-Gomez	MedInformatix
Ben Leonard	POLITICo
Carissa Lewis	HHS/CMS
Amy Lightstone	LA County Government
Terry Lucherini	Utah Government
Mary Lynam	Independent Contractor
Michael Mabry	RadNet
Maureen Madden	National Library of Medicine
Tyler Magley	CoverMyMeds
Karen Mandelbaum	Epstein Becker and Green
Jeanine "Nini" Martin	Olive AI
Jordan Martin	CoverMyMeds
Mark Martin	Availity
Phung Matthews	POCP
Nancy May	Actionet

Jim McCabe	ANSI
Deborah McCachern	Change Healthcare
Kristina McCann	CoverMyMeds
Rena McClain	CMS
Tracey McCutcheon	KPMG
Patrick McLaughlin	National Library of Medicine
Anne Mcnealis	Kaiser Permanente
Michael McNutt	WEDI
Linda Michaelsen	Optum
Michelle Miles	California Department of Public Health
Dana Moore	California Department of Public Health
Devaiah Muccatira	North Dakota Department of Health
Alexandra Mugge	CMS
Taylor Musser	Avalere Health
Jan Nagle	
Jean Narcisi	American Dental Association
Mostafa Nawabi	Deloitte
Viet Nguyen	
Paul Oates	Cigna
Amy O'Hara	Georgetown
Jameelah O'Neal	Medical Mutual
Michelle Panneton	Centers for Disease Control and Prevention / CDC Foundation
Michael Peters	ACR
Adam Pettis	Ohio Medicaid
Mariah Pokorny	South Dakota
Frank Pokorny	American Dental Association
Don Quackenbush	Cognizant
Hibah Qudsi	The MITRE Corporation
Deneen Ratchford	CMS
Molly Reese	AMA
Matt Reid	American Medical Association
Lyubov Remennik	NIH, NCI
Jenny Rewolinski	National Institutes of Health, National Library of Medicine
Sam Roosz	
Tara Rose	Optum
Suzy Roy	SNOMED International
Joel Ruhter	HHS
Katie Russell	CoverMyMeds
Patricia Ryan	Maryland Department of Health
Dan Ryan	HHS
Claudia Salzberg	MITRE
Mary Saunders	American National Standards Institute
Patrick Schoen	HRSA BPHC
Michael Schoenbaum	NIMH/NIH
Marsha Schofield	Academy of Nutrition and Dietetics
Patricia Serpico	AAOMS
Rashmi Shetgiri	LA County Government

Kristi Siahaya	AIRA
Sarah Singer	Genesis Systems Inc.
Samantha Singer	Cityblock Health
Kathy Sites	Availity
Nichole Small	Ohio Department of Medicaid
Gwyn Smith	VA
John Snyder	U.S. National Library of Medicine, National Institutes of Health
David Sosnow	AMA
Ashley Southerland	American Medical Association
Shelly Spiro	Pharmacy HIT Collaborative
Howard Sragow	Evernorth
Marta Steliac	FDA
Charles Stellar	WEDI
Pamela Stephenson	HHS/CDC
Merri-Lee Stine	Aetna
Kimberly Strand	Aetna
Kelly Strong	
Walter Suarez	Kaiser Permanente
Erin Sutton	AMA
William Swan	Self
Greg Szuman	Genesis Systems, Inc.
Jessica Tavares	CVS Health
Robert Tennant	WEDI
Maja Thagaard	Embassy of Denmark to the United States
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Appendix D: List of Acronyms

AEOB	advanced explanation of benefit
AMA	American Medical Association
ANAB	American National Standards Institute Accreditation Board
ANSI	American National Standards Institute
API	Application Programming Interface
BCBSA	Blue Cross and Blue Shield Association
CAQH	Council for Affordable Quality Healthcare, Inc.
CDC	U.S. Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CMT	Convergent Medical Terminology
COVID-19	coronavirus disease 2019
CPT	Current Procedural Terminology
CSTE	Council of State and Territorial Epidemiologists
EDI	electronic data interchange
EHR	Electronic Health Record
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
GFE	good faith estimate
HL7	Health Level 7 International
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	Health Information Technology
HITAC	Health Information Technology Advisory Committee
HSC	Health Standards Collaborative
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KP	Kaiser Permanente
LOINC	Logical Observation Identifiers Names and Codes
NAPHSIS	National Association for Public Health Statistics and Information Systems
NCHS	National Center for Health Statistics
NCVHS	National Committee on Vital and Health Statistics
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
NTTAA	National Technology Transfer and Advancement Act
OMB	Office of Management and Budget
OMH	Office of Minority Health
ONC	Office of the National Coordinator for Health Information Technology
PA	prior authorization
ROI	Release of Information
RTPB	real-time pharmacy benefit
S-CAP	Standards and Conformity Assessment Program
SDO	Standards Development Organization
SDOH	social determinants of health
SNOMED	Systemized Nomenclature of Medicine
SSA	Social Security Administration
U.S.	United States
USCDI	U.S. Core Data for Interoperability
WEDI	Workgroup for Electronic Data Interchange