NCVHS Subcommittee on Standards

Comments Received in Response to Request for Comment
Federal Register Notice: 86 FR 33318

Input on Healthcare Standards, Development, Adoption and Implementation

Received as of November 8, 2021

	Organization	Signatory	Notes
1	68 organizations representing medical specialty societies	Matt Reid, MS Sr. Health IT Consultant Federal Affairs, AMA	
2	ADA	Corey McGee Manager, Legislative and Regulatory Policy	
3	AHA	Mike Schiller, CMRP Senior Director, Supply Chain	
4	AHA	Terrence Cunningham Director, Administrative Simplification Policy	
5	AHIMA	Wylecia Wiggs Harris, PhD, CAE Chief Executive Officer	
6	AHIP	Danielle A. Lloyd Sr. VP, Private Market Innovations & Quality Initiatives	
7	Altarum	Rick Keller VP for Connected Health	
8	AMA	James L. Madara, MD CEO and Executive VP	
9	APCD Council	Norm Thurston, PhD Executive Director, NAHDO, and Josephine Porter, MPH Director, IHPP, UNH	
10	BCBSA	Kris Haltmeyer VP, Legislative and Regulatory Policy	
11	CAQH CORE	April Todd Sr. Vice President	
12	Cleveland Clinic	Amy Merlino, MD, FACOG Enterprise Chief Medical Information Officer	
13	Comagine Health	Daniel Hollander Business Development Manager - Federal	
14	Confidentiality Coalition	Tina O. Grande Chair, Confidentiality Coalition and Executive VP, Policy, Healthcare Leadership Council	

15	Cooperative Exchange	Crystal Ewing Board Chair	
16	EHNAC	Lee Barrett Executive Director and CEO	
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23	NCPDP	Lee Ann C. Stember President & CEO	
24	NUCC	Nancy Spector Chairperson	
25	Premier healthcare alliance	Blair Childs Sr. VP, Public Affairs	
26	SNOMED International	Don Sweete CEO	
27	Surescripts	Mary Ann Chaffee VP, Policy and Federal Affairs	
28	Texas Medical Association	Ogechika Alozie, MD, MPH Chair, Committee on Health Information Technology	
29	WEDI	Nancy Spector Chairperson	
30	World Privacy Forum	Pam Dixon Executive Director	
31	X12	Cathy Sheppard Executive Director	

July 30, 2021

Richard W. Landen, MPH, MBA
Denise E. Love, BSN, MBA
Co-Chairs, National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Co-Chairs Mr. Landen and Ms. Love,

The undersigned organizations representing the nation's medical specialty societies write to express support for the National Committee on Vital and Health Statistics' (NCVHS) efforts to enhance the exchange of clinical and administrative data through their recommendations to the Secretary. Data interoperability enables clinicians to coordinate care among institutions and act based on comprehensive and current information. Interoperability also enables individual access to and ownership of health data. Interoperability is critical to safe, responsible, and transparent public health reporting and monitoring. Further, interoperability is also a key component in the Learning Health System and—when data are properly coded in consensus-based standards—makes the promise of the Quadruple Aim achievable.[1,2]

The scope of data sharing has expanded to encompass social and behavioral services, public health, cost and quality assessment, and research, in addition to administrative uses. Data standards, therefore, must be multifaceted and meet the needs of several stakeholders. The clinical community relies on high-quality data, which can literally make the difference in life-or-death situations. Physicians require data standards that are credible, comprehensive, and that are developed using a rigorous and evidence-based process.

The Current Procedural Terminology (CPT®) code set serves the needs of a data-driven health system by allowing physicians, patients, researchers, medical groups, allied health care professionals, health systems, hospitals, medical coders, accreditation organizations, payers, and health information technology professionals to easily exchange data on the medical services and procedures provided to our patients. This seamless flow of complex medical information across the health system using this uniform code set allows for the reporting, measuring, analyzing, and benchmarking needed to ensure the provision of high-quality care in a sustainable health delivery system.

The CPT code set is a foundational element for describing medical services and procedures and is universally trusted by the health care system. CPT codes are evidence-based, timely, and reflect current clinical practice to provide a common language for medical services and procedures. The CPT code set not only enables the effective transfer of vital clinical data, but also facilitates the exchange of administrative claims processing information. Furthermore, CPT codes are well-understood and tightly integrated within physician workflows.

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[1] The Agency for Healthcare Research and Quality defines a Learning Health System as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice. As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.

[2] The Quadruple Aim enhances the patient experience of care and outcomes, improves population health, reduces overall costs for the health care system while increasing value, and supports the professional satisfaction of physicians and the health care team.

Significantly, CPT codes have also been developed to describe services that address identified social determinants of health (SDOH) concerns, problems, or diagnoses because they are integral to medical services and procedures used by clinicians. These SDOH CPT codes are recognized by The Office of the National Coordinator for Health Information Technology (ONC) in the United States Core Data for Interoperability (USCDI) version 2.

The CPT Editorial Panel is an independent body of expert physicians and qualified health care professionals convened by the American Medical Association (AMA) with the unique ability to manage an open, transparent, consensus-based and stakeholder-driven editorial process. The CPT Editorial Panel and the CPT code set is unique across terminologies curators in that procedure code development is directly informed by a broad spectrum of medical and clinical experts. This ensures that the CPT code set reflects the coding demands of digital health, precision medicine, augmented intelligence (AI), and other aspects of a modern health care system. This rigorous, tested and evolving editorial process keeps the CPT code set current and is open to everyone.

The AMA and the CPT Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of health data standards across disparate health-related data systems. Moreover, the CPT code set meets the business needs of the health care system. Health insurers and payers use the same codes for all medical services and procedures, which ensures uniformity and reduces waste. CPT codes serve as the foundation for health plans' claims adjudication systems.

CPT Consumer Friendly Descriptors play a vital role in helping patients and consumers better understand the medical services and procedures their clinicians prescribe as they navigate the health care system. This level of engagement (a) supports a patient's active role in decision making; (b) improves compliance with care plans; (c) helps patients better understand important health information communicated to them by their physicians; and (d) expands equitable access to health information and knowledge—all of which contribute to improved health outcomes. The CPT Consumer Friendly Descriptors also support federal and regulatory initiatives to provide patients with their health information through claims data.

The CPT code set will continue to play a vital role in data sharing among physicians and other qualified health care professionals, patients, payers, public health systems, and other actors in health care. As health care evolves, reliable and trusted data, coding, and terminologies—such as the CPT code set—must continue to receive support.

We recognize the important role that NCVHS plays in making recommendations to the Secretary of the Department of Health and Human Services related to the adoption of code sets and standards under The Health Insurance Portability and Accountability Act (HIPAA). As you are aware, the CPT code set already is an adopted standard for HIPAA purposes. In its recommendations to the Secretary, we urge NCVHS to continue to support the foundational role that the CPT code set and the CPT Editorial Panel play in the efficient and effective exchange of electronic health related data under HIPAA.

Sincerely,

American Medical Association
AMDA – The Society for PALTC Medicine

American Academy of Allergy, Asthma & Immunology
American Academy of Audiology
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American Academy of Pediatrics
American Academy of Physical Medicine & Rehabilitation
American Academy of Physician Assistants
American Academy of Sleep Medicine
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic
American Association of Oral and Maxillofacial Surgery
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Medical Genetics and Genomics
American College of Obstetricians and Gynecologists
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American Dental Association
American Gastroenterological Association
American Nurses Association
American Optometric Association
American Osteopathic Association
American Physical Therapy Association
American Academy of Pain Medicine
American Podiatric Medical Association
American Psychiatric Association
American Psychological Association
American Roentgen Ray Society
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Radiation Oncology
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Dermatopathology
American Society of Echocardiography
American Society of Hematology

American Society of Neuroradiology
American Society of Plastic Surgeons
American Society of Retina Specialists
American Thoracic Society
American Urological Association
American Vein & Lymphatic Society
Association for Clinical Oncology
College of American Pathologists
Congress of Neurological Surgeons
Endocrine Society
Heart Rhythm Society
Infectious Diseases Society of America
International Society for Advancement of Spine Surgery
Medical Group Management Association
National Athletic Trainers' Association
National Society of Genetic Counselors
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Interventional Radiology
Spine Intervention Society American College of Surgeons
The Aesthetic Society
Triological Society

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July 30, 2021

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Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

July 30, 2021

Via: NCVHSmail@cdc.gov

Re: Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

Dear Mr. Landen and Ms. Love:

On behalf of its more than 162,000 members, the American Dental Association (ADA) is pleased to provide comments in response to the request for public comment from the National Committee on Vital and Health Statistics (NCVHS), entitled "Healthcare Standards Development, Adoption and Implementation" published on June 18, 2021. The ADA is the world's oldest and largest professional dental association and is named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as an advisor to the Secretary. As an advisor, the ADA is typically invited to provide testimony to the NCVHS. While we are pleased to share our enclosed thoughts in response to this Request for Public Comment (RPC), we look forward to being able to continue to provide in-person testimony to NCVHS as the Committee reviews standards development, adoption and implementation for dentistry.

The ADA is in favor of data sharing policy that empowers patients. In particular, the ADA supports requiring payers to make enrollees' data available via Application Program Interfaces (APIs), and requiring payers to facilitate identification of in-network providers for current and prospective enrollees. The adoption and implementation by dental practice management systems and electronic dental record systems of Fast Healthcare Interoperability Resources (FHIR) and the United States Core Data for Interoperability (USCDI), along with the essential dental terminologies CDT and SNODENT, should be encouraged. The ADA's Dental Experience and Research Exchange is an example of a use case that relies on interoperability standards such as FHIR for API's and the USCDI for core data elements. The ADA supports the review of mechanisms to promote use of these standards across the health system including dentistry.

The ADA encourages developments that improve the return on investment dentists obtain from information technology, and has actively been involved in such efforts. The ADA suggests that any future interoperability standards for use in dentist-dentist and dentist-physician exchange be established by defining clinical requirements at the ADA Standards

Committee on Dental Informatics (SCDI), and definition of technical implementation requirements at Health Level 7 (HL7).

In order to ensure that terminology standards are credible, comprehensive, and developed using rigorous and evidence-based processes, the ADA recommends that NCVHS continue to support trusted, evidence-based, flexible, and universally used terminology standards that reflect current clinical practice such as: Current Dental Terminology (CDT) for dental services; CPT; International Classification of Diseases; Tenth Revision, Clinical Modification (ICD-10-CM) International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS); and National Drug Codes (NDC). SNOMED CT should **not** be the only terminology identified in the USCDI for use in interoperability clinical standards.

The ADA recommends that ONC Innovation Center findings, successes, and challenges be shared with the public so that the industry may learn and grow from them. The Innovation Center should be mindful of implementation challenges in the dental provider sector and look for ways to avoid burdening participating dentists while still meeting program goals. The ADA also recommends that the Innovation Center avail itself of the CDT code set and the SNODENT® terminology standard (ANSI Standard No. 2000) as well as ADA/HL7 joint standards work products for purposes of interoperability testing, problem solving, and improvements in the multi-specialty provider setting.

In order for open Application Program Interfaces (APIs) to be successfully used as information sharing tools for consumers to access and to share their electronic health information, HHS will need to publish very clear guidance and decision trees on when it is, or is not, appropriate to disclose PHI to a third party application in the proposed new API environment. The ADA urges a strict regulatory approach for entry into the direct-to-consumer health information sharing API market, rather than the unsound approach of after-the-fact enforcement. Finally, the ADA agrees that both providers and health plans regulated by a rule should have sole authority to permit third party applications to access electronic health information via their APIs.

Please see the attached comments for more information. If you have any questions, please feel free to contact Ms. Jean Narcisi, Director of Dental Informatics at the American Dental Association at (312) 440-2750 or narcisij@ada.org.

Sincerely,

Daniel J. Klemmedson, D.D.S, M.D.
President

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

DJK:KTO:cm

As a longstanding member of the standards development community, the ADA appreciates the opportunity to submit the following information in response to the RPC from NCVHS entitled “Healthcare Standards Development, Adoption and Implementation” published on June 18, 2021. We believe this RPC process is an important step toward improving the identification and implementation of standards that will streamline communications between patients, providers, health plans and other health care stakeholders.

The ADA itself is a leader in the development, publication, and implementation of interoperability standards in the oral health care setting, and is an American National Standards Institute (ANSI) Accredited Standards Development Organization for dental information technology through its Standards Committee on Dental Informatics (SCDI). The SCDI membership consists of a broad range of stakeholder interests, including technology vendors, dental plans, clearinghouses, national dental specialty organizations, federal sector representatives, practicing dentists, and academics.

1. How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

The ADA is in favor of empowering patients by requiring payers to make their enrollees’ data available via APIs through which third party software applications may connect. The ADA believes this should give patients the ability to take charge of their health care and could help to improve outcomes. The ADA especially supports the requirement for payers to make it easy for current and prospective enrollees to identify which providers are within a given plan’s network in a way that is easy for them to access and to understand.

In addition, the ADA believes that data interchange between providers and public health systems is essential to improving population health. To this end, the ADA believes that mechanisms should be in place to encourage adoption and implementation of FHIR and the USCDI along with the essential dental terminologies CDT and SNODENT by dental practice management systems and electronic dental record systems.

The use and exchange of health data is fundamental for providing equitable high-quality care. The digital transformation of health and care will bring many benefits to patients, healthcare professionals and society. The use of FHIR can help to make this contribution. The X12 standards are not working for dentistry, therefore, the ADA believes that FHIR-based solutions should be developed and replace the HIPAA transactions for dentistry.

In contrast to the older X12 standards for the exchange of health data, FHIR has been designed with a very strong focus on implementation and interoperability. Additionally, it leverages contemporary web standards, has good tooling support and is licensed for free use without restrictions. Together with the base domain model of modular FHIR “Resources”, standard developers can create useful, interoperable applications for exchange of administrative and clinical data in dentistry.

ADA Clinical Data Warehouse:

The American Dental Association has established a clinical data warehouse, using FHIR as the base standard, to collect data from dental practices, including solo and small groups. The ADA Dental Experience and Research Exchange (“DERE”) is an outcomes assessment, research and reporting program intended to promote excellence in dental care

by helping dental care providers create a culture of self-examination and improvement. DERE provides a process for standardized assessment of care and reliable information to help focus quality improvement activities where they are most needed.

DERE allows dental practices to submit practice data and patient data (a Limited Data Set as defined by HIPAA), every two weeks, directly from the practice's electronic health record systems and practice management systems, to the ADA Clinical Data Warehouse (ADA CDW), a protected cloud-based repository. CDT and SNODENT are the core terminologies used by the registry.

DERE is an example of a use case that relies on interoperability standards such as FHIR for API's and the USCDI for core data elements. As mentioned above, the lack of mechanisms to encourage adoption of these standards by the dental electronic system vendors limits the availability of data for such initiatives. The ADA encourages NCVHS to review mechanisms to promote use of these standards across the health system including dentistry.

2. Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification?

The ADA advocates for the dental profession through active participation in the standards community. The ADA participates with HL7 to develop interoperable solutions for dental data exchange. The ADA is also actively involved in the advancement of electronic data interchange (EDI) through its participation in the Accredited Standards Committee (ASC) X12. The ADA encourages developments that improve the return on investment dentists obtain from information technology not only in practice management but also in care delivery.

HL7: ADA's work with HL7 will allow for provider-to-provider exchange as well as provider-to-payer and provider-to-patient exchange through trusted exchange networks.

The ADA has had an ongoing partnership with HL7 for many years and this has allowed for the creation of HL7/ADA standards utilizing standard dental data content specifications originally developed by the ADA's SCDI. The ADA has a Statement of Understanding with HL7 which specifies that development of the dental content of standards rests with ADA, while HL7 provides the technical elements of the standard. The Department of Defense (DoD) participates in the development of the ADA standards and has provided a great deal of push in the form of support for a consultant to HL7 to aid in the development of HL7/ADA standards. The DoD is sponsoring further development of ADA Standard No. 1084, *Reference Core Data Set for Communication Among Dental and other Health Information Systems*, which is expected to aid significantly in interoperability between dental information systems and other forms of health information exchange. The DoD plans to implement these standards as part of their dental readiness program for reservists and active duty personnel. Currently, there is no standard for the exchange of discrete dental observations between dental providers. While some electronic health record systems have implemented the consolidated-clinical data architecture (C-CDA) for data exchange, these implementations are primarily for medical care, and do not include the structured data elements necessary for use by dental providers. We believe that all interoperability standards must be responsive to the needs of the dental community.

ANSI/ADA Standard No. 1084 provides the technical specifications to extract, format, and transmit a patient's demographic, dental, medical encounter, and clinical data for exchange between information systems to achieve syntactic and semantic interoperability. In 2020

HL7 approved moving forward with the development of a dental C-CDA implementation guide and a FHIR implementation guide based on ANSI/ADA Standard No. 1084.

That work has progressed rapidly, and the C-CDA implementation guide in addition to the FHIR guide for implementing Standard No. 1084's data content are completed, balloted and ballot reconciliation was recently finalized. Draft versions of these guides were used in the May 2020 FHIR Connectathon and illustrated the viability of the draft guides while identifying some action items for further development.

The exchange scenario use cases that have been developed for these guides include the following:

Medical to dental referral;
Dental to medical consult note;
General dentistry to dental specialist referral;
Dental specialist to general dentist referral result.

The ADA suggests that any future interoperability standards for use in dentist-dentist and dentist-physician exchange follow a similar development path; that is, definition of clinical requirements at the ADA SCDI and definition of technical implementation requirements at HL7, as this combines the best of both worlds. The ADA's ANSI-accredited standards development process and diverse dental sector stakeholders ensures a valid consensus about content requirements, and HL7 C-CDA and FHIR standards are already named standards for information exchange by the Office of the National Coordinator (ONC). Given the forward movement of this standards development work, we believe that mechanisms to encourage adoption and implementation of these standards by electronic dental record systems is the required next step.

The following code sets are used in the HL7/ADA newly published C-CDA and FHIR implementation guides for dental exchange:

The Code on Dental Procedures and Nomenclature, also known as Current Dental Terminology (CDT), maintained and distributed by the American Dental Association, for dental services is the only code set used in dentistry to document and report dental procedures. The CDT is a HIPAA named standard and is mandated for use by dental providers and payers for dental claims.

CDT is also the only code set used to document dental procedures that have been performed on patients in dental record systems. CDT is currently included in the United States Core Data for Interoperability (USCDI) and is identified as required for technology which records dental procedures.

The ADA also continues to maintain ANSI/ADA Standard No. 2000, Systematized Nomenclature of Dentistry (SNODENT®), a standard that has been recognized as an American National Standard by the American National Standards Institute, and is harmonized with SNOMED CT, with annual updates. SNODENT and its subsets provide dentists and developers with a standard, structured, clinical terminology that can work independently of platform or care setting to facilitate information exchange. SNODENT also enables data aggregation for quality assessment, quality improvement, and longitudinal studies.

HIPAA Code Sets

Data interoperability enables providers and payers to coordinate care among organizations and act based on comprehensive and current information. The scope of data interoperability has expanded to encompass social and behavioral services, public health, cost and quality assessment, and research, in addition to administrative uses. Terminology standards, therefore must be multifaceted and meet the varied needs of the industry. They must be credible, comprehensive, and developed using rigorous and evidence-based processes.

The CPT, International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) are terminology standards that are vital for describing medical services, procedures, and diagnoses. Additional crucial terminology standards are the Current Dental Terminology (CDT) for describing dental services and the National Drug Codes (NDC) for describing drugs and biologics. They are all evidence-based, flexible, reflect current clinical practice, are universally used, and are trusted by the health care system.

The terminology curators for these standards continually demonstrate successful coordination in the development, adoption, implementation, and conformity of the standards across disparate health-related data systems. The code sets will continue to play a vital role in data sharing among providers, patients, payers, public health systems, and other actors in health care. **The ADA recommends that NCVHS continue to support these trusted terminology standards and their guidelines.**

SNOMED CT should **not** be the only terminology recognized for use in interoperability clinical standards as identified in the USCDI. SNODENT is used by dental vendors to document dental patient problems and disorders. Most of it is harmonized with SNOMED CT but ADA has found that the process to submit changes and updates to SNOMED CT is sometimes very challenging and certain concepts that are used in the US are not used internationally. SNODENT includes oral anatomical sites, oral health conditions, findings, and other clinical concepts unique to dentistry. SNODENT enables patient data to be recorded by different people in different locations, and to be combined into simple information views in the patient record. It provides a standardized way to represent clinical oral health descriptions captured by dentists and enables automated interpretation of their observations. SNODENT is mapped to CDT and together they are designed for use in the electronic health records with features that include:

- An oral health resource with a granular clinical content;
- Consistent oral health content for use in electronic dental records;
- Mappings to ICD-10 CM;
- SNODENT is included in the ONC ISA and CDT is part of the USCDI;
  Both are recognized by and included in HL7/FHIR standards developed for dental data exchange.

X12: The ADA believes that administrative efficiency can only be achieved if we have robust standards and all business partners use these standards to communicate information. Currently, many of the administrative transaction standards do not meet the needs of dentistry.

The ADA's SCDI recently established a Memorandum of Understanding (MOU) with X12 to explore options for improving eligibility determination. A companion implementation guide to the X12 eligibility transaction to support better use of the existing electronic standards to convey eligibility and benefit information between third-party payers and dental practices is currently being developed. The current 270/271 eligibility standard is not effective for dental offices to determine eligibility.

As mentioned previously, the X12 standards are not working for dentistry, therefore, the ADA believes that FHIR-based solutions should be developed and replace the HIPAA transactions for dentistry.

Maturity of Application Program Interface (API) Functionality, Timelines, and Resources

The ADA believes that API technology can, and should, play a significant role in solving interoperability problems. Although there is a shortage of workforce sufficiently trained in FHIR implementation, naming the FHIR standard in federal rulemaking will drive recruiting and training of the needed workforce.

There will also need to be a significant amount of money earmarked for implementing these technologies if historically under-resourced payers, e.g., State Medicaid Organizations, are to participate in this effort successfully.

ADA Standard No. 1084 and the HL7/ADA Dental Exchange Implementation Guide should also be the core content standard for dental information sharing via APIs.

3. How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

The ADA believes that the proposed ONC Innovation Center models can offer a test bed for better integration across the health care spectrum and would ask that participating dentists be included in the Innovation Center's programs. The ADA recommends that the program findings, successes, and challenges be shared with the public so that the industry may learn and grow from them as well. We would ask that the Innovation Center be particularly mindful of the implementation challenges in the dental provider sector and look for ways to avoid burdening participating dentists while still meeting program goals.

These implementation challenges are:

Cost;
Availability of suitable technologies from mainstream dental information system vendors is not typically available because mainstream dental information systems are not enabled well for information exchange and there is little market incentive to change this. Integration of interoperable information exchange within dental information systems that use optimized workflows will help lower cost.

The ADA also recommends that the Innovation Center avail itself of the CDT code set and the SNODENT® terminology standard (ANSI Standard No. 2000) as well as ADA/HL7 joint standards work products for purposes of interoperability testing, problem solving, and improvements in the multi-specialty provider setting.

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS in the next 5 to 10 years?

Privacy and Security Concerns in the Context of APIs

The ADA has some concerns related to the proposed Open APIs as information sharing tools that will be used by consumers to access and to share their electronic health information.

First, although a covered health care provider is not responsible for the security of HIPAA Protected Health Information (PHI) once it has been received by a third-party application chosen by an individual, HHS will need to publish very clear guidance and decision trees on when it is, or is not, appropriate to disclose PHI to a third party application in the proposed new API environment. Such distinctions are quite nuanced and providers without a full-time legal analyst on staff need resources to help them adjust to their changing environment.

Secondly, the ADA believes that relying on after-the-fact enforcement action by an agency is an unsound approach to ensure that API developers adhere to the law. Rather, the ADA and its members would prefer to see a high bar for entry into the direct-to-consumer health information sharing API market. This high bar would include strict criteria and testing by independent accredited certifying bodies, in much the same manner as the Certified Health IT developers' certification process defined by the ONC. This will slow developers' ability to bring their products to market and will cost more money up front. However, it is money well spent if it prevents some avoidable security breaches.

The ADA also agrees that both providers and health plans regulated by a rule should have sole authority to permit third party applications to access electronic health information via their APIs.

Thank you for the opportunity to provide information relative to dentistry's position on Healthcare Standards Development, Adoption and Implementation. If you should have any questions, please feel free to contact Ms. Jean Narcisi, Director of Dental Informatics at the American Dental Association at (312) 440-2750 or narcisij@ada.org.

From: Schiller, Mike
To: NCVHS Mail (CDC)
Subject: Request for Public Comment on Healthcare Standards Development,
Date: Wednesday, July 28, 2021 7:23:32 PM

Response to National Committee on Vital and Health Statistics
Request for Public Comment on Health Care Data Standards Development, Adoption, and Implementation

The American Hospital Association's professional membership group, Association for Health Care Resource & Materials Management (AHRMM), sponsors the Learning UDI Community (LUC). The LUC is comprised of physicians, clinicians, hospital supply chain professionals, manufacturers, distributors, software application providers, health care consultants and representatives from Group Purchasing Organizations (GPOs), GS1, HIBCC, HIDA and the FDA. The mission of the LUC is to enhance patient safety and improve supply chain efficiency by developing recommended practices that speed the adoption and maximize the utilization of the UDI.

We appreciate the opportunity to provide the following comments related to the following NCVHS's questions.

1. **How can data sharing be improved between patients, providers, payors, public health systems, and other actors in health care? What are the barriers to these improvements?**

It is extremely important that medical devices be tracked from manufacture through the supply chain and point of use, into the patient record and medical device registries. Doing so allows patient level data to be connected to specific medical devices to enable the collection of real-world evidence. It allows researchers to study the clinical efficacy of devices and should improve the adverse reporting process. Additionally, it allows patients to be notified in the event they were treated with a recalled device. To achieve this goal, the following actions are recommended:

- All HHS agencies review the inclusion of the Unique Device Identifier (UDI) as a structured data element in all submissions, proposals, and reporting requirements. Specific examples of immediate requirements for including UDI in HHS policy and submissions are listed below:
  - CMS: NCVHS should recommend to CMS that the UDI-DI specified in the latest version of the ANSI/X12 standard be included in appropriate CMS regulatory policy.
  - FDA: Create a streamlined and digitized process for reporting adverse events and recalls. Ensure common data fields (which require the UDI-DI and UDI-PI) with common definitions are used consistently by manufacturers. Make manufacturer's electronic submissions immediately available to health care providers and other stakeholders involved in adverse event and recall processes. Simplify the electronic reporting process by enabling a scan of the barcode containing the UDI to auto populate fields and ensure there is one data dictionary across the FDA.

- Reduce redundancy and enhance data quality by using the GUDID as a foundational

master data source for government support of the healthcare supply chain.
    - Government Health Systems (VA, DOD, IHS)

Barriers to achieving the above recommendations include:

- Lack of standardized definitions, policies, and procedures between the various HHS agencies.
- Lack of structured data fields for the submission of the UDI.
- Lack of UDI in crucial device-related regulations related to government device purchasing, receiving, use and reimbursement.

2. What short-term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

The COVID-19 pandemic has highlighted the need for additional focus on supply chain resiliency. In addition to being able to track the flow of medical devices through the supply chain, it also requires the ability to quickly identify and locate substitutable products. Maximizing use of the UDI and Global Unique Device Database (GUDID) is critical to achieving these goals but improvements are required. Specifically:

- Set up and appropriately staff an FDA/NIH data quality assurance process that includes enforcement of minimum UDI requirements by manufacturers as well as collaborative efforts with data users to encourage reporting and correction of data errors.
- Evaluate the need for an open source DeviceNorm database (similar to RxNorm) that would be more responsive to health system requirements for normalized data based upon user feedback.
- Develop a collaborative stakeholder group to establish DeviceNorm that would identify gaps in GUDID that cannot be addressed by regulatory action and, establish data elements that should be required versus optional elements (e.g., catalog number, description, size) for a non-regulatory DeviceNorm.

Respectfully submitted,
Mike

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National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards Healthcare Standards Development, Adoption, and Implementation

Comments from the American Hospital Association

Dear Subcommittee Members:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) appreciates the opportunity to comment on the direction of healthcare standards development, adoption, and implementation for consideration of the National Council on Vital and Health Statistics (NCVHS).

The current state of healthcare standards leaves significant room for improvement. From a procedural standpoint, development of new standards and updates to current Health Insurance Portability and Accountability Act (HIPAA) standards to meet the needs of industry stakeholders takes far too long, as evidenced by the lengthy delay to mandate an attachments standard and the significant lag between updates to transaction sets. From a technological perspective, the inability of the system to establish timely and efficient information interchange to meet the needs of patients, such as in the burdensome and timely prior authorization process, is an area ripe for advancement.

In order to effectively update and create standard transactions without unduly burdening healthcare payment processes, regulators should approach potential changes judiciously. **Any substantial change in the technology and/or standards used in healthcare information exchange should be sufficiently tested to ensure functionality, prioritized to ensure that efforts are focused on areas in need of reformation, analyzed to establish projected return on investment, and incorporated according to an appropriate glide path to minimize systematic disruption**.

Testing

Although healthcare participants have some justifiable concerns with current administrative standards, the transactions collectively provide a framework that has promoted efficiencies and saved the industry billions of dollars over the years. In fact, according to the 2020 CAQH Index[1], the HIPAA transactions saved the industry over $122 billion during 2019. These standards are utilized across healthcare and are the technical foundation of the majority of business conducted between plans and providers today.

As the backbone of the revenue cycle, **the AHA recommends that any potential changes to the administrative standards be fully developed and tested prior to their incorporation as a standard.** This process should include careful consideration as to the transactions scalability and its ability to complete administrative tasks in a real world setting, rather than a controlled environment such as a connectathon. The industry should have learned the hard way with the 2003 introduction of the X12 4010 transactions, a process that required over 500 emergency changes by the Designated Standards Maintenance Organizations to meet the industry needs and caused significant administrative hassles for utilizing participants. In order to avoid a similar

[1] https://www.caqh.org/sites/default/files/explorations/index/2020-caqh-index.pdf

scramble, the industry must take adequate care to ensure that the transactions are fully ready for wide-scale usage. Robust pilot testing would ensure that the crucial processes completed by current standards are only replaced or altered with technology that is fully functional.

Prioritization

It would be extremely costly and disruptive to replace all administrative transactions in healthcare, as many of these provide the foundation for healthcare payments and operations. In order to focus efforts to be most effective, **the AHA recommends that NCVHS prioritize technology updates towards transactions where additional regulatory directives are most in need.** Although each transaction was designed to streamline an interaction in healthcare to become the primary usage method for all, stakeholder utilization has varied significantly across the various standards. For example, according to the 2020 CAQH Index, the standard electronic medical claims (X12N 837) and acknowledgements (X12N 277CA/999) are each utilized at overwhelmingly high rates (96% and 98% respectively), while standards for prior authorizations (X12N 278) and attachments (ASC X12N 275, HL7 CDA) are utilized much less frequently (21% and 22% respectively). These figures provide clear guidance that there are some standard transactions currently achieving their intended goals of administrative streamlining and standardization, while others have failed to do so. Regulators should use these indicators to focus their work towards underutilized transactions that are failing to meet stakeholder needs.

Cost/Benefit Analysis

Although new technology can provide new functionality, it frequently comes with a sizeable price tag. In order to ensure that new or updated standards promote administrative efficiencies and systematic savings, **NCVHS or CMS should perform a financial and clinical cost-benefit analysis to ensure that any transition will ultimately provide an appropriate return on investment**. Such analysis should include both a rigorous economic analysis as well as an examination of any impact on clinical care and patient privacy. This will not only ensure the appropriate expenditure of valued resources, but it will also help promote greater adoption of new technologies by industry participants.

Implementation Glide Path

Once a transaction has successfully been tested, prioritized, and analyzed to ensure appropriate investment return, the industry should incorporate this advancement into the existing workflow. The incorporation of new technology can be an extremely resource-intensive process for hospitals and other providers, requiring systematic updates, testing, personnel education and training, workflow adjustments, and potential policy changes all while performing their standard revenue cycle functions. This process can present significant challenges to hospitals and other providers, particularly smaller entities without the financial liquidity to spend on implementation costs. In order to ensure that new technology is implemented in a manner that ensures that all interested industry participants can make the necessary technological updates and workflow adjustments, the NCVHS should announce a transitional glide path for any new transaction. This transitional period should be no less than 2 years from announcement to enforcement (the timeframe previously allotted for updates, such as the transition from the X12 4010 and 4010A to the 5010 transaction sets) and should feature

substantial educational outreach and HHS analysis to gauge industry progress. Additionally, in order to prevent providers with less available resources from being left behind, HHS should consider establishing a mechanism to provide financial support for providers seeking to upgrade their systems.

We believe that by adhering to these concepts, NCVHS, CMS, and HHS can successfully update transactions to meet newer business needs without disrupting the healthcare system. We look forward to continuing to work with NCVHS as they fulfill their responsibilities as an advisor to HHS on these important matters.

Through this lens, we offer the following responses to the NCVHS questions:

1. How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Healthcare strongly needs an efficient way of transmitting appropriate clinical data from providers to health plans and other entities in an appropriate fashion. Technological advancements and regulatory directives to supplement existing efforts could benefit the industry, particularly in administrative functions, such as attachments and prior authorization, to enable plans to adjudicate patients coverage for their care.

Attachments

The need for a standard method of attaching clinical data to claims has been recognized since Congress enacted the HIPAA administrative simplification provisions, which called for the creation of a claims attachment standard to facilitate the exchange of such information. Despite legislative requirements (HIPAA and the Affordable Care Act), significant industry recommendations seeking action, including numerous NCVHS letters recommending adoption, and the creation of transactions to meet the industry need, the attachments transaction has yet to be mandated. Without this mandate, the industry has been limited when instances call for provider sharing of patient information needed for coverage purposes, such as prior authorization and establishing medical necessity.

Prior Authorization

Prior authorization is a utilization review process that requires health care providers to qualify for payment by obtaining approval from health insurers before performing a service. Despite the HIPAA standard 278 transaction for the completion of prior authorization, plans vary widely on accepted methods of prior authorization requests and supporting documentation submission. The most common method remains using fax machines and contacting call centers, with regular hold times of 20 to 30 minutes. In addition, plans offering electronic methods of submission most commonly use proprietary plan portals, which require a significant amount of time spent logging into a system, extracting data from the provider's clinical system and completing idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. For each plan, providers and their staff must ensure they are following the right rules and processes, which may change from one request to the next.

The widespread concerns with current prior authorization processes make this transaction particularly ripe for regulatory action. As a result, the AHA was pleased with the release of the

"Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information" proposed rule in December 2020. This rule attempts to streamline prior authorization processes by utilizing FHIR API technology to increase consistency and timeliness in these processes.

The proposed rule falls short, however, in its applicability being limited to Medicaid, Children's Health Insurance Plans, and Qualified Health Plan issuers on the Federally-facilitated Exchanges, which represent only a fraction of the plans with whom providers do business. The lack of applicability across a significant number of health plans represents a significant barrier to adoption, as providers would be less likely to invest resources in a solution that does not apply to the majority of its business. We would recommend that any transaction updates be applicable to all health plans in order to maximize provider administrative savings.

2. Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

The AHA recommends that HHS work to ensure successful implementation of the forthcoming attachment regulation and prior authorization transactions, each of which present significant opportunity for systematic improvements. In addition, we encourage NCVHS to explore how additional standards and use cases would benefit the industry. Such consideration should be viewed through the lens of how the technology could be incorporated into the current workflow and should follow the prioritization, testing, cost/benefit analysis, and implementation plan described above.

3. How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

A significant number of other industries have made technological and procedural advancements to data exchange that should be explored by NCVHS. These include banking, retail, and manufacturing, each of which have utilized new technologies to speed up processing of transactions and the delivery of important data.

It is important to recognize, however, that the healthcare system is often inherently more complex than these other industries, as a result of the large and diverse number of stakeholders impacted by changes. As a result, the success of a technology in one space should not be taken as an indication of success within the healthcare space. Careful testing and analysis is essential to any consideration.

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Passage of the No Surprises Act has created an urgent need for additional standardization in the administrative space. The legislation creates the need for health plans to send patients Advanced Explanation of Benefits in order to help patients understand their financial obligations for a prospective treatment or procedure. As part of this process, providers are expected to

send good faith estimates to plans, indicating the services and charges that they expect to be included in the service. In order to minimize the administrative burden caused by this process, HHS should establish a standard mechanism for transmitting good faith estimates to health plans and for plans to send advanced explanation of benefits to patients.

As alluded to above, we recommend that NCVHS prioritize areas in which there are current underutilization of standards, or where the industry had a widespread variance in how necessary data interchange takes place. Although the current system of transactions have a number of areas for potential improvement, efforts to revise these should be taken judiciously to ensure that there is no disruption in patient care or essential revenue cycle tasks.

Sincerely

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July 19, 2021

Richard W. Landen, MPH, MBA
Denise E. Love, BSN, MBA
Co-Chairs, National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards
3311 Toledo Road
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Re: Request for Comment

Submitted electronically to: NCVHSmail@cdc.gov

Dear Mr. Landen and Ms. Love:

Thank you for the opportunity to provide input to the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

AHIMA applauds the Subcommittee's intention to understand the extent to which current and emerging standards for exchanging electronic health-related data under the Health Insurance Portability and Accountability Act (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the healthcare system.

AHIMA offers the following comments regarding the request for public comments.

Opportunities to Improve Data Sharing (Question 1)

This section of AHIMA's comments is focused on the area of enhancing the exchange of clinical and administrative data, and particularly the exchange of clinical data in support of administrative activities. As noted in the background section of the Request for Comment, "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." However, administrative transactions that require the sharing of clinical information often includes time-consuming and costly processes that involves a considerable amount of manual work and use of multiple portals, phone calls, and faxes.

AHIMA members experience numerous challenges exchanging health information between providers and payers on a routine basis. Last year, AHIMA convened a group of members to examine what is happening on the ground when providers share clinical data with payers, including various prior

authorization processes, concurrent reviews, and post-discharge processes. Our members' experiences confirm that exchanges of all sorts suffer from variability, lack of clarity about the documentation that is needed, changes in rules over time and without notice, and the need for multiple formats for sharing information, even for a single patient stay or encounter.

AHIMA believes there are a number of things that could be done to improve data sharing between different actors including advancement of a number of recommendations made to the Office of the National Coordinator for Health IT by the Health Information Advisory Committee (HITAC) in 2020. Key recommendations that AHIMA believes should be advanced include:

- **Convergence of Healthcare Standards:** Harmonizing standards to create a consistent set of standards for code sets, content, and services must evolve together to address clinical and administrative workflows. Such harmonization must include content and classification standards to enable more automated transactions. Additionally, such efforts should allow for all stakeholders to participate in the process to allow for input from frontline professionals that understand the data and workflow needs required by administrative and clinical processes. Consistent with the HITAC's recommendations, the principle of minimum necessary must also apply to limit unnecessary or inappropriate access to and disclosure of protected health information. Given the considerable expertise the NCVHS brings, the Committee could make significant contributions in this area.

- **Harmonized Code and Value Sets:** Integration of clinical and administrative data will only be successful if code and value sets used to encode clinical data are linked to the code and value sets used to determine administrative authorization for payment for the orderable, procedure, or referral. Having a detailed and transparent understanding of how code sets are used for administrative and clinical purposes is critical to successful integration of these two distinct data streams, particularly when different code sets are used for the same data element (e.g., SNOMED-CT versus ICD/CPT). The Committee could make significant contributions in this area by recommending the National Library of Medicine (NLM) examine how code sets are used for administrative and clinical purposes, and share such findings with relevant stakeholders.

- **Clear Roadmap and Timeline for Harmonized Standards:** A clear roadmap and timeline are necessary to ensure the successful convergence of clinical and administrative data streams. This roadmap must include reasonable timelines that reflect the operational realities of the providers and payers that will be expected to use the harmonized standards. This means recognizing workforce development needs, including shifts in needed capabilities and training on new standards or new versions of existing standards, vocabularies, technologies, and processes.

- **Develop Patient-centered Workflows and Standards:** "Patients at the center" must include a systems-design philosophy and be built in from the ground up. Patients and caregivers need to be at the center of administrative workflows. Administrative standards should be developed and prioritized to enable patients to engage as key actors. Application programming interfaces and modern technical standards also should be leveraged to facilitate the development of administrative standards designed for digital access and engagement.

- **Adopt a Member ID Card Standard:** A standard ID card would enhance patient identification, thereby reducing burdens for patient, providers, and payers and enhancing clinical and administrative automation and transparency between the member/patient, provider, and plan.

- **Name an Attachment Standard:** The naming of a HIPAA attachment standard would be a positive step forward in helping to establish a national approach to exchanging clinical data to support clinical information exchange, whether for care delivery or for administrative processes.

- **Include the Patient in Prior Authorization:** Prior authorization systems must be designed with patient engagement as a critical design goal to ensure that patients and/or caregivers have the opportunity to participate and engage throughout the process.

- **Establish Patient Authentication and Authorization to Support Consent:** Standards should be created to enable patients and caregivers to authorize the sharing of their data with a tool of their choice to interface with their corresponding provider and payer systems. This includes the establishment of a standard for third-party authorization that allows patients to access and bi-directionally share their data across the landscape. Consideration must be given to the security implications associated with third-party authentication. Additionally, consideration must be given to the operational impact of sharing bi-directionally data between provider and payer systems at the patient's request, including the need for robust data integrity and data quality practices.

- **Establish Test Data Capability to Support Interoperability:** Establishing a national approach to testing capabilities is necessary to drive innovation and ensure real-world functionality and interoperability. Additionally, such capability is foundational to ensuring the success of many of the recommendations put forth by the HITAC ICAD Task Force.

In addition to the HITAC recommendations cited above, AHIMA believes that a number of recommendations proposed by this Committee as part of its Predictability Roadmap in 2019 to improve the adoption of national standards for the healthcare industry should be advanced, including modernization of the existing HIPAA transaction standard and operating rule process to one that is industry-driven and supports the use of updated transaction standards and operating rules when updates to the named standards become available. Furthermore, the promotion and facilitation of voluntary testing and use of new and/or updated transaction standards and operating rules prior to their adoption through sub-regulatory guidance should also be advanced to improve data sharing. That said, the use of updated transaction standards and operating rules should be voluntary. Positive incentives should also be deployed to encourage the adoption and use of transaction standards and operating rules. Key findings also should be disseminated and shared when new and/or updated transaction standards and operating rules are tested or used to identify challenges, improve processes, and encourage adoption of the transaction standards and operating rules by other stakeholders.

Barriers to Improving Data Sharing (Question 1)

There are a number of challenges associated with improving data sharing among patients, providers, payers, public health systems, and other actors in healthcare that must be addressed**.** These include:

- **Lack of Standardization for Business Processes:** As noted above, existing prior authorizations and authorizations for inpatient care are characterized by variability in the data requested to make a determination—both across payers and across plans offered by a given payer. Greater predictability is needed by providers and payers should provide notice to providers if their criteria changes. Opportunities for providers and payers to work together to create more standardization and predictability, such as CAQH CORE's creation of operating rules for administrative transactions, might be one pathway to further standardize business processes.

- **Operational Issues:** New approaches to enhancing data sharing must take into account existing workflows and operations to better understand how future roles and technologies will need to evolve. Furthermore, administrative transactions currently flow through a significant existing infrastructure. As policymakers contemplate changes to the existing system, consideration should be given to "what works today" to avoid disruption to the revenue cycle.

- **Technical Issues:** New approaches will require a deeper understanding of the shift in information technology needs, as well as investment and deployment of appropriate systems which could impose a significant cost burden on providers. Additional challenges may include the timing and scale of deployment. Expectations must be clear as to whether all plans will be required to shift to more automated approaches or whether there will be a mixed model where providers are expected to send data to different places in different formats.

- **Workforce Implications:** New approaches to data sharing may require a different skill mix, including shifts in needed capabilities, training on new technologies and processes, and the potential for significant workforce re-alignment.

- **Alignment and Accuracy of Vocabulary Standards:** Data interoperability enables providers and payers to coordinate care among organizations and act based on comprehensive and current information. The scope of data interoperability has expanded to encompass social and behavioral services, public health, cost and quality assessment, and research, in addition to administrative uses. Terminology standards, therefore, must be multifaceted and meet the needs of the industry. They must be credible, comprehensive, and developed using rigorous and evidence-based processes.

  ICD-10-CM, ICD-10-PCS, and CPT® are terminologies that are foundational for describing medical services and procedures. They are universally trusted by the health care system, evidence-based, timely, and reflect current clinical practice in a common medical language. They are also embedded into today's operations of coordinating patient care in a manner that cannot be simply replaced.

  The maintenance bodies for these terminologies continually demonstrate successful coordination in the development, adoption, implementation, and conformity of the standards across disparate health-related data systems. The code sets will continue to play a critical role in data sharing among providers, patients, payers, public health systems, and other actors in healthcare. These reliable and trusted terminologies must continue to be supported.

  Today, clinical and administrative data may rely on different standards for similar data elements (such as SNOMED/HL7 versus ICD/CPT for problems and diagnoses). Currently, we lack a consensus-based map to accurately and consistently link the different standards. While many

electronic health record (EHR) vendors include mappings, they are generally unique and proprietary. A single, transparent, national mapping effort led by the NLM could possibly address this issue, but would need to be accompanied by an external validation process, including experts in the codes sets being mapped to ensure widespread acceptance and use. Similarly, the Secretary of the US Department of Health and Human Services (HHS) should approve the *Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards* and the *Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards* to guide current and future health terminology and vocabulary initiatives and to assist with further alignment, curation, and dissemination. Given the considerable work the NCVHS has done in developing these criteria and guidelines, the Committee could provide significant insight in this area.

- **Data Integrity**: Data integrity is a particular challenge today and limits the ability for semantic interoperability. In addition, given the lack of a solution to the patient matching problem, high duplicate error and/or overlays can lead to patient safety issues. Additional work is needed to advance a national strategy to address patient identification and matching, which could improve data integrity.

- **Privacy and Security**: Ensuring the privacy, security, and confidentiality of a patient's health information is an obligation that providers take seriously. Increased sharing of health information across payers and providers requires careful consideration of privacy issues, including ensuring that only the minimum necessary information is shared and uses beyond the specific transaction are limited. With respect to security, challenges with authorizing and authenticating data recipients before exchange represents a particular challenge. The lack of a national approach to accurately identify patients further complicates this issue.

- **Trust and Representation:** Trust among individuals, payers, and providers is key to improving data sharing. Should clinical data be re-used for other purposes outside of the specific transaction in question (e.g., underwriting, setting premiums, or benefits design), it could have a profound impact on individuals. Similarly, such information could be used for other purposes such as contract negotiations between providers and payers. In both instances, trust may be easily eroded. Participation by all parties is critical to ensure that operational and trust considerations are addressed.

Considerations to Support Interoperability, Burden Reduction and Administrative Simplification (Question 2)

We applaud the Subcommittee for recognizing in the background section of the Request for Comment the need to improve "coordination of standards development, adoption, implementation, and conformity across disparate health-related data systems." As the NCVHS examines new standards or use cases for recommendation to HHS in support of interoperability, burden reduction and administrative simplification, multi-stakeholder collaboration and coordination are a critical aspect of this effort. This includes establishing clear roles and responsibilities of stakeholders and agencies involved in the process. Such collaboration and coordination is necessary when considering the roles and responsibilities the advisory committees, such as this Committee and the HITAC, have to play as well as federal agencies such as CMS, ONC, NLM, and others with respect to the convergence of clinical and administrative data. Without strong coordination, stakeholders may be left with inconsistent or

incomplete direction, or find themselves in a situation where systems are still not able to communicate efficiently and effectively even after adoption of new standards.

Along these lines, we believe that the NCVHS has a unique role to play in aligning standards and ensuring that as data are exchanged, they are semantically interoperable to ensure the integrity and fidelity of the data itself. This means leveraging the NCVHS' unique expertise to promote the development of code sets, terminologies, and value sets that support semantic interoperability.

Ensuring that all stakeholders "move together" to create more certainty and consistency for providers and payers when adopting new standards is also a key consideration in supporting interoperability, burden reduction, and administrative simplification. This includes having a clear and comprehensive understanding of the impact of the standard and related implications. For example, as the US begins to contemplate a transition from ICD-10 to ICD-11, there are still considerations related to ICD-11 that must be taken into account, including whether ICD-11 provides significant opportunity to reduce provider burden and increase interoperability of electronic health information. Research and evaluation of ICD-11 are needed to estimate the costs, benefits, and opportunities of moving to ICD-11, as well as to evaluate the impact of alternative transition timelines. However, as ICD-11 evaluation activities and development of a transition strategy move forward, there remains an opportunity to more fully realize the benefits of ICD-10 and further demonstrate ICD-10's return on investment in the interim. Since ICD-10 was implemented in the US for morbidity use just six years ago, the growing amount of high-quality ICD-10 data offers opportunities to further leverage the increased specificity and level of detail in ICD-10-CM and ICD-10-PCS and begin to realize some of the longer-term benefits of ICD-10.

Role of NCVHS (Question 4)

As an advisory body to HHS, the NCVHS has a crucial role to play given its knowledge of terminologies, use of standards, and the importance of such standards to be specific and communicated to healthcare stakeholders at-large on a transparent timeline that takes into account both standards adoption and implementation. This includes the Committee's knowledge and understanding of the operating rules and how new standards may be used and implemented, consistent with the operating rules, or with similar types of guidance if the standards do not support specific HIPAA transactions. Given the depth of the Committee's expertise, the NCVHS can play a critical role with the detailed-level coordination needed to advance this critical work.

We appreciate the opportunity to respond to the Subcommittee's request for public comment. Should you or your staff have any additional questions or comments, please contact Sue Bowman, Senior Director, Coding Policy and Compliance at sue.bowman@ahima.org or Lauren Riplinger, Vice President of Policy & Government Affairs, at lauren.riplinger@ahima.org.

Sincerely,

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July 30, 2021

Submitted Electronically to: *NCVHSmail@cdc.gov*

Richard Landen and Denise Love, Co-Chairs
National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards
CDC/National Center for Health Statistics
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RE: NCVHS Notice of Meeting and Request for Public Comment

Dear Mr. Landen and Ms. Love:

AHIP is responding to the NCVHS Notice of Meeting and Request for Public Comment that was published in the *Federal Register* on June 24, 2021.[1]

The purpose of the Listening Session and Public Comments are to obtain information related to data standards, harmonization of standards and code sets, the new Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) to enhance the exchange of clinical and administrative data, the state of readiness for certain administrative and clinical standards to be considered for adoption or use as standards under the Health Insurance Portability and Accountability Act (HIPAA), for interoperability, and other subjects beyond HIPAA transactions.

AHIP believes that every American deserves access to affordable, high-quality health care and coverage, so that everyone can achieve their best health. AHIP works to improve health care in America, promote better affordability and choice, and advance health equity. We believe that a powerful framework built on technical infrastructure, electronic and clinical standards as well as solid privacy and security practices can facilitate data and transparency tools so that Americans can be in charge of their health choices and finances in a 21st century model. We offer several primary considerations:

[1] 86 Fed. Reg 33318. AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

- **Policy Makers should support Standards Development Organizations (SDOs) and should account for standards maturity in implementation timelines, but should not delegate policy development.** In the haste to promulgate new requirements many policies have not been sufficiently fleshed out to support implementation leaving the SDOs to fill in the gaps. Thus, policy-relevant decisions are being made at a subregulatory level without sufficient public transparency and input.

  In addition, content and technical standards as well as implementation guides must be fully developed and sufficiently tested for successful implementation of truly interoperable sharing and transparency. Often, in this speed for adoption, rules and deadlines are promulgated without sufficient time for testing, troubleshooting, and implementing resolutions. Mature standards should be a precursor to implementation. The standards development process must call-out the need for testing time. Where possible, existing SDOs recognized under HIPAA and other federal laws should be utilized as part of the overall plan.

  We recognize that Health Level Seven (HL7) and the Office of the National Coordinator for Health Information Technology (ONC) expressed support for development of a FHIR "testing sandbox" that will enable providers, vendors and payers to sufficiently test clinical data exchange implementation guides. The Centers for Medicare & Medicaid Services (CMS) has also recently expressed support and possible funding. We believe this is a step in the right direction as FHIR is still in its early stages.

- **FHIR and New Technical Standards Need Further Evaluation.** We appreciate that the NCVHS is considering this issue and we look forward to ongoing dialogue. The NCVHS should use the August Listening Session to evaluate what role it can play in identifying scalable solutions to speed the adoption of FHIR standards. We urge NCVHS, however, to be cautious in its approach. We need to build off lessons learned as we build out the infrastructure within the health care ecosystem and work to understand what can and cannot be feasibly supported and used. Additionally, we are analyzing whether clinical transactions are properly within the purview of the formal HIPAA process (and thus the NCVHS' jurisdiction) or whether these transactions can exist within the ecosystem without being mandated but still used on a voluntary basis.

  FHIR-based standards and updates must be readily available and developed with multi-stakeholder considerations in order to promote widespread adoption. We support efforts (e.g., HL7's Da Vinci Project) to advance current use cases, as well as development of future use cases. Encouraging sharing of data between both

payers and providers, as well as other appropriate healthcare stakeholders, could provide more efficiency and improve outcomes.

We also believe that to harness the real value of interoperability, connections must exist across the ecosystem, not just between specific parties. For example, if payers must share data with one another, a payer directory with each payer's digital endpoint (that is, the technical details of an electronic location to deliver or retrieve information) is needed to prevent each payer individually having to ask each other payer how to reach them. A similar directory is required for provider "digital contact" information. Thus, the FHIR at Scale Taskforce (FAST) is actively identifying common scalability approaches that are more efficient and will speed adoption. A directory of FHIR endpoints, for example, is critical to being able to "find" the organizations with which the payers are to share data.

Consideration should be given to situations where different solutions have or are being built for the same process. For example, due to the lack of an attachment standard, a FHIR standard has been build out both around the 278 prior authorization transaction as well as a FHIR end-to-end standard. As another example of this tension, despite there being a solution for the Advanced Explanation of Benefits (EOB) requirement in the No Surprises Act in the ANSI X12 transaction sets version 8010, there is now a solution being built out in FHIR. This lack of clarity and coordination could serve to further delay and fragment the industry.

A cost/benefit analysis of any new or revised standard or operating rules must be an integral part of any new or revised process. The NCVHS should solicit testimony and make this information known to HHS before more work to adopt FHIR-based standards is done.

- **The Standards Modifications Process Could be Improved, But Do Not Sacrifice Substance and Practical Stakeholder Experiences.** The current process for developing and adopting new and revised health care standards, encouraging wide-spread use of the standards, and enforcing compliance can be improved. Some stakeholders believe that the adoption and change procedures for standards can be slow and protracted, while mandates and potential compliance penalties exist for non-compliance with the standards, even if they are not fully working within the healthcare system. For example, transitioning from one version of the X12 standards (4010 to 5010, 5010 to 7030) has been long and some aspects remain pending regulatory promulgation (e.g., the X12 275 electronic transaction has yet to be published, despite two statutory requirements and four NCVHS letters calling for

its release). The current HIPAA process for standards' adoption and revision can take significant time. Likewise, issues that are explained in the Implementation Guides can be difficult to find as the guides availability is not open-sourced and transparent. The standardization process should allow the industry more flexibility to decide when to advance to a new telecommunication version and promote faster adoption for implementation. This can promote innovations and allow the standards to evolve.

The HIPAA process is vital because mandated transactions are the accepted industry standard. Albeit, despite HIPAA being enacted over two decades ago, many of the currently mandated standards remain underutilized and proprietary web portals have become more widespread, thereby undermining the adoption and broad use of the HIPAA transactions and code sets and changing ways for electronic data interchange. This reality should be discussed and evaluated by the NCVHS for a path forward, whether that be a change to the HIPAA transactions or movement toward a more interoperable, consumer-focused model. This dialog should not discourage FHIR nor slow down acceptance of APIs in exchange, but, perhaps augment the ability for organizations to prove ability to add API based interoperability that goes beyond X12 and HIPAA mandates.

- **Improve Compliance by Moving Away From an Enforcement-Driven Model.** Regulatory deadlines should not be imposed, especially when affected stakeholders advocate a need for additional time for implementation and/or compliance adoption. When establishing compliance timelines, the federal government should also take into account other mandates and implementation priorities that HIPAA covered entities must meet. Financial and administrative resources are planned in advance by private entities and competing regulatory priorities should be coordinated across federal partners so as to not impose undue burdens on private entities.

- **The COVID-19 Pandemic.** The global pandemic has highlighted how improved data sharing among public and private stakeholders can be beneficial for responding to a national emergency. For example, the immunization registries have struggled with collecting information across different data standards and this information has been largely unavailable to private entities such as health insurance providers.

- **Progress for Specific Standards and Industry Needs.** We support the NCVHS' recommendation to adopt standards to support interoperability, burden reduction and administrative simplification, and we are open to evaluating the DaVinci standards (e.g., Burden Reduction, Data Exchange for Quality Measures, Clinical Data Exchange (CDex), Payer Data Exchange (PDex), Project US@ – Unified Specification for Address). However, we recognize that many of the new Standards

Organizations are for-profit, and as a general matter we do not endorse proprietary products. We will continue to evaluate how best to advise the Committee on this work as it relates to the healthcare infrastructure.

- **Privacy and Security Must Remain Key Foundational Elements and Concepts.** While not specifically enumerated in the RFI, we encourage the NCVHS to keep the HIPAA privacy and security requirements as a cornerstone of any work. In this context, however, we need to think differently about consent models and the operational processes primarily because not all entities operating in the new environment will be covered by HIPAA. We continue to advocate for a more expanded role for the Federal Trade Commission over non-HIPAA covered applications, but we recognize that the NCVHS cannot make the statutory changes to implement such requirements. We do encourage the Committee to note these gaps and the remedies for protecting health data consistently across all applications and platforms.

- **Interoperable Patient Data and Overarching Legal and Structural Requirements.** As the industry continues to blend clinical and administrative data as well as pharmacy and medical services to achieve improved patient outcomes, several opportunities can streamline processes and achieve interoperability:

  (1) Adopting a universal government issued patient identifier improve access to care while mitigating safety concerns. Patient Identity Management in Healthcare today relies primarily on Patient Matching approaches with the relatively newer trend of Digital Identity Management. There is an opportunity to develop guidance on how implementers and organizations can leverage their Patient Matching and Digital Identity capabilities together to improve quality and overall identity assurance. In addition, we are working with a patient identity coalition. We also await ONC's issuance of a report on patient identity. Perhaps more federal participation in defining identity, aligned with privacy needs, can foster digital identities as an industry topic and can be a priority to work on together to ensure individual privacy.
  (2) Standardizing state-to-state regulations regarding privacy regulations and required/informational exchanges of data.
  (3) Integrating real-time communication protocols and the use of shared code list terminology allows processes to be expedited and coordinated between a prescriber and pharmacy, pharmacy and payer, and payer and prescriber.
  (4) Creating methods or standards to support electronic member communication within the prescription workflow.
  (5) Harmonizing technical specifications for secure data exchange across any system that contains data about an individual needs to be able to easily share data with other systems (i.e., data sharing needs to be simple and secure).

The attached document sets out some key considerations responding to the specific questions outlined in the RFI. Please contact me at dlloyd@ahip.org if you require any additional clarification.

Sincerely,

Danielle A. Lloyd
Senior Vice President, Private Market Innovations & Quality Initiatives
AHIP

Attachment A

Key Questions Posed in the RFI

RFI Question	Key Considerations	AHIP Response
(1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care?	Health care providers are often the key source for generating individuals' data. Entities such as health insurance providers generate claims and other data types, but are more often part of different information streams compared to providers, and possibly do not receive updated information in all contexts. Thus, the current model does not appear to have a way for payers to validate data or to ensure that it is "clean" data. The current proposed and final rules for interoperability assume that payers as HIPAA covered entities receive complete and accurate data relating to individuals' health care.	• Data is only as good as the accuracy of key elements. The standards process should recognize that some data streams are subject to incompleteness or errors or are missing based on the request and decision of the individual and / or treating provider. Correction processes are governed by the entity generating the data; providers of care, individuals and other entities should strive to update any inconsistencies in data. • The implementation guides should address these realities and they should be publicly accessible and available. • More work can be done to better capture Social Determinant of Health (SDOH) data to promote health equity. This can include: o Data standards for collection of sexual orientation gender identity data. o HL7's Gravity Project for SDOH data standards and codes. o Incentives to enhance bi-directional, standards-based data exchange between payers and providers for care coordination.

		o Finalizing the HIPAA privacy regulations for sharing data with community-based organizations. • Privacy regulations should be promulgated so that when an individual grants access to allow for data sharing, the benefits and risks should be made known prior to open access. When feasible, the NCVHS should advance recommendations for Congress to act. • A fundamental ability to scale interoperability is needed. The ONC FAST project has identified and is moving key solutions to the barriers in API directory, security scaling, identity, data exchange across trust networks, and basic scaling/versioning. These efforts should continue. • Implementation guides need more specificity to clarify the uses for individual consent and the overall model, based on cost-effective solutions and ease of implementation. • Efforts could be made to standardize health care documentation practices to help ensure consistency and practical interoperability of data. Standards for data sharing should apply to both the federal and state stakeholders. Some States vary in the standards adoption process and some require non-HIPAA formats (e.g., flat files with complex data layouts with data not present on a claim, a non-standards making

		organization with incomplete data definitions) which results in compliance concerns and data alignment issues.
1 (a) What are the barriers to these improvements?		• More progress needs to be made on implementing: o The Trusted Exchange Framework and Common Agreement (TEFCA). We believe that the recent industry focus to scale and move forward with APIs should be encouraged and will likely be a catalyst for "trust networks" to develop across willing trading partners, informed by TEFCA. NCVHS can play a role to align, encourage adoption, and appropriate rules of the road for such trust networks as we move the country forward to a national API exchange. o Unifying identity or mechanisms to standardize identity validation. o Unifying Cross-SDO Data Element Standardization. • In addition, the NCVHS should consider removing the following barriers to improve data sharing between patients, providers, payers, public health system, and other actors within health care: o Inconsistencies within the standards implementation timelines hinders

		harmonization and interoperability. o Different incentives for interoperable standards for data in motion between trading partners (i.e., with uncertainty by some entities for what constitutes a trading partner). o Unclear priorities and development of use-case specific implementation guides. o Efforts to standardize security mechanisms without consideration for an organization's unique risk analysis. o Determining data elements worthy of standardization (e.g., address or contact information) can be a barrier in achieving Unified Cross SDO Data Element Standardization. o Need for creating standards that support transfer and sharing of patient consent. o Not requiring a single version of a standard to be adopted by the entire industry sometimes requires organizations to maintain multiple versions of a single standard to support data exchange. o Barriers also include unwillingness or inability to share data across companies and platforms, lack of resource dedication to initiatives not driven by financial gain, disparity

		in patient knowledge, skill and access to electronic data.
(2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases (APCDs). Please do not limit responses to these examples.	APCD submissions should be evaluated for adopted as HIPAA Standard Transactions. The claims attachment standard has been pending for over a decade. More should be done to move the process forward quicker, albeit while allowing for adequate time for testing, understanding, and adoption.	• The NCPDP Post Adjudication History, PACDR 837, and Plan Member Reporting 834 could be the named transactions. • Acknowledgement should be named as Standard Transactions. This will facilitate the exchange of current Standard Transactions. If Acknowledgements are named as Standard Transactions, then the 277DRA (Data Reporting Acknowledgement) could be included as it is the PACDR equivalent to the 277CA to standardize submissions to state APCDs. • State APCDs could also be named in a statute as Covered Entities so that HIPAA rules apply to them. HHS should work with Congress to accomplish this task. • Hospital Discharge submissions should be Standard Transactions so the 837R Health Care Reporting guide should be named. Similar to the PACDR 837, if Acknowledgements are named as Standard Transactions, then the 277DRA (Data Reporting Acknowledgement) should be included as it is the 837R equivalent to the 277CA. The use of Hospital Discharge submissions could be an extension of the

		APCDs (e.g., New York as an example). • HIPPS Codes should be named as a Medical Code set so that they are valid based upon date of service and not the date of the transaction. HIPPS Code Receivers have challenges when then submitting to an APCD or to a reporting agency. Once the code expires, it is invalid even though it was valid at the time of the service and subsequently for the claim submission. • HL7's Gravity Project's SDOH data elements in the USCDI, Version 2 (v2) includes SDoH as a new data class in the USCDI and supports the federal policy objectives to focus on improving the experience of care, improving the health of populations, and avoiding unnecessary costs in healthcare. • PDex could be evaluated for adoption as the standard for State APCD Advisory Committee adoption to report ERISA plans to state APCDs. This standard was created by a SDO with significant cross-stakeholder input and ensures the data is consistent with claims and eligibility reporting requirements. ONC has recommended for research and aligns to the interoperability standards.
(3) How have other industries effectively implemented, tested, and certified standards for data		• We support evaluating the financial industry trust framework for exchanging financial transactions,

and their exchange that could be considered for health care?		identity proofing, image recognition, and underlying security for third party data access. Many of our members have driven the FAST project, informed by API scaling in other industries. • The banking industry adopted a standard exchange requirement ensure proper authorization and consistent data standards across banking and investment data exchange. This may be evaluated for claims, eligibility and clinical data. • In addition, the pharmacy industry has been highly effective in establishing NCPDP Standards for billing and electronic prescribing. We would work with CMS to established mandatory standards that have become highly adopted and enforceable. • As the pharmacy industry model continues to evolve into an electronic based model, interoperability and information sharing with patients and providers is also a long-term focus and should align with HHS' long-term strategy.
(4) What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?	Claims attachment standards remain overdue.	• Continuing to build the asset and capabilities needed to scale FHIR, including the recent decisions on implementation guides for API directories, security, and testing that CMS is supporting. • Issuing an Attachments Rule to encourage attachments and to

		standardize the processes will help facilitate electronic adoption and administrative simplification. • Prioritizing short-term solutions to ensure minimal disruption to the industry while concurrently creating a mid-term and long-term strategic roadmap. • Focusing on short-term needs, HHS should name the next version of the Telecommunication Standard vF6. This is already in progress. • Focusing on two critical short-term data exchange elements: standardizing security mechanisms and creating/promoting a Universal Patient Identifier. These two items specifically will promote safe data exchange while preventing patient safety risks as mid to long-term solutions are developed. • Harmonizing the standardize type and format for healthcare data sharing that supports the multiple roles/industry types. • Allowing patient access to real-time communications from prescribers and payers, and allowing payers real-time communications with providers to address any delays in therapy (e.g., standardize Prior Authorization requests to support electronic submission and responses while also notifying the patient of delay to therapy or possible alternate therapy). • Opening the use of exceptions to allow

		healthcare entities to use newer transactions standards with willing trading partners. • Considering bi-directional sharing needs as a focus area of future policies and rulemaking. • Working between HHS, related entities and stakeholders to consider support and guidance for secure data exchange technologies, including distributed ledgers and blockchain. • Providing ongoing support for stakeholder consensus-building efforts

ALTARUM

SOLUTIONS THAT MATTER. HEALTH CARE THAT WORKS.

July 30, 2021

To Whom it May Concern,

On behalf of Altarum, we are pleased to submit comments on the Request for Public Comment on Healthcare Standards Development, Adoption and Implementation. Altarum is a non-profit committed to creating and implementing solutions to advance health focused on underserved populations. Our work spans 50 years of solving critical health IT problems, including capturing clinical data from Electronic Health Record (EHR) systems across a wide array of products and settings; utilizing tools built to collect patient-reported outcomes in multi-site global registries; and developing and successfully deploying registries and clinical decision-support tools used by physicians and clinical researchers alike. Our experience ranges from facilitating some of the earliest health information exchange (HIE) planning projects to directly supporting provider adoption of electronic health records (EHRs) as the boots on the ground for Michigan's Regional Extension Center and facilitating the development and implementation of national standards for information exchange and public health reporting.

Our comments for the four questions provided are as follows:

1. **How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?**

   While the use of APIs represents a revolutionary advance in interoperability, the utility APIs is constrained by the types of data exposed by data holders. A significant barrier to improved Public Health reporting is the limited scope of data elements called out by the USCDI and supported by the US Core FHIR Profiles. Due to this limited scope, key Public Health reporting data elements are often inaccessible via standard FHIR APIs exposed by EHR implementations. Access to data relating to pregnancy, delivery and maternal and child health are particularly inaccessible despite the critical roles these elements play in a wide variety of Public Health reporting requirements.

   As well, Public Health programs lack sufficient resources (time, personnel and funding) to develop, test and implement the tools and processes necessary to onboard reporting providers and healthcare organizations at scale. HIT vendors often face the same limitation resulting in EHR systems which only support a limited set of Public Health reporting standards required for certification and specifically named in regulations. This results in many published interoperability standards not being implemented in the real world. An increased emphasis on programs and resources to support implementation of existing standards would greatly facilitate the adoption of electronic data exchange between providers, patients and Public Health.

2. **Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.**

The Public Health reporting section of the ONC's Interoperability Standards Advisory (ISA) includes a number of existing and emerging Public Health reporting specifications including those related to:

- Newborn Screening Results
  - Early Hearing Detection and Intervention and Diagnostic Audiology Reporting
  - Critical Congenital Heart Defects
  - Dried Blood Spot Testing
- Vital Records Reporting
  - Birth and Fetal Death Reporting
  - Death Reporting
- Birth Defect Reporting
- Cancer Reporting
- Immunization Clinical Decision Support
- Occupational Data for Health

All of these standards would greatly benefit from HHS recognition and support. The inclusion of these standards would reduce both the burden on providers and public health. Most of the states and jurisdictions have mandatory reporting requirements. Paper-based reporting, manual entry, and unstandardized spreadsheets continues to be the only submission options. The inclusion of these standards, at a minimum, as optional to meet reporting requirements under programs such as the Quality Payment Program and the ONC Health IT Certification Program would facilitate Public Health and Health IT vendor adoption.

3. **How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?**

   No specific comment

4. **What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?**

   A targeted expansion of the USCDI and FHIR US Core profiles to include core data elements crucial to Public Health reporting would greatly improve Public Health access to key information. Making such data available via EHR FHIR APIs, would allow Public Health programs to develop and implement novel reporting mechanism, reducing provider burden and reliance on Health IT vendors to support individual reporting standards. While we recognize that any expansion of USCDI represents work for Health IT vendors to expand the volume of data accessible via API, having ready access to this data would transform the way that data is shared with Public Health.

Please contact Craig Newman (Craig.Newman@altarum.org) with any questions.

Sincerely,

Rick Keller, Vice President for Connected Health

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

July 30, 2021

Richard W. Landen, MPH, MBA
Co-Chair
National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Denise E. Love, BSN, MBA
Co-Chair
National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Co-Chairs Landen and Love:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to respond to the *Request for Public Comment on Healthcare Standards Development, Adoption and Implementation* (the Notice) issued by the Subcommittee on Standards (the Subcommittee) of the National Committee on Vital and Health Statistics (NCVHS).[1] While the AMA provides remarks below in response to the four general questions posed in the Notice, the AMA also appreciates the opportunity to speak at the August 25, 2021 Listening Session on Healthcare Standards Development, Adoption and Implementation (the Listening Session) and looks forward to providing more detail for the Subcommittee's consideration at that time. The AMA intends to submit a more comprehensive set of comments following the Listening Session after the rich dialogue it is expecting from the variety of speakers.

As you know, the AMA is very committed to promoting interoperability and encouraging health care innovation and supports efforts to enhance the exchange of clinical and administrative data. The health care community relies on high-quality data that can literally make the difference in life-or-death situations. To that end, the entire health care system, including physicians, requires data standards that are credible and comprehensive and that adopt code sets developed using a rigorous and evidence-based process fit for the purposes for which they are meant to be used. The scope of data sharing within the health care system has expanded to encompass several clinical and administrative needs. Interoperability—the seamless exchange of electronic health-related data—enables clinicians to coordinate care among institutions and act based on current and comprehensive information.

[1] This Request for Public Comment is also published in the Federal Register at 86 FR 33318, "National Committee on Vital Health Statistics: Notice of Meeting and Request for Public Comment" (June 24, 2021).

Interoperability also enables individual access to and ownership of one's health data and is critical to safe, responsible, and transparent public health reporting and monitoring. Further, interoperability is a key component in the Learning Health System[2] and—when data are properly coded in consensus-based standards—makes the promise of the Quadruple Aim achievable.[3]

As we understand it, in this RFI, the Subcommittee seeks to understand the extent to which current and emerging standards for exchanging electronic health-related data under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the health care system. The AMA supports NCVHS' role and responsibility in providing recommendations to the Secretary of the U.S. Department of Health and Human Services (the Secretary). While the AMA commends the Subcommittee for issuing the RFI and holding the Listening Session, and recognizes the importance of the issues raised, **the AMA urges the Subcommittee to ensure that its work aligns with the requirements and processes outlined in Title XI of the Social Security Act, the Administrative Simplification provisions of HIPAA, to include: adoption of standards that will reduce the costs of providing and delivering health care; consultation with designated organizations in standards development and advancement; and ensuring protections against the wrongful disclosure of individually identifiable health information.**

The AMA urges that, in the Subcommittee's eventual report of recommendations to the NCVHS, the following fundamental points be included. These fundamental points are listed here and are addressed in more detail in our responses to specific questions below:

- **The Subcommittee should recommend that any changes in federal standards as to which code sets should be selected within a government-adopted standard should be implemented incrementally to minimize the disruption to the flow of information among physicians, providers, health insurance organizations, and government agencies of varying sizes and capabilities. The unique needs of patients and the way that physicians fulfill those needs must not be endangered from rapid, significant changes.**

- **The Subcommittee should recognize and reconfirm the foundational role that the efficient and low-cost Current Procedure Terminology (CPT®) code set provides, having been selected to be included within various government-adopted standards.**

- **The Subcommittee should recognize and reconfirm that the entire health care system, including physicians, requires health-related data standards that are credible, comprehensive, and developed using a collaborative, rigorous, evidence-based process. As the definition of "health care" broadens and drives the need for additional codes, the CPT® Editorial Panel must play a key role in creating or facilitating the creation of these additional codes to address these emerging needs, including social determinants of health (SDoH) and public health. Coordination with existing foundational vocabulary**

[2] The Agency for Healthcare Research and Quality defines a Learning Health System as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice. As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.

[3] The Quadruple Aim enhances the patient experience of care and outcomes, improves population health, reduces overall costs for the health care system while increasing value, and supports the professional satisfaction of physicians and the health care team.

sets, such as with the CPT® code set, is key to having the least amount of disruption and burden when adding such codes to the health care system.

The AMA provides the following comments in response to the four questions the Notice presents and looks forward to further expounding upon our remarks during and after the Listening Session.

1. ***How can data sharing be improved between patients, providers, payers, [the] public health system, and other actors in health care? What are the barriers to these improvements?***

Improving data sharing begins with recognizing the important role that the CPT® code set currently plays in our health care system. The CPT® code set is the most widely accepted nomenclature for the reporting of physician and other qualified health care professional procedures and services under government and private health insurance programs. Code sets such as the International Classification of Diseases (ICD) and CPT® are the backbone of interoperable health information.[4] These code sets ensure consistency of meaning as data are exchanged and used for a broad range of essential purposes. These code sets are the content foundation for clinical and administrative transactions and for use by electronic health records (EHRs) and health information systems. Uniformity is critical to achieving both the administrative simplification requirements of HIPAA, which are aimed at reducing the administrative costs of providing and paying for health care, as well as current efforts to achieve the nation's goals related to health care information interoperability. Further improvements to data sharing should build upon this efficient, low cost, and effective foundation.

Through the Editorial Panel, the AMA has curated and maintained the physician-developed CPT® code set for 55 years. The CPT® Editorial Panel—an expert, volunteer group of physicians and other qualified health care professionals—devotes hundreds of hours of their time to the maintenance of the CPT® code set. The CPT® Editorial Panel uses a public, transparent, consensus-driven development process open to all interested parties, which results in a trusted, evidence-based standard. The CPT® code set serves the needs of a data-driven health system, allowing physicians, patients, researchers, medical groups, allied health care professionals, health systems, hospitals, medical coders, accreditation organizations, payers, and health information technology (Health IT) professionals to easily exchange data on the medical services and procedures provided to patients. The CPT® code set is updated annually on a predictable schedule to meet the health care industry's needs in a timely manner.

Additionally, as the curator of the CPT® code set, the AMA, along with the CPT® Editorial Panel, are proud to highlight that, as the definition of health care has expanded to include other aspects of health—such as SDoH and in rapid response to the emerging pandemic—the AMA has already played a key role in the development of new codes, and has been working with other industry stakeholders to create and promote these new, needed codes.

SDoH

The AMA has facilitated collaboration with other stakeholders to begin creating codes for SDoH. CPT® codes have been developed to describe services that address identified SDoH concerns, problems, or diagnoses. These SDoH concepts are integral to medical services and procedures used by clinicians. SDoH CPT® codes have also been recognized by the Office of the

[4] See, https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf.

National Coordinator for Health Information Technology (ONC) and included in the United States Core Data for Interoperability (USCDI) version 2. The AMA is also a founding member of the Gravity Project, which is responsible for developing SDoH standards included in the USCDI v2. The AMA's years of experience maintaining complex code sets has served as a critical resource to the Gravity Project, a multi-stakeholder group that seeks to create and maintain a consensus-building community focused on expanding available SDoH core data for interoperability and accelerating standards-based information exchange by using Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®). Since the Gravity Project's inception, the AMA has played a major role in the Project's governing bodies, and was critical in the development, standardization, and testing of the HL7® FHIR® SDoH implementation guide.

Addressing COVID-19 Pandemic Needs

The current COVID-19 pandemic has also highlighted that the rapid need for trusted coding in public health remains paramount. Delays in the development of new codes could have derailed vaccination efforts. However, due to the CPT® code set's flexibility, agility, and foundational presence throughout the health care system, new CPT® codes were created to effectively meet the industry's ever-changing public health needs. During the public health emergency, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) approached the CPT® Editorial Panel with ideas for COVID-19 vaccine and vaccine administration codes to support the agencies' tracking requirements. Responding to the federal government's needs, the CPT® Editorial Panel met multiple times to review, approve, and rapidly make available new COVID-19 vaccine codes. The AMA also quickly developed, produced, and distributed various educational resources to assist the nation's health care professionals in understanding and implementing the new codes. The AMA was and is proud to support this national imperative and has embraced its role as a rapid responder in the midst of this international crisis.

The COVID-19 public health emergency exposed several faults in the nation's health care system. Inconsistent guidance, inept or legacy technology, and a lack of rapid response to public health needs made clear that improvements are needed. Fortunately, vaccine administration has fared better. While more must be done to address inequities, access, and vaccination hesitancy, progress cannot happen without tracking vaccine distribution and administration. In other words, one cannot improve what one cannot measure. Similarly, long-term research on COVID-19 variant/vaccination efficacy, breakthrough infections, and "long-haul" COVID-19 survivor recovery will require the close monitoring of vaccine administration.

In furtherance of the Subcommittee's recommendations to NCVHS to build off of the foundation established by the CPT® code set, the AMA has identified barriers and gaps upon which the Subcommittee may wish to recommend improved data sharing. These are summarized as follows and are illustrated in more detail in the **Appendix**.

Barriers/Gaps	Overview of the AMA's Recommendation
Physicians lack access to usable health information	The Subcommittee should recognize and reconfirm the foundational role of the CPT® code set to address high-impact use cases with known needs and identified gaps.

Meeting patients where they are and addressing consumer needs	Patients should be empowered through accessible and consumable data. Resources like the CPT® Consumer-Friendly Descriptors meet clinical, administrative, and consumer needs by empowering patients to take ownership of their care through straightforward, consumable descriptions of health care procedures and claims data.
The complexity and clinical utility considerations of data and third-party billing	Standardizing the rules of data submissions that use the CPT® code set would reduce the burden on hundreds of thousands of physicians contracted with multiple health plans by streamlining compliance with different billing rules and requirements. Wide-spread adoption of the CPT® Guidelines and Conventions (Guidelines)—which are readily available and freely included with a CPT® license—provides an opportunity for substantial burden relief by promoting the use of a single transparent set of data submission rules for multiple payers. More broadly, the Subcommittee should challenge assumptions that physicians and other medical providers can simply "purchase more management services" to manage complex health care operations. Scarce physician resources should not be used to solve for payer-generated complexities. The AMA also recommends the federal government conduct a national effort to analyze inconsistencies in prior authorization (PA) data requirements and criteria across the payer community and review the clinical validity of payers' PA guidelines. Federal regulatory levers should be considered to ensure such guidelines and data requirements are made publicly available for review.
Excessive physician burden due to the churn in health IT adoption	The adoption of reusable clinical and administrative concepts—leveraging the appropriate terminologies—promotes consistent data representation across the entirety of the health care system, reduces burden, and improves efficiency.

2. ***Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to Health and Human Services (HHS) for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for SDoH, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.***

With its knowledge and experience as the curator of the CPT® code set, the AMA and the CPT® Editorial Panel have sought out opportunities to bring other stakeholders to the table to collaborate and continue advancing the CPT® code set forward as health care advances. For example, the CPT® Editorial Panel has made significant progress in establishing CPT® codes for digital medicine services. In addition, the AMA has been instrumental in informing the analysis of digital health reimbursement through the Digital Medicine Payment Advisory, a collaborative initiative of a diverse cross-section of nationally recognized experts convened by the AMA.

As the Subcommittee considers new use cases, the AMA encourages the Subcommittee to identify ways to strengthen existing foundational code sets, terminologies, vocabularies, and value sets used in the health care system—including for public health, social services, clinical, and administrative functions. The AMA supports NCVHS' desire to improve interoperability, reduce burden, and promote administrative simplification. Care coordination requires standardized data and individuals' ownership of their health care information. Likewise, efforts to promote health equity, public health, price transparency, burden reduction, and data privacy are essential.

The AMA stresses, however, that any changes in the selection of code sets within federal standards must evolve at a practical and incremental pace. Large and sophisticated academic medical centers are uniquely different environments than small, solo, and rural medical practices and federally funded health centers (e.g., FQHCs, Title X clinics, etc.). Administrative and workflow disruptions have an outsized impact on these less-resourced health care facilities. Also, while technical expertise is important, that should not supplant the real-world knowledge and experience that clinical, operational, and administrative personnel bring to the table. Efforts should allow for all stakeholders to participate in the process, and with its knowledge and experience as the curator of the CPT® code set, the AMA, and its Editorial Panel, have unique expertise in bringing other stakeholders to the table to collaborate and continue advancing the CPT® code set as health care advances. Capturing input from frontline professionals who understand the data and workflow needs required by administrative and clinical processes is critical. Lastly, standards maturity, impact to the health care system, transition costs, workforce capacity, and industry consensus/readiness for implementing new/emergent standards should be factored into the Subcommittee's recommendations.

The AMA has detailed several examples of priority use cases, including those that build off of the CPT® code set, which the AMA encourages the Subcommittee to include in its recommendation to NCVHS. These are listed below and described in more detail in the Appendix.

Examples of Use Cases	Overview of the AMA's Recommendation
Consumer Empowerment/ Consumer Shopping	The AMA and the CPT® Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of procedure coding, with the CPT® code set meeting the needs of both business and consumers. Recent industry initiatives seeking to address patients' critical need for accurate information about the anticipated costs of their health care and aiming to promote transparency in pricing for "shoppable services" are supported by the trusted, unambiguous procedure definitions that the CPT® code set provides.
Prior Authorization (PA) Automation	The AMA believes the current manual PA process should be a priority use case for new standards adoption due to the significant burdens it currently imposes on both patients and physician practices. The overall PA volume reduction; improved transparency of PA requirements, criteria, and decision rationale; and protections for continuity of patient care must be part of any meaningful effort to reform PA programs. Any electronic PA technology involving health plans' access to EHR data must include appropriate guardrails so that the privacy and security of patients' health information is not sacrificed in the name of efficiency.
Medical Service PA	The AMA urges the Subcommittee to address the critical need for electronic standards to support medical services PA and clinical data exchange between

	physician practices and health plans. Any recommendations for such standards should: 1) apply to all health plans; 2) have undergone sufficient real-world testing in practices of all sizes to ensure viability and the ability to handle errors and situations beyond the "happy path" demonstrated in Connectathons and other closed testing systems; 3) show sufficient return on investment (ROI) across stakeholder groups; and 4) ensure that payer access to patient EHR clinical data is limited only to information needed to support a particular PA.
Prescription Drug PA	The AMA urges the Subcommittee to recommend the adoption of the National Council for Prescription Drug Programs (NCPDP) ePA standard for all types of prescription drug plans to eliminate industry confusion and ensure that patients covered by any plan type benefit from the reduced processing time offered by the ePA standard. The AMA requests that the Subcommittee recommend that support of the NCPDP ePA standard be incorporated into the ONC EHR certification program.
Real-Time Pharmacy Benefit (RTPB) Standard	To meaningfully improve physicians' ability to prescribe clinically appropriate medications that patients can access and afford, the industry needs an electronic standard that provides information on coverage, patient financial responsibility, utilization management requirements, and alternative therapies across all patients, plans, and EHRs. To facilitate informed conversations between physicians and patients regarding drug selection, the AMA urges the Subcommittee to recommend adoption of a standard RTPB technology that integrates with all EHRs and provides accurate information for all drug plans and patients.
All Payer Claims Databases (APCDs)	The AMA has long supported the development of APCDs, recognizing the value of aggregated, independent claims data in many state and national health initiatives. The AMA emphasizes the important role the CPT® code set plays in making these databases of health information a valuable resource for cost, outcome, and utilization analyses. The CPT® code set is key in the analysis of APCD data. CPT® codes directly identify the services or procedures a patient undergoes. These codes facilitate establishing, implementing, revising, or monitoring the care plan; coordinating the care of other professionals and agencies; and educating the patient or caregiver about the patient's condition, care plan, and prognosis.
Advanced Explanation of Benefits (AEOB)	Given the fast-approaching implementation deadline, the AMA urges NCVHS to prioritize this issue and engage in a thorough study of how existing or emerging electronic transactions could be leveraged to meet the AEOBs requirement, as well as recommend a standard solution for the industry. The AMA recommends the Subcommittee evaluate the underlying physician practice and health plan workflows needed to prepare "good faith estimates" and AEOBs, as the similarities between the AEOB use case and the current claims submission and adjudication processes suggest that the most appropriate electronic standards for this new functionality would mirror those currently used in claim and remittance advice transactions.
Clinical Data Registries	The CPT® code set plays a key role in clinical data registries, as CPT® codes directly identify the services provided to the patient. CPT® Category II codes are supplemental tracking codes that can be used for performance measurement and support registry reporting.

Augmented Intelligence (AI)	Through its partnerships and collaborations, the AMA has quickly gained capacity to help set priorities for health care AI; integrate the perspective of practicing physicians into the design, validation, and implementation of high-quality, clinically valuable health care AI; and promote greater understanding of the promise and limitations of AI across the health care community. The CPT® Editorial Panel has responded to the need for algorithmic and machine-driven services with several additions to the CPT® codes set.
International Use Cases	In support of multi-regional pooled research, the CPT® code set is used internationally by several countries for a variety of use cases. Altogether, the CPT® code set is licensed in over 40 countries globally to support interoperability, research, quality improvement, and efficient care.
Considerations Applicable Across All Use Cases	The AMA encourages that the Subcommittee recommend consideration of the following issues for applicability across all use cases: operational issues, technical issues, workforce implications, establishing patient authentication and authorization to support consent, privacy and security, trust and representation, and equity.

Success of these use cases will require semantic interoperability across multiple stakeholders. Ensuring that all stakeholders "move together" will create certainty and consistency for physicians and payers, while avoiding needless disruption and harm to patients. The federal government also must have a clear and comprehensive understanding of the impact of its policy changes and related implications. For instance, should the Subcommittee ultimately recommend the development of standards adoption toolkits and resources to assist under-resourced or new digital health entrants in the health care system, then the Subcommittee also should recommend increased coordination of shared value sets for administrative transactions, clinical care, and quality assessments while promoting broader stakeholder engagement in voluntary consensus activities.

3. ***How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?***

The AMA notes that the Subcommittee has dedicated the first panel of the Listening Session to this question. However, the current list of invited speakers comes from the health care industry or government. While the health care industry has its own unique footprint in the United States because of its vibrancy and diversity of providers and payers, **perhaps the Subcommittee may wish to seek out panel participants from other industries who can comment on industry standards for data sharing**. This might enable the Subcommittee to better explore whether other industries have effectively implemented and tested standards for data. For example, panels might include stakeholders from the American Society of Heating, Refrigerating & Air Conditioning Engineers; the American Society of Mechanical Engineers; ASTM International; and the Underwriters Laboratories, Inc.

Additionally, the AMA highlights that current federal law and policy regarding standard-setting promotes the use of marketplace-developed, proprietary consensus code sets—including those protected by copyright and available at a reasonable fee—and seeks to minimize any use of government unique standards.[5] While the AMA holds the intellectual property rights to the CPT® code set, the AMA has

[5] Pub. L. 104-113, The "National Technology Transfer and Advancement Act of 1995" and A-119 (revised), "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."

made the CPT® code set available royalty-free to the federal government, through long-standing public-private cooperation, for the benefit of the public. This is instead of charging the reasonable licensing fee the AMA typically charges third parties who are seeking to commercialize the AMA's copyrighted CPT® code set in their various products. This collaboration has allowed for widespread use of the CPT® code set to increase efficient operation of the health care system, while enabling the federal government to avoid the substantial administrative and financial burdens associated with creating, maintaining, and updating a code set. Such code sets can be most effectively authored and kept current by private entities that are most knowledgeable about their respective fields. Federal law also has long protected the copyrights in privately created works that are used by the federal government and whose use is incorporated by the government.

4. ***What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?***

The open-ended nature of this question illustrates HHS' very broad responsibilities as a federal agency. The AMA urges the Subcommittee to focus its attention, instead, on NCVHS' statutory responsibility to assist the Secretary in implementing the Administrative Simplification provisions of HIPAA. In doing so, the Subcommittee should recognize and reconfirm the foundational role that the efficient and low-cost CPT® code set provides having been selected to be included within various government-adopted standards. The AMA has invested a significant amount of time and resources over many years in creating and maintaining the CPT® Code Set. The AMA encourages the Subcommittee to recognize the value that the CPT® Code Set provides in increasing accuracy and efficiency. The CPT® Code Set is a critical working component within the data-sharing health care system, as a universally adopted and relied-upon code set developed through consensus and informed by practicing physicians. Indeed, in the preamble to the 2000 Final Regulations implementing the HIPAA administrative simplification standards, HHS noted "The comments we received regarding code sets were overwhelmingly in favor of the selection of currently used code sets as the initial standards."[6]

In its recommendations to the Secretary, the Subcommittee should recognize the strong foundation that currently exists through the CPT® Code Set and should prioritize its recommendations to focus on identifying and implementing incremental changes to areas and processes in the data-sharing continuum that may require further innovation and attention to facilitate and improve the exchange of clinical data under HIPAA. The AMA also urges the Subcommittee to prioritize employing a moderate, realistic path that fully considers the overwhelming success of many electronic transactions and existing code sets used today, the significant risks to patient safety and our entire health care system posed by a complete overhaul in administrative and clinical standards, and the finite resources available across stakeholder groups that will limit their ability to operationalize the massive system changes.

Regarding further opportunities for successful adoption and implementation of any standards, the AMA urges the Subcommittee to consider the following, as further detailed in the Appendix:

Short Term Priorities	The AMA recommends HHS study end-to-end data exchange workflows from the health care professional, health plan, and vendor prospective and identify "detours" where processes drop into manual workflows due to limitations in current electronic standards

[6] Health Insurance Reform: Standards for Electronic Transactions Final Rules (65 Fed. Reg. 50313, August 17, 2000).

	It is imperative that NCVHS address the lack of clarity in PA electronic standards—both for medical services and for prescription drugs—in the very near term. Other immediate priorities should be adopting standards that will support improved price transparency, as outlined in the above sections discussing RTPB and AEOBs.
Mid Term and Long Term Priorities	**The AMA urges consideration of certain criteria before recommending any standards or code sets for adoption. Specifically, the AMA recommends:** • Evaluation of several key criteria, such as through real-world piloting in physician practices, medical groups, and hospitals of all sizes, to ensure that the benefits of new technology will offset what will likely be significant implementation costs • A thorough analysis of the ROI across all stakeholders, of all sizes, before recommending a new electronic standard or code set for adoption • Careful consideration of the privacy and security implications of bidirectional provider-to-payer exchange of patient clinical data and establish the appropriate guardrails so that health plan access to EHR data is limited to what is needed to complete a particular business function • Acknowledgment that abandonment of standards and code sets that are working extremely well in our current health care ecosystem would lead to a massive disruption in the current claim submission and adjudication process and threaten the existence of physician practices, particularly those of small size

Conclusion

The AMA appreciates the Subcommittee's efforts to improve our health care system through adoption of electronic standards that will improve efficiency and reduce administrative costs. In formulating its recommendations and plans to NCVHS, we urge the Subcommittee to continue to seek input from individuals representing the business and operational units of various stakeholder groups. This will ensure a full understanding of workflow complexities, potential for disruptions, and the ability of a proposed recommendation or plan to work in a real-world, full-scale production environment. The AMA stands ready to assist the Subcommittee and NCVHS in providing the perspective of practicing physicians that have created and maintained an efficient, low-cost, and consensus-based code set for many years. If you have any further questions or need additional information, please contact Matt Reid, Senior Health IT Consultant, at matt.reid@ama-assn.org.

Sincerely,

James L. Madara, MD

APPENDIX

The following points provide further information and examples for the Subcommittee's consideration their recommendations to the Secretary.

Supplemental Information for Question 1

In furtherance of its encouragement for HHS to build off the foundation set by the CPT® code set, the AMA has identified and illustrated below barriers and gaps to data sharing between patients, providers, payers, the public health system, and other actors in health care that the AMA encourages HHS to address.

(1) Physicians lack access to usable health information

The AMA recommends that NCVHS leverage the foundational language of the CPT® code to address high-impact use cases with known needs and identified gaps. Sharing patient health information continues to be a challenge for physicians, who still often lack access to usable health information. There is a gap between certified capabilities of EHR systems and actual interoperability in the field, especially among smaller practices and among patients. Achieving the goals of data sharing requires addressing uniformity and consistency in information access, exchange, and use. Yet, data sharing is too big of an ocean to boil at once. As such, the AMA urges the Subcommittee to consider a sensible and realistic approach to improving data exchange.

Further, the AMA recommends that any recommendations to improve data sharing should be practical and scalable across the health care system. An examination of care coordination would best enable HHS to identify, prioritize, and address barriers to data sharing. Care coordination is the movement of patient information from one setting of care (e.g., hospital, ambulatory physician practice, home health, long-term care, rehabilitation facility) to another, as well as from providers to payers. Care coordination not only requires that disparate health IT systems function at syntactic (information structure) and semantic (information meaning) levels, but also—to be most effective—requires all participants to agree upon certain rules and policies. Common agreements are needed in several areas for each participant-type within the health care ecosystem regarding transaction types, purposes (acceptable uses), transport standards, format standards, vocabulary standards, patient access, security levels, patient matching, and consequences for violating the rules. Data governance, trust, business, and administrative processes must also be established and supported to facilitate care coordination.

(2) Meeting patients where they are and addressing consumer needs

Empowering patients effectively requires clearing two key hurdles: patients' data must be both *accessible* and *consumable*. As patients play a central role in their own care, the lack of an informed patient compromises care coordination. Yet, physicians often hear that patients desire information and knowledge—rather than raw data—to take charge of their own care.

Resources like the CPT® code set's Consumer-Friendly Descriptors meet clinical, administrative, *and* consumer needs by empowering patients to take ownership of their care through straightforward, consumable descriptions of health care procedures and claims data. Claims data are a combination of administrative data (e.g., patient demographic information, dates of service, provider name and address,

and health plan information) with coded health data (e.g., diagnosis code and procedure code). While physician and qualified health care professional-developed CPT® codes play a critical role in supporting clinical and administrative communications using detailed clinical elements of a procedure, CPT® Consumer Friendly Descriptors extend the use of the CPT® code set by translating the medical terminology required by physicians and payers into terms that patients and their caregivers will better understand. Information-blocking regulations further pave the way for improved patient access. Examples of CPT® Consumer Friendly Descriptors include:

CPT® Code	Long Descriptor	Consumer Friendly Descriptor
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	Screening mammogram
47562	Laparoscopy, surgical; cholecystectomy	Removal of gallbladder using an endoscope
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	Vaginal delivery with post-delivery care

(3) The complexity and clinical utility considerations of data and third-party billing

The AMA strongly urges the Subcommittee to consider actions the federal government can take to incentivize the adoption of consistent coding guidelines and rules across payers so code sets can better support traditional fee-for-service, value-based care, and quality measures. The AMA appreciates that the Subcommittee seeks information to help assess the "state of readiness for certain administrative and clinical standards to be considered for adoption or use as standards under HIPAA, for interoperability, and other subjects beyond HIPAA transactions." The AMA wishes to emphasize that requirements to comply with third-party billing often add significant administrative burden to physicians, clinical staff, and their medical practices. For example, regulatory and payer demands for point-of-care information have increasingly shifted documentation requirements. Payers' third-party billing systems are complex, expensive, and inefficient with billing rules varying by payer. Physicians who contract with multiple payers encounter an array of disjointed rules—often without justification or evidence of improved patient outcomes or quality.

Standardizing the rules of data submissions that use the CPT® code set would reduce the burden on hundreds of thousands of physicians contracted with multiple health plans by streamlining compliance with different billing rules and requirements. The wide-spread adoption of the CPT® Guidelines and Conventions (Guidelines)—which are readily available and freely included with a CPT® license—provides an opportunity for substantial burden relief by promoting the use of a single transparent set of rules for multiple payers. The AMA wishes to emphasize its belief that the Guidelines are critical to the correct use of the CPT® code set. Payers, however, have not consistently adopted the Guidelines and have instead created their own instructions for CPT® code reporting. In addition to the costs payers incur by developing and maintaining their own codes, the resulting variation imposes a burden on the entire health care system that requires extra effort and special attention to payer-specific rules and adds unnecessary time and resources to the billing process. For example, physicians must monitor and track

rules from different payers and must alter the coding of their claims dependent on the specific payer. Failure to follow the payer-specific rules results in the denial and claim rework of even "clean claims," which burdens the entire health care system. Further, third-party variation hinders the coordination of patient benefits in instances when a secondary payer does not recognize a primary payer's rules, which may also result in additional rounds of denials and claim rework. Third-party variation also inhibits the transfer of procedure data, disrupting aggregation and analysis for utilization, payment, and other purposes.

More broadly, the AMA recommends NCVHS conduct a study of end-to-end data exchange workflows from the health care professional, health plan, and vendor prospective. Such a study should identify disorganized or inconsistent segments of the health care revenue cycle. Significant physician time and resources are wasted on administering health care operations. Stricter adherence to existing or new policies standardizing health care PA operations could reduce the costly reliance on health care technology companies, e.g., analytics and solution providers, who financially thrive due to its complexity. Assumptions that physicians and other medical providers can simply "purchase more management services" should be challenged. More should be done to make PA tools and resources more accessible, available, and better support physicians' needs for health care operations. This is increasingly true to ensure the stability of our nation's independent medical practices. This could be accomplished through a mixture of federal policy interventions, normalizing payer requirements, fewer custom and more "off-the-shelf" health IT solutions that align with standard payer processes, moving to bi-directional information exchange, and promptly making data available to health care facilities.

As an example, NCVHS should make recommendations to ONC and CMS to standardize health care analytics/operational functionality and payers' administrative practices—embedding them in EHR certification and CMS' administration of Medicare Advantage plans. The intent is to shift costs away from physicians and other providers and promote uniformity in payer operations. Likewise, the AMA would encourage ONC and CMS to incent the private payer industry to align with these requirements. Furthermore, the AMA recommends the federal government conduct a national effort to analyze inconsistencies in PA data requirements and criteria across the payer community and review the clinical validity of payers' PA guidelines. There is concern that payer PA guidelines prioritize revenue ahead of patient health, wellness, or quality of life. Federal regulatory levers should be considered to ensure such guidelines and data requirements are made publicly available for review.

The AMA also urges NCVHS to take stock in systems that are working extremely well in the health care ecosystem. There are revenue cycle functions that are exclusively administrative and have been functioning well for decades. While improvements can be made, such as adopting an attachments standard, these processes do not require new linkages to clinical exchanges or transitioning code sets. As we state throughout this letter, any such unnecessary changes in mandated standards and code sets would jeopardize well-functioning current processes and waste limited resources that would be better directed towards high-priority areas that could reduce administrative burdens.

(4) Excessive physician burden due to the churn in health IT adoption

The adoption of reusable clinical and administrative concepts—leveraging the appropriate terminologies—promotes consistent data representation across the entirety of the health care system, reduces burden, and improves efficiency. The dual challenges of consistent data representation and information access compromises the ability of payers and physicians to create efficient care delivery solutions and care coordination models. Health IT continues to cause frustration, burden, and burnout

among physicians, while medical information mismanagement by health IT systems leads to waste, data fragmentation and inconsistency. Difficulty using EHRs stems from both poor usability and the challenges with accessing, exchanging, and using data. Yet, impediments to data sharing are often a result of bad front-end system design rather than back-end data coding.

Real-world testing is necessary to develop a detailed analysis of a code set's costs and benefits, and understanding the economic impact of a new or revised standard is critical. As curator of the CPT® code set, the AMA has been working with other stakeholders, such as the Health Level 7 (HL7), to promote more seamless data-sharing operations. Solutions built on Fast Healthcare Interoperability Resources (FHIR)-based Application Programing Interfaces (APIs) use common data models and value sets to correct for these issues. FHIR profiles, developed to address known gaps and weak points in the health care system, incorporate coding terminologies used by millions of clinicians and medical professionals. HL7 efforts like Da Vinci and the Gravity Project, for instance, address gaps in payer/provider information exchange and improve SDoH data management. Further, efforts like Da Vinci leverage procedure coding to unleash critical data between payers and physicians required for value-based care workflows.

Supplemental Information for Question 2

The AMA has detailed several examples of priority use cases for which the AMA encourages the Subcommittee to consider new standards, including those that build off of the CPT® code set, in its recommendation to the Secretary.

(1) Consumer Empowerment/Consumer Shopping

The AMA and the CPT® Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of procedure coding, with the CPT® code set meeting the needs of both business and consumers. Health insurers and payers use the same codes for all medical services and procedures, ensuring uniformity and reducing waste. CPT® codes also serve as the foundation for health plans' claims adjudication systems. The effective use of existing standards provides an important path to consumer empowerment. This consistency—combined with the power of Consumer-Friendly Descriptors—enables consumers to clearly understand which services are described and allows an "apples-to-apples" comparison across health care organizations and the entire health care ecosystem.

Recent industry initiatives seeking to address patients' critical need for accurate information about the anticipated costs of their health care and aiming to promote transparency in pricing for "shoppable services" are supported by trusted, unambiguous procedure definitions the CPT® code set provides. The AMA supports adoption of new standards that build off of the CPT® code set to improve and facilitate informed conversations between physicians and their patients about treatment costs while minimizing burden on the health care system.

(2) PA Automation

The current manual prior authorization (PA) process should be a priority use case for new standards adoption due to the significant burdens it currently imposes on both patients and physician practices. In a December 2020 AMA survey, 94 percent of physicians reported that PA can delay access to medically necessary treatment, with an alarming 30 percent stating that PA has led to a serious adverse event (e.g., hospitalization, life-threatening event, or death) for a patient in their care. Practices reported completing an average of 40 PAs per physician per week, with this weekly PA workload for a *single physician* consuming two business days of physician and staff time. Notably, these PA practice burdens reflect physicians' experiences between 11/23/20 and 12/14/20, when COVID-19 cases were surging in the United States.

As stated in the 2018 Consensus Statement on Improving the Prior Authorization Process released by national health care professional organizations and health plan trade associations, any meaningful effort to reform PA programs must include an overall PA volume reduction; improved transparency of PA requirements, criteria, and decision rationale; and protections for continuity of patient care. While automation using standard electronic transactions has the potential to reduce the patient harms and practice hassles associated with PA, technology must not be viewed as the single "silver bullet" solution to address the complex challenges PA poses to our health care systems. Additionally, any electronic PA technology involving health plans' access to EHR data must include appropriate guardrails so that the privacy and security of patients' health information is not sacrificed in the name of efficiency.

(2a) Medical Service PA

The AMA urges the Subcommittee to address the critical need for electronic standards to support medical services PA and clinical data exchange between physician practices and health plans. Any recommendations for such standards should: 1) apply to all health plans; 2) have undergone sufficient real-world testing in practices of all sizes to ensure viability and the ability to handle errors and situations beyond the "happy path" demonstrated in Connectathons and other closed testing systems; 3) show sufficient return on investment across stakeholder groups; and 4) ensure that payer access to patient EHR clinical data is limited only to information needed to support a particular PA.

It is widely acknowledged that implementation of the HIPAA-mandated X12 278 for medical services PA is subpar: the 2020 CAQH Index reports industry adoption of the X12 278 at a meager 21 percent. In comparison, 96 percent of claims are submitted using the X12 837, making it the "star" of the electronic transactions. In robust discussions over the past few years—including at NCVHS hearings—industry stakeholders have explored the reasons for this limited use of the X12 278. Health plans, vendors, and health care professionals agree that the major contributing factor is the lack of a standard to exchange the supporting clinical documentation needed to approve the overwhelming majority of medical service PAs. Despite multiple NCVHS letters to the Secretary recommending adoption of an electronic attachment standard (the most recent from July 2016, with the recommendation reiterated in a November 2020 letter regarding operating rules), an electronic attachment standard has not been named and required. The lack of an attachments standard has been a rate-limiting factor in PA automation, as is perhaps best captured by a quote from a large EHR vendor in the June 2014 NCVHS Subcommittee on Standards Meeting transcript: ". . . the uncertainty in the area has a paralyzing effect . . . There's a huge disincentive for me to allocate resources for my team to any specific changes."

In the absence of regulatory direction on attachments, newer technologies to exchange clinical documentation between health care professionals and health plans, such as FHIR, have been explored to advance electronic PA for medical services. In alignment with a December 2020 NPRM[7] issued by CMS that proposed adoption of three HL7 Da Vinci FHIR Implementation Guides (IGs) to support PA automation, the AMA strongly supports efforts that simplify PA requirements and embed payer documentation needs within physicians' EHR workflow, **which the specifications of these FHIR IGs should promote**. However, as detailed in the AMA's comments on the NPRM, we have concerns about the maturity of the IGs and the lack of real-world testing in physician practices of all sizes. Moreover, the provisions of the NPRM applied to a narrow set of health plans (i.e., Medicaid, CHIP, and federally facilitated exchange health plans). This sets an alarming precedent, as the benefits of HIPAA administrative simplification will only be realized if all health plans are required to use the same electronic standards.

(2b) Prescription Drug PA

Unlike medical services PA, the industry has developed and implemented a standard for prescription drug electronic PA—the National Council for Prescription Drug Programs (NCPDP) SCRIPT electronic PA (ePA) standard. The AMA supports adoption of the NCPDP ePA standard due to the multiple efficiencies it offers to physician practices, including a uniform electronic PA process across all prescription drug plans, integration of the PA process within the EHR/e-prescribing system, and conditional logic that skips

[7] A final rule was released in January but has since been withdrawn.

questions that do not apply to a particular patient. The AMA offers a three-part educational video series on prescription drug ePA to support physician practices in using this technology.

We urge the Subcommittee to recommend the adoption of the NCPDP ePA standard for all types of prescription drug plans to eliminate industry confusion and ensure that patients covered by any plan type benefit from the reduced processing time offered by the ePA standard. In December 2020, CMS issued a final rule mandating use of the NCPDP ePA standard in Part D plans, with compliance enforcement effective January 1, 2022. However, the rule notes that its provisions do not apply to non-Part D plans, for which the X12 278 remains the HIPAA-mandated standard. As with the previously mentioned CMS PA NPRM, this sets a disturbing precedent in which rulemaking carves out standards mandates for only certain plan types. Again, the efficiencies gained through standards transactions can only be achieved if mandates apply to all plans.

Along with expanding the NCPDP ePA mandate to all plan types, it is critical that all physicians be aware of this new technology and have access to it in their EHRs. As mentioned above, the AMA offers resources and an ongoing educational campaign to ensure that practices are aware of ePA and can request this functionality from their EHR vendors. Unfortunately, under one-quarter (24 percent) of physician respondents in the 2020 AMA PA survey reported that their EHR system offers ePA for prescription drugs. As such, the AMA requests that Subcommittee recommend that support of the NCPDP ePA standard be incorporated into the ONC EHR certification program.

(3) Real-Time Pharmacy Benefit (RTPB) Standard

To meaningfully improve physicians' ability to prescribe clinically appropriate medications that patients can access and afford, the industry needs an electronic standard that provides information on coverage, patient financial responsibility, utilization management requirements, and alternative therapies across all patients, plans, and EHRs. The current lack of transparency regarding prescription drug benefits and costs at the point of prescribing poses enormous challenges to both physicians and patients. Physicians select the most clinically appropriate prescription drug for a particular patient and send the electronic prescription to the patient's pharmacy of choice, usually with no idea: (1) if the patient's plan will cover the drug; (2) if there are utilization management requirements (i.e., PA or step therapy); (3) the scope of the patient's out-of-pocket cost; or (4) any preferred formulary alternatives. Unfortunately, this sets the stage for treatment abandonment: patients arrive at the pharmacy to pick up a prescription only to be stymied by unmet PA requirements or the sticker shock of high out-of-pocket costs. These pharmacy counter surprises harm patients, with 74 percent of surveyed physicians reporting that PA can lead to treatment abandonment—with devastating effects on clinical outcomes. For example, Benjamin Galper, MD, MPH, details in a FixPriorAuth video clip how his patient suffered a second heart attack after being unable to obtain the medication needed to keep a stent open due to an unknown PA requirement. Beyond these patient harms, the lack of transparency surrounding drug coverage and costs at the point of care lead to enormous administrative burdens and workflow disruptions for both physician practices and pharmacies.

To facilitate informed conversations between physicians and patients regarding drug selection, the AMA urges the Subcommittee to recommend adoption of a standard RTPB technology that integrates with all EHRs and provides accurate information for all drug plans and patients. Effective January 1, 2021, CMS requires Part D plans to support at least one prescriber real-time drug benefit tool that integrates with at least one EHR system. While the AMA appreciates CMS' underlying intention, this requirement does

little to improve transparency of drug coverage and pricing at the point of prescribing: only Part D plans are subject to the requirement, and physicians' access to this information completely depends upon the integration of their EHR with a particular plan's RTPB tool. For physicians to routinely use RTPB EHR technology, they must be able to access drug coverage and pricing information for *every patient* in their panel; physicians' frustration with the current proprietary tools that only provide information for a limited number of plans discourages adoption. Of note, NCPDP has developed an RTPB standard that should support uniform provision of these critical data across all patients, plans, and EHRs.

(4) All Payer Claims Databases

The AMA has long supported the development of All Payer Claims Databases (APCD), recognizing the value of aggregated, independent claims data in many state and national health initiatives. We believe APCDs have the potential to advance not only price transparency as it pertains to benefits consumers purchase, but also to assist policymakers in understanding price variation, trends in costs, and gaps in service. Additionally, as value-based contracting continues to grow and payers and physicians explore alternative payment models, physicians and other health care providers, as well as payers, can benefit from APCD data to evaluate the feasibility and impact contract arrangements. Additionally, state stakeholders may use the data to better assess changes in spending, utilization, and quality that result from certain payment models. The AMA sees much promise in the availability of independent health care data to help move the needle on alternative payment models and value-based care. APCD data can also be excellent tools for studying utilization trends, health care disparities, the impact of chronic conditions, and more broadly, population health. Furthermore, APCDs can serve to evaluate, address, and improve health outcomes among historically marginalized and marginalized populations. The AMA advocates for improved price transparency in health care, an issue of great importance to the Biden Administration.

The AMA emphasizes the important role the CPT® code set plays in making these databases of health information a valuable resource for cost, outcome, and utilization analyses. APCDs are state-based, which may make the scope, intended uses, and goals of APCDs—such as for utilization analysis, costs, quality of care, or other aspects of care delivery—unclear to physicians. This variation further highlights that the CPT® code set is key in the analysis of APCD data. CPT® codes directly identify the services or procedures a patient undergoes. These codes facilitate establishing, implementing, revising, or monitoring the care plan; coordinating the care of other professionals and agencies; and educating the patient or caregiver about the patient's condition, care plan, and prognosis. The CPT® also meets the needs of a bundled coding structure for chronic conditions with care management services. The physician or other health care professional provides or oversees the management and/or coordination of services, as needed, for all medical conditions, psychosocial needs, and activities of daily living. In addition, CPT® has maintained Category II Performance Measurement codes designed to support alternative payment models. These codes facilitate data collection about the quality of care rendered. Coding for certain services and test results supports nationally established performance measures.

(5) Advanced Explanation of Benefits

In late 2020, Congress passed the No Surprises Act, which requires health plans to provide patients with an advanced explanation of benefits (AEOB) prior to scheduled care or upon patient request prior to scheduling. Health care professionals trigger the need to create the AEOB by sending the health plan a "good faith estimated amount" for scheduled services. These requirements go into effect on January 1, 2022.

Given the fast-approaching implementation deadline, the AMA urges NCVHS to prioritize this issue and engage in a thorough study of how existing or emerging electronic transactions could be leveraged to meet the AEOB requirement and recommend a standard solution for the industry. While the AMA strongly supports patient access to accurate information regarding the costs of their health care, we note that there is currently no electronic standard to support a uniform process for physician practices to submit "good faith estimates" to health plans, nor for health plans to send AEOBs to patients and physicians. While the No Surprise Act does not require health plans to send AEOBs to physicians, we maintain that such information must also be provided to practices to support informed conversations with patients about the costs of scheduled care. The AEOB is critical in cost-of-care discussions, as it reflects the health plan's prediction of how the claim for the scheduled service will be adjudicated. Without this information, physicians and practice staff will be unprepared to have a detailed discussion about treatment costs with patients, which could undermine the patient-physician relationship and erode trust.

The AMA recommends the Subcommittee evaluate the underlying physician practice and health plan workflows needed to prepare "good faith estimates" and AEOBs, as the similarities between the AEOB use case and the current claims submission and adjudication processes suggest that the most appropriate electronic standards for this new functionality would mirror those currently used in claim and remittance advice transactions. This approach would minimize administrative burdens for both practices and health plans, as well as have a realistic chance of meeting the aggressive legislative deadline. As stated above, it is crucial for any electronic standard transaction adopted for this purpose to support delivery of the AEOB to both the *physician* and the *patient*. Leveraging existing claim and remittance advice electronic standards for the AEOB requirement would also support provision of this information to physician practices.

Without a standard electronic transaction, health plans will develop proprietary tools (i.e., portals) to satisfy the AEOB provision of the No Surprises Act. While portals may be efficient solutions for health plans, they are incredibly burdensome for physician practices, as they require maintenance of logins/passwords for many different health plans' systems and re-keying of data from the EHR. Moreover, lack of an electronic standard to support the "good faith estimate" submission and provision of an AEOB will no doubt lead to many different approaches to data content and formats across health plans, which will undoubtedly be highly confusing to both physician practices and patients.

(6) Clinical Data Registries

The CPT® code set plays a key role in clinical data registries as CPT® codes directly identify the services provided to the patient. Consistent procedure identification and data representation are critical to a registry's analytics and quality improvement functions. Although not new, registries play a key role in broader interoperability needs. A clinical data registry is an interactive database that collects, organizes, and displays health care information. Registries collect and store specific health information for various purposes, often organized by disease or condition. Data collection and use specifics depend on the purpose of the registry. As demonstrated by the examples below, registries may collect data from a single practice or across multiple organizations.

- Clinical registries—also known as patient registries—can be used to analyze clinical practice, disease management, patient outcomes, and quality of care, as well as other patient-related priorities. The focus of these registries is to evaluate patient outcomes over time.

- Product registries are typically used to track implanted medical devices and pharmaceuticals. These registries allow for analysis of various factors including patient outcomes, device or drug performance, and efficacy of the device or drug. These registries can be used to detect device failures or drug side effects and identify patients for recalls.
- Public health registries are usually set up to identify specific information, such as vaccine administration rates or disease case numbers, but do not track patient outcomes.

CPT® Category II codes are supplemental tracking codes that can be used for performance measurement and support registry reporting. The use of the tracking codes for performance measurement decreases the need for record abstraction and chart review, thereby minimizing administrative burdens on physicians and their medical practice. These codes are intended to facilitate data collection about quality of care by coding certain services and/or test results needed for performance measurement and reporting.

(7) Augmented Intelligence (AI)

Patients, physicians, and the U.S. health care system are facing enormous challenges. The combined impact of a rapidly aging population, a relative decline in the working population that reduces revenue essential for safety net programs, and persistent high costs of care will strain the nation's ability to support affordable, accessible, high-quality care. Augmented intelligence (AI) covers a range of methods, techniques, and systems that may help combat these challenges. Common examples of AI systems include natural language processing, computer vision, and machine learning. In health care, as in other sectors, AI solutions may include a combination of these systems and methods. The AMA has adopted the term "augmented intelligence" since it more accurately reflects the purpose of such systems, whether assistive or fully autonomous, because they are intended to coexist with human decision-making.

Ensuring the appropriate implementation of AI in health care requires that all stakeholders forthrightly address challenges in the design, evaluation, implementation, and oversight of AI systems. Software algorithms, coupled with proliferating sources of data (datasets) pertinent to health and medicine, offer the promise of new and more powerful ways to augment human intelligence and expertise in health care. With the engagement of physicians to identify needs and set priorities for design, development, and implementation, health care AI can offer a transformative set of tools to help patients, physicians, and the nation face these looming challenges.

The use of AI and machine learning in health care may be best applied to precision medicine, predictive analytics, and outcomes assessments. AI, for instance, is offering various benefits to medical imaging, including augmenting the capabilities of radiologists to enhance their efficiency and accuracy, as well as reducing costs by improving the appropriateness and cost-effectiveness of medical imaging utilization. AI can streamline health care workflow and improve triage of patients (especially in acute care settings), reduce clinician fatigue, and increase the efficiency and efficacy of training. Moreover, shortages of medical experts to meet the needs of vulnerable and underserved populations could potentially be relieved, in part, by AI.

Applying AI to improve care is another area of rapid evolution. The University of Pittsburgh Medical Center (UPMC) launched a systemwide effort to reduce hospital readmissions and enhance clinical decision making while a patient is receiving care. UPMC applies machine learning to claims data to predict a patient's risk of readmission before the patient arrives. A second algorithm uses laboratory and clinical metrics extracted from clinical records to update the risk prediction every 15 minutes over the

course of the patient's admission. Before discharge, if the risk prediction's two models are in conflict, UPMC uses machine learning to come up with a set of rules that dictate which model takes precedence to inform clinician discharge decisions.

Through its partnerships and collaborations, the AMA has quickly gained capacity to help set priorities for health care AI; integrate the perspective of practicing physicians into the design, validation, and implementation of high-quality, clinically valuable health care AI; and promote greater understanding of the promise and limitations of AI across the health care community. The AMA has also developed comprehensive policy on AI, including AI payment and regulation. Moreover, the AMA created and convened the Digital Medicine Payment Advisory Group (DMPAG), a collaborative initiative of a diverse cross-section of nationally recognized experts, to tackle some of the health care system's biggest challenges in digital medicine.

The CPT® Editorial Panel has responded to the need for algorithmic and machine-driven services with several additions to the CPT® code set. This includes Multi Analyte Algorithmic Analyses (MAAA), which are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays (e.g., proteins, polypeptides, lipids, carbohydrates). The CPT® Editorial Panel has also added new AI services to the code set, including a point of care imaging service performed in the primary care setting for the detection of advanced eye disease, such as diabetic retinopathy. A new definitional structure for AI services in the CPT® code set will be considered at the 2021 fall CPT® Editorial Panel meeting. If approved, it will newly define the work of the machines and physicians in an AI service—helping promote a better understanding of how AI can analyze data at distinct levels of autonomy and differentiate between types of AI services.

(8) International Use Cases

In support of multi-regional pooled research, the CPT® code set is used internationally by several countries for a variety of use cases. Altogether, the CPT® code set is licensed in over 40 countries globally to support interoperability, research, quality improvement, and efficient care.

Several years ago, the Department of Health of Abu Dhabi (DOH) and the Dubai Health Authority in the United Arab Emirates selected the CPT® code set as the procedural terminology for their national health insurance programs, claims adjudication systems and/or health information exchanges. Recently, both Emirates adopted a more current version of the CPT® code set to allow their local ecosystem of payers and providers to keep pace with modern medicine and, in the case of DOH, support critical public health initiatives related to the COVID-19 pandemic.

In parallel, the CPT® code set was adopted by the South African Medical Association to describe procedures and services performed by medical practitioners in that country's private sector. Linked to these procedures and services is the use of the resource-based relative value scale (RBRVS)—the physician payment system used by CMS and most other payers.

In 2019, the CPT® code set was selected by the Health Insurance Organization of the Republic of Cyprus to drive standardization and improve data quality for outpatient services. Data captured and reported by the CPT® code set has helped inform and guide local policy decisions. More specifically, guidelines are

being issued to health care providers as a measure to promote better health care quality and correct coding, but also to control costs and define coverage of services.

The CPT® content is also used internationally in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP). NSQIP is a risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. It includes all major cases as determined by the CPT® code set.

(9) Considerations Applicable Across All Use Cases

Issues	Considerations Applicable Across All Use Cases
Operational Issues	New approaches to enhancing interoperability must consider existing workflows and operations to better understand how future roles and technologies will need to evolve. Furthermore, administrative transactions currently flow through a significant existing infrastructure. As policymakers contemplate changes to the existing system, consideration should be given to "what works today" to avoid disruption to the revenue cycle.
Technical Issues	New approaches will require a deeper understanding of the shift in information technology needs, as well as investment and deployment of appropriate systems which could impose a significant cost burden on physicians. Additional challenges may include the timing and scale of deployment. Expectations must be clear as to whether all plans will be required to shift to more automated approaches or whether there will be a mixed model where physicians are expected to send data to different places in different formats.
Workforce Implications	New approaches to data sharing may require a different skill mix, including shifts in needed capabilities, training on new technologies and processes, and the potential for significant workforce re-alignment.
Establish Patient Authentication and Authorization to Support Consent	Standards should be created to enable patients and caregivers to authorize the sharing of their data with a tool of their choice to interface with their corresponding provider and payer systems. This includes the establishment of a standard for third-party authorization that allows patients to access and bi-directionally share their data across the landscape. Consideration must be given to the security implications associated with third-party authentication. Additionally, consideration must be given to the operational impact of bi-directionally sharing data between physician and payer systems at the patient's request, including the need for robust data integrity and data quality practices.
Privacy and Security:	Ensuring the privacy, security, and confidentiality of a patient's health information is an obligation that physicians take seriously. Increased sharing of health information across payers and providers requires careful consideration of privacy issues, including ensuring that only the minimum necessary information is shared and uses of such data beyond the initial specific transaction are limited. With respect to security, challenges with authorizing and authenticating data recipients before exchange represents a particular challenge. The lack of a national approach to accurately identify patients further complicates this issue.

Trust and Representation	Trust among individuals, payers, and physicians is key to improving data sharing. Should clinical data be reused for other purposes outside of the initial specific transaction in question (e.g., underwriting, setting premiums, or benefits design), it could have a profound impact on individuals' lives and their overall trust in the health care system. Similarly, such information could be used for other purposes such as contract negotiations between payers and physicians. In both instances, trust may be easily eroded. Participation by all parties is critical to ensure that operational and trust considerations are addressed.
Equity	An equity-centric vision is a nation where all people live in thriving communities where resources work well, systems are equitable and create no harm, and everyone has the power to achieve optimal health—and all physicians are equipped with the consciousness, tools, and resources to confront inequities as well as embed and advance equity within and across all aspects of the health system. As our society becomes more attentive to prioritizing health equity, significant barriers in the form of the digital divide—along with gaps in digital and health literacy—continue to prevent populations from having equitable access to their health data and tools of communication with their physicians. Inadequate funding and staff resources necessary for technology implementation that can enhance connectivity and data sharing while also ensuring privacy and security of data also create barriers to health equity.

Supplemental Information for Question 4

Regarding further opportunities for successful adoption and implementation of any standards, the AMA urges the Subcommittee to consider the following proposals in its recommendation for short-term, mid-term and long-term priorities for HHS.

(1) *Short-Term Priorities*: The AMA recommends HHS study end-to-end data exchange workflows from the health care professional, health plan, and vendor perspective and identify "detours" where processes drop into manual workflows due to limitations in current electronic standards.

As outlined above, the medical services PA process is in desperate need of a standard electronic solution to automate what is now an extremely manual, time-consuming process. Moreover, unlike many other revenue cycle functions, PA also directly impacts patients' ability to obtain timely, medically necessary care. Despite intense industry attention over the past few years, we appear no closer to adoption of an electronic standard to exchange clinical data to support medical services PA; meanwhile, patients continue to suffer from care delays and negative clinical outcomes. It is imperative that NCVHS address this lack of clarity in PA electronic standards—both for medical services and for prescription drugs—in the very near term. Other immediate priorities should be adopting standards that will support improved price transparency, as outlined in the above sections discussing RTPB and AEOBs.

(2) *Mid-Term and Long-Term Priorities*: The AMA urges consideration of certain criteria before recommending any standards or code sets for adoption.

The AMA recommends evaluation of several key criteria to ensure that the benefits of new technology will offset what will likely be significant implementation costs. As such, any electronic standard under consideration for a federal mandate should first be proven successful in real-world piloting in physician practices, medical groups, and hospitals of all sizes. While Connectathons and similar closed testing systems are an important first step in advancing new technology, they do not accurately reflect real-world workflows in small- to medium-size physician practices with fewer resources, nor do they support the error messaging needed when transactions inevitably fall off the "happy path."

The AMA recommends a thorough analysis of the ROI across all stakeholders, of all sizes, before NCVHS recommends a new electronic standard or new code set for adoption. Again, this assessment must account for the costs of a full-scale implementation and all the underpinning development, not just the minimal work needed to program a single demonstration. For example, in evaluating the costs involved in implementing the Da Vinci FHIR PA-related guides, NCVHS should detail the resources and time involved in digitizing each health plan's proprietary PA criteria, across all medical services, for both payers and EHR vendors. This work would be consistent with NCVHS' statutory responsibility to assist the Secretary in implementing Part C of Title XI of the Social Security Act.

The AMA recommends careful consideration of the privacy and security implications of bidirectional provider-to-payer exchange of patient clinical data and the establishment of the appropriate guardrails so that health plan access to EHR data is limited to what is needed to complete a particular business function. While NCVHS rightfully points out that our health care world has changed in ways that the HIPAA framers could not have predicted or envisioned, the sacred protection of patients' medical information remains as relevant, if not more so, today. Health plans are already partnering with EHR

vendors to cull clinical data from patients' medical records for various use cases, and it is unclear what privacy and security guardrails, if any, have been put in place. With unfettered access to EHRs, health plans could misuse patient health information, with the end result being the destruction of patient trust in physicians as curators and protectors of the medical record. With the rapid development of FHIR-based technology, it is crucial that 1) health plan contracts not require EHR access as a condition of a physician's network status and 2) physicians have full line-of-sight into exactly what EHR data health plans will be able to access, and for what purposes. Without such safeguards, any efficiency gains may come at the price of patient privacy and data security.

The AMA urges NCVHS to recommend that HHS take stock of standards and code sets that are working extremely well in our current health care ecosystem. Abandonment of the standard electronic claims process, whether it be the transaction itself or associated code sets, would lead to a massive disruption in the current claim submission and adjudication process and threaten the existence of physician practices, particularly those of small size. As mentioned previously, the overwhelming adoption of the X12 837 electronic claim reflects a clear HIPAA administrative simplification victory. Although we recognize that certain use cases involve co-mingling of administrative and clinical data (such as PA, as referenced above), we maintain that there are revenue cycle functions that are exclusively administrative and therefore do not require a transition to clinical transactions or code sets. As stated throughout this letter, any such unnecessary changes in mandated standards and code sets would jeopardize well-functioning current processes and waste limited resources that would be better directed towards high-priority areas that could reduce administrative burdens.

July 30, 2021

To: National Center for Health Statistics
From: APCD Council, on behalf of State APCDs
RE: Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

On behalf of our member health data organizations that collect and maintain All-Payer Claims Databases (APCD), the APCD Council submits these comments in response to request for public comments for the August 25, 2021 meeting of the National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards.

The APCD Council is a learning collaborative of government, private, non-profit, and academic organizations focused on improving the development and deployment of state based APCDs. The APCD Council is a program of the National Association of Health Data Organizations (NAHDO) operated in partnership with the Institute for Health Policy and Practice (IHPP) at the University of New Hampshire (UNH).

We appreciate the opportunity to provide comments on this important topic. States have a long history of using administrative claims data to better understand health care services costs, utilization, and access, and support public health information needs. As custodians of statewide hospital discharge data and claims data reporting systems, states have been advancing the policies and practices necessary to effectively use and collect data. While there is much that can be said about each of the guiding questions in the public comment request, this response focuses on some key issues in specific to two of the questions.

Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

The APCD Council has been supporting efforts for more uniform APCD data collection for over ten years culminating in the creation and continued maintenance of the APCD Common Data Layout (APCD-CDL™). The APCD-CDL™ consists of technical specifications and multiple file layouts composed of data elements, data types, maximum field lengths, descriptions, valid values, and references to industry standards.

APCD-CDL™ files collect adjudicated medical, pharmacy, and dental claims data for all eligible members, with data about members and providers.

- **Member Eligibility**: demographic data for members eligible for medical, pharmacy, and dental benefits, including references to ASC X12 270/271 and 834 implementation guides.
- **Medical Claims**: service-level remittance with clinical diagnosis codes, medical procedure codes, and charges and payments data, including references to the ASC X12 Post Adjudicated Claims Data Reporting Guides (Institutional and Professional).
- **Pharmacy Claims**: service-level remittance with drug-dispensing, pharmacy and prescribing physician, and charges and payments data, including references to the NCPDP Uniform Healthcare Payer Data Standard Implementation Guide.
- **Dental Claims**: service-level remittance with clinical diagnosis codes, dental procedure codes, teeth treated, and charges and payments data, including references to the ASC X12 Post Adjudicated Claims Data Reporting Guide (Dental).
- **Providers**: provider identifiers, such as the National Provider Identifiers (NPI), with provider name, practice location(s), and specialty data for all providers on all other files.
- **Header and Trailer Records**: support successful data exchange.

Most recently, the APCD-CDL™ has been evaluated as part of the U.S. Department of Labor's (DOL) State All Payer Claims Database Advisory Committee (SAPCDAC). As summarized by the DOL:

The State All Payer Claims Databases Advisory Committee (SAPCDAC) was established in 2021. The SAPCDAC was established by Section 735 of ERISA (as added by section 115(b) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act 2021 (Dec. 27, 2020)). The SAPCDAC will advise the Secretary of Labor on the standardized reporting format for the voluntary reporting by group health plans to State All Payer Claims Databases, as well as guidance provided to States on the process by which States may collect such data.

We recommend that HHS stay closely connected to DOL in its final recommendations about the standardized reporting format for voluntary APCD data submission. The testimony to the committee included both content and process for data submission, and both will be topics of the final SAPCDAC report due at the end of July 2021. State-sponsored APCDs will remain critical data resources, and coordination with entities in HHS that review and maintain standards will be important for the long-term work of DOL.

What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Lack of reliable race and ethnicity information in administrative data: There is a critical need to collect better race and ethnicity data in state data systems, including APCDs. We understand that NCVHS recognizes this need and dedicated a recent meeting to this issue. We applaud that focus and reiterate that the need to support better collection of these data by health plans for APCDs is one of the most important needs in the health data ecosystem today. One state's data analysis found that race was missing in 80% of commercial claims. In the absence of race and ethnicity data provided by individual members, patients, and consumers in eligibility and claims data, data users may not be able to study and monitor progress in addressing racial disparities in health care. Because this is such a critical issue, researchers may feel compelled to impute race or fill in race/ethnicity data to estimate racial disparities, which has inherent risks and ethical concerns as outlined in this article. Finding solutions to improve the quality and completeness of race and ethnicity data in administrative databases should be a high priority.

We appreciate this opportunity to comment on NCVHS' work on the important topic of data standards. Our member organizations have learned many lessons over decades of data collection and reporting that could be beneficial to the committee. We welcome the opportunity to discuss these issues further.

Sincerely,

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BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
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August 13, 2021

Richard W. Landen, MPH, MBA, Co-chair
Denise E. Love, BSN, MBA, Co-Chair
National Committee for Vital and Health Statistics Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted via email to: NCVHSmail@cdc.gov

Dear Mr. Landen and Ms. Love:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide written comments in addition to our panelist remarks for the *Healthcare Standards Development, Adoption and Implementation Listening Session*.

BCBSA is a national federation of 35 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBS companies have a long-standing commitment to improving interoperability and transparency of health care information and believe that the secure and seamless flow of health data between stakeholders is essential to driving improved health outcomes. The use of standards, operating rules and code sets is critical to enabling this seamless data flow for administrative data.

Our comments also reflect our extensive experience around data exchange and interoperability as the operator of the BlueCard® Program, one of the largest health claims processing and reimbursement programs in the nation, providing BCBS members seamless national access to 95 percent of physicians and 96 percent of hospitals that participate in BCBS Plans' health care networks.

We have the following overarching points which we will address in more detail below in responding to the National Committee for Vital and Health Statistics Subcommittee on Standards (NCVHS) Subcommittee's questions:

- We continue to uphold the adoption of standards, operating rules and code sets as a key component towards greater interoperability and more efficient exchange of health care data between payers, providers and members.
- We support the use of the exception process under the Health Insurance Portability and Accountability Act (HIPAA) to pilot test newer versions of existing standards; or new standards to address underutilized transactions or new data exchange use cases.
- We suggest that any information technology (IT) requirements must be considered in the context of the broader environment of mandates and requirements with significant IT implications, including interoperability, transparency and surprise billing mandates.

As noted above, Plans continue to face a multitude of health information technology imperatives, both from federal mandates as well as from their own strategic goals to improve consumer experience. For instance, the recently enacted health IT provisions in the Consolidated Appropriations Act (CAA) is one of the most complicated government mandates for health plans since the major insurance reforms required in the Affordable Care Act. As such, the successful implementation of the CAA provisions has been a monumental undertaking within a short timeframe as the new mandates are required within less than one year. All this during a timeframe where clarifying regulations are still outstanding in many instances to implement, and new and complex operational solutions deployed. This includes new IT builds to integrate information from health care providers and health plans to ensure an effective consumer experience for health plan members. The fact that stakeholders have to implement these new requirements as they are still working to figure out the many rule changes of the last administration (and how these rules may be modified under the Biden administration), and are still responding to the demands of the COVID-19 pandemic, creates an unprecedented situation for the regulated community.

Plans also indicate that implementing administrative simplification standards requires time and resources that are incommensurate with the business value achieved (in part, because business partners are not all required to use the standards and sometimes interpret standards differently).

Given the multitude of regulatory mandates as discussed above and below, the adoption timing of additional provisions related to administrative simplification must consider the time and effort needed to implement other regulatory requirements as it will require freeing up resources while accelerating other standards/specifications to enable greater interoperability, including the exchange of clinical data.

Below, we address the specific questions posed by the Subcommittee:

1. **What new standards and technologies should NCVHS be considering for review and recommendation for HIPAA transactions in the next decade and why? What are the opportunities, what are the barriers and what is the mitigation strategy?**

It is essential that the evaluation of new standards and technologies takes several factors into consideration. A major point to consider is whether the current infrastructure is sufficiently meeting the business needs of the industry or whether there are gaps or additional business needs with workarounds in the current environment. Moving to newer versions or different standards when there is no added business value diverts resources from other implementation efforts.

When gaps in business needs are found, consideration should be given to the exchange use case in which the gap is present. Some use cases under HIPAA currently work well and have a solid infrastructure, (e.g. health care claims, claim payment/remittance advice, and changing to an entirely different underlying data exchange architecture) is likely to have a greater impact than a move to a newer version of existing standards. Other standards such as health care services review or health care attachments, for example, present an opportunity to look to whether emerging technology standards might enable greater industry adoption (health care services review) or pave the way for voluntary industry adoption absent a HIPAA-mandated standard (attachments).

The complexity of the underlying business processes at either end of the data exchange must be considered as well. Processes like health care claims adjudication, claim payment/remittance, and eligibility and benefits are all highly complex and well ingrained within the infrastructures of all stakeholders. Electronic exchanges of these transactions are very high industrywide and would benefit more immediately by moving to a newer version than by moving to an entirely different transaction methodology, especially for which further development efforts related to the exchange of data for these use cases in the United States is warranted.

One must also factor in the maturity of the standards when considering newer technologies, i.e. are they complete and published or still in initial development? The ability to pilot newer standards, especially when the underlying technology is not yet implemented widely for a specific business use case, is critical to successfully enabling other technologies. Pilots allow for real-world testing, which then can identify potential gaps in data or implementation barriers, which can be modified in the standard prior to broader industry adoption.

Consideration for all stakeholders in the process must be taken into account as well. Providers rely heavily in many cases on vendors which are not covered entities under HIPAA. Changes to the underlying standard can result in significant changes to provider systems. Smaller providers often do not have the resources to implement as quickly as other stakeholders. Any new standards, whether newer versions or newer technologies, must consider the impact to all stakeholders with respect to costs and non-monetary resources.

Regardless of the standards named, aligning them with HIPAA allows covered entities to more seamlessly share data without the need for data segmentation tied to different privacy

or security standards. This alignment is especially valuable when facilitating information exchange with third-party applications.

2. **What should be the role for the HL7 Fast Healthcare Interoperability Resources (FHIR) standards and APIs (Application Programming Interface) for HIPAA transactions? What pilots use cases are under development?**

HL7 FHIR standards should be considered for HIPAA transactions where such a standard exists that is fully developed, published and ready for pilot testing; for transactions where there is industry appetite to consider them. As an industry, we need to look for the opportunities where a FHIR standard will enable use and provide a pathway to increase adoption rather than the approach that everything should be moved solely for the sake of moving to a different technology.

FHIR can be used to transmit the data needed for the business exchange from provider electronic health records (EHRs) to an intermediary, which can convert to the X12 standard when necessary to transfer to the payer. The Da Vinci Project is currently piloting this under a HIPAA exception for prior authorization. The pilot results will be instrumental in determining whether the standards are sufficient and the overall impact to the workflow for the business use case.

FHIR API standards can be considered not as sole replacements, but as an additional option for industry adoption. Depending on the business use, FHIR and X12 can coexist side-by-side, and in other instances, it may make the most business sense to move to FHIR after a sufficient period of transition. Either way, pilots are instrumental to this process and should be robust and conducted between willing trading partners, using the HIPAA exception process where applicable. In the instances where a FHIR standard proves itself more robust than an X12 equivalent when used by all stakeholders, then consideration can be given to moving fully to that standard.

The transition from current to next standards must always be done with overlapping implementations in production environments. In no instance should there be an approach where any shift in underlying messaging infrastructure is turnkey.

3. **Are there updated options for the exchange of attachments that NCVHS might consider recommending to the Department of Health and Human Services (HHS)?**

The Da Vinci Project has also developed the *Da Vinci Clinical Data Exchange (CDex) Implementation Guide (IG)* which uses FHIR for the exchange of clinical data. Further evaluation of this IG and its ability to meet the data needs to support the exchange of attachments is warranted.

4. **Are there barriers to use (of standards or implementation guides) that we need to understand that impede access and use? What changes would make use affordable**

and enable simplicity of use? What changes would support financial sustainability for standards development and maintenance?

The significant barriers to the use of standards and implementation guides are access to all the standards, lack of participation in the development process and lack of broader knowledge of the business impacts from the technical aspects of the standards. Depending on the standard, access is gained through membership or other fees, which can be a burden for some stakeholders to obtain. The greater the ease of availability of the standards for use enables greater stakeholder direct engagement in implementations. This also applies to enabling greater stakeholder participation in the development process when barriers such as cost are limited or eliminated.

We support encouraging a higher level of diversity in stakeholder participation in the standard development organization (SDO) processes, at the highest levels of stakeholder leadership and subject matter expertise. Having such a message come from HHS lends value in that it is likely to have the message be heard by the leadership levels within organizations that are making budget and resource decisions. Greater participation ultimately improves the development processes in that more business needs and rationale are available during development as opposed to items not being identified until public review periods are occurring.

5. **What pilots or tests of standards would support innovation, development or engagement of stakeholders or policy makers to innovate on standards?**

We support pilot testing of new voluntary and innovative standards, but caution that the wholesale encouragement of voluntary and innovative standards may undermine the goals of interoperability, transparency of data use and enforcement of data transaction standards implementation in support of data exchange and consumer access and use.

We also support HHS continuing to publish a universal dictionary of clinical, administrative and financial standards that are or will be available for use, e.g. the Office of the National Coordinator for Health Information Technology (ONC) Interoperability Standards Advisory (ISA). This existing dictionary should have ongoing maintenance in lieu of creating a new and separate dictionary for administrative transactions and operating rules.

Additionally, we want to share with you our vision for the future of interoperability, as addressed in BCBSA's letter to ONC in response to its request for information (RFI) on interoperability outcomes by 2030. As illustrated below, we raise the importance of achieving interoperability in key areas such as health equity and social determinants of health data, which will be foundational in enabling a higher quality, more efficient and effective health system overall (See Appendix).

We welcome the opportunity to discuss our comments with the Subcommittee at the upcoming listening session. If you have questions in advance of the session, please contact Lauren Choi, Managing Director for Health Data and Technology Policy, at lauren.choi@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Office of Policy and Representation

Appendix: BCBSA Response to ONC Request for Information (RFI) on Health Interoperability Outcomes 2030

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

July 30, 2021

Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted via HealthIT.gov

RE: Request for Information (RFI) on Health Interoperability Outcomes 2030

Dear Dr. Tripathi:

The Blue Cross Blue Shield Association (BCBSA) is pleased to have the opportunity to respond to the call for public comment on the Office of the National Coordinator for Health Information Technology's (ONC) Health Interoperability Outcomes for 2030.[1]

BCBSA is a national federation of 35 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, BCBS Plans have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBS companies have a long-standing commitment to improving interoperability and transparency of health care information and believe that secure and seamless flow of health data among patients, doctors, hospitals and insurance companies is essential to driving improved health outcomes. As leaders in advancing data interoperability and consumer access, BCBSA and its member Plans have engaged in numerous initiatives to empower patients by providing online consumer tools, voluntary expansion of the Blue Button 2.0 initiative, being a founding member in the Health Level 7 (HL7) Fast Healthcare Interoperability Resource (FHIR)

[1] https://www.healthit.gov/topic/interoperability/health-interoperability-outcomes-2030

Application Programming Interface (API) standards development effort Da Vinci Project, and being an active member in the Creating Access to Real-Time Information Now (CARIN) Alliance Common Payer Consumer Data Set (CPCDS) Workgroup.

Our comments also reflect our extensive experience around data exchange and interoperability as the operator of the BlueCard® Program, one of the largest health claims processing and reimbursement programs in the nation, providing BCBS members seamless national access to 95 percent of physicians and 96 percent of hospitals that participate in BCBS Plans' health care networks.

Informed by our experience, we believe actionable, secure, reliable and interoperable data that are shared through a trusted exchange will enable a higher quality, more efficient and effective health system. To make these goals a reality, we summarize the following suggested outcomes (explained in more detail with supporting recommendations throughout this letter) for inclusion in ONC's planned set of interoperability outcomes:

- **Public Health and Vaccines**: Because of interoperability, by 2030, our system will have seamless, timely exchange and access of vaccine data among federal and state vaccine registries and health plans.
- **Health Equity**: By 2030, interoperable socio-demographic data, including social determinants of health (SDOH) that includes race, ethnicity and Language (REL) and sexual orientation and gender identity (SO/GI) data will be available in a secure and standardized way for appropriate use among health care stakeholders to engage in addressing health equity concerns. Additionally, patients will have access to provider or community support resource information in a standardized electronic format by 2030.
- **Consumer Access to Health Information**: Because of interoperability, by 2030, consumers will be able to access their health information when and where they need it, and will be knowledgeable about their conditions and care costs, thereby empowering them with the resources to make better health care/lifestyle choices.
- **Care Coordination/Care Management Interoperability and Data Exchange**: Because of interoperability by 2030, seamless exchange of standardized data relevant to care coordination and management, including SDOH data, will be available. Additionally, because of interoperability, supplemental data files from providers are no longer needed for the Healthcare Effectiveness Data and Information Set (HEDIS) and Centers for Medicare and Medicaid Services' (CMS) quality, risk and accreditation reporting by or before 2030.

We appreciate your consideration of our comments and look forward to working with you as you proceed in developing ONC priorities to achieve the vision of what interoperability by 2030 encompasses.

We welcome the opportunity to discuss our comments with you and your staff and would be happy to provide additional details on any of the recommendations discussed below. If you have questions on our recommendations, please contact Lauren Choi, managing director for health information technology policy, at lauren.choi@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Office of Policy and Representation

Health Interoperability Outcomes 2030

Per ONC's request in the RFI, we have framed our recommendations for fostering technology-driven solutions around interoperability outcome statements for 2030 in four areas:

1) Public Health and Vaccines

Suggested Outcome: Because of interoperability, by 2030, our system will have seamless, timely exchange and access of vaccine data among federal and state vaccine registries and health plans.

Issue: Currently, health plans have incomplete immunization information for their members across all vaccines. This lack of access hinders a plan's ability to target outreach around vaccinations, especially those in underserved communities.

Recommendation: Vaccine data from state and federal registries should be readily and seamlessly available for preventative response measures and care management before 2030. Industry standards around data elements and exchange mechanisms should be operational in an interoperable way for the vaccine data to flow securely within the health care ecosystem, including health plans, by 2030. This will allow patients to have access to a trusted source of vaccination reference information through a standardized electronic format that incorporates elements such as vaccination recommendations based on patient characteristics (age, gender, etc.) and vaccination implications (benefits, risks, side effects, etc.). We ask that ONC coordinate with federal and state partners on this effort and provide stakeholders with guidance and best practices needed to make vaccine data more interoperable and available so we can better work together to advance critical public health initiatives. We appreciate ONC's recent observations about this specific challenge.[2] Interoperable immunization information will be necessary beyond the current COVID-19 vaccination campaign, particularly as the health care system sees a growing cohort of vaccine hesitancy generally and early evidence of delayed or deferred care including for pediatric vaccinations.[3]

2) Health Equity

Suggested Outcomes: By 2030, interoperable socio-demographic data, including SDOH that includes race, ethnicity and Language (REL) and sexual orientation and gender identity (SO/GI) data will be available in a secure and standardized way for appropriate use among health care stakeholders to engage in addressing health equity concerns. Additionally, patients will have access to provider or community support resource information in a standardized electronic format by 2030.

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[2] "The COVID-19 pandemic made abundantly clear that our clinical and public health systems live in different interoperability universes. For example, it is not easy for public health authorities and individual clinicians to bring information together on seemingly simple questions such as: Which of my patients are not yet vaccinated?" ONC, Health IT Buzz Blog, "TEFCA Will be Live in 2022," available at: https://www.healthit.gov/buzz-blog/health-it/tefca-will-be-live-in-2022.

[3] CMS Issues Urgent Call to Action Following Drastic Decline in Care for Children in Medicaid and Children's Health Insurance Program Due to COVID-19 Pandemic, September 23, 2020, available at https://www.cms.gov/newsroom/press-releases/cms-issues-urgent-call-action-following-drastic-decline-care-children-medicaid-and-childrens-health

Issues: While interoperable SDOH data should be captured electronically, seamlessly and be made accessible without significant burden to appropriate care teams, in real-time, to address health equity, care coordination and management, the reality is socio-demographic data including REL and SO/GI data standards currently do not exist in the private sector, hindering consistent and appropriate ways for the health care ecosystem to capture and share this information for health equity programs.

Additionally, the United States Core Data for Interoperability (USCDI) Version 2 announced on July 9, 2021, includes three new data classes and 22 new data elements, four of which are SDOH data elements, in addition to data elements for sexual orientation and gender identity (SO/GI). While this is a step forward toward standardization, additional work is needed in this area to encourage systems development to collect structured SDOH and SO/GI data. We thank ONC for its recent focus on how SDOH standards are evolving, their inclusion in the USCDI and future consideration by its Standards Version Advancement Process (SVAP) this fall, and also the challenges of SDOH standards and how health IT can improve health care for underserved and disadvantaged communities.

In order to continue improving the quality and accuracy of necessary data to drive health equity, BCBSA believes that the availability of interoperable and accurate quality SDOH data, including REL and SO/GI data, are key to improving health equity outcomes in all communities across the country. For instance, the COVID-19 pandemic highlighted the critical need for accurate data collection to be a part of our public health surveillance system so that we can estimate the magnitude of a problem, identify groups at higher risk of having poorer outcomes, examine relationships between risk factors and outcomes and develop targeted and equitable interventions. However, today, there are no national industrywide standards in the health sector to facilitate consistent SDOH, REL and SO/GI data collection and appropriate use, leading to challenges around the accuracy, quality and consistency of the data collected. Compounding the challenges are the many overlapping and complex federal and state laws governing aspects of REL and SO/GI data collection and use in the health care sector. We note these challenges for ONC's awareness so that ONC and its federal agency partners can consult and coordinate with each other appropriately in evaluating current policy barriers and support standardization of SDOH, REL and SO/GI data.

Recommendations: To be able to address the issues regarding health equity and interoperability and meet the suggested outcomes by 2030, BCBSA encourages ONC to reflect on these challenges in the following ways:

- **Continue to support data standardization efforts across the industry.** We encourage ONC to support the work of HL7's Gravity Project and its efforts around identification of socio-economic data including SDOH, REL and SO/GI data sets necessary for addressing the needs of underserved communities in chronic disease management. The Gravity Project seeks to identify coded data elements and associated value sets to represent socio-economic data documented in electronic health records (EHRs) across four clinical activities: screening, diagnosis, planning and interventions. Supporting the Gravity Project will enhance ONC's own efforts to improve health care for underserved and disadvantaged communities.

- **Invest in interoperable and secure data infrastructure that connects with all stakeholders including community-based organizations**. Because there are a variety of entities in the community who can meet consumers where they are to facilitate the collection, exchange and appropriate use of secure data, ONC and its federal partners should focus on working within their respective jurisdictions and with each other on creating infrastructure and standards (e.g., Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule) that connect all stakeholders. For example, community-based organizations serve as critical links in the collection of standardized SDOH data, but may require flexibilities and burden reduction measures to effectively serve their communities via data exchange. Development and investment in a data infrastructure that engages these culturally appropriate networks allow opportunities to get the right information in addressing diverse communities' health risk factors.

3) Consumer Access to Health Information

Suggested Outcome: Because of interoperability, by 2030, consumers will be able to access their health information when and where they need it and be knowledgeable about their conditions and care costs, thereby empowering them with the resources to make better health care/lifestyle choices.

This outcome means consumers would have seamless access to their health information and be active participants in their care, and interoperable health data should reduce costs and redundant care (e.g., testing) while improving outcomes and consumer insights. In addition, consumers' health data would be integrated into their electronic patient records, creating a seamless and holistic longitudinal view of the consumer by 2030 for care teams and consumers alike.

Issues: The CMS Interoperability Patient Access Final Rule provides guidance around consumer education, but more needs to be done to expand consumer education around accessing and using their health data.

Recommendation: To meet this suggested outcome, action is needed by all stakeholders, including policymakers, to enhance consumer education and implement data standards. Consumer education is needed to empower consumers with information on what to do to access and use their information and how their data can be valuable. If consumers know that their information is handled by systems that are subject to data standards to keep their information secure, they will be more confident about sharing and asking for it, thereby facilitating better informed health care choices.

Additionally, we recommend ONC support these initiatives in particular:

- **HL7 Da Vinci Project**, which is a private sector initiative to define, design and create use case-specific reference implementations of solutions based upon the HL7 FHIR platform to address value-based care initiatives.
- **A fully operational Trusted Exchange Framework and Common Agreement (TEFCA)**. We are pleased that ONC recently announced that TEFCA will go live in 2022

in order to bring together disparate networks into alignment and look forward to the continued steps to operationalize TEFCA.

- **Secure data exchanges that align with HIPAA**. Health data is shared between and among HIPAA covered entities, but more and more sharing will be done with third party mobile health applications. Aligning the privacy and security obligations of these third party applications with HIPAA allows covered entities to more seamlessly share data without the need for data segmentation tied to different privacy or security standards. We recommend ONC and its federal agency partners to look for opportunities (statutory and regulatory) to develop a framework that ensures data that is shared with third-party applications has privacy and security safeguards consistent with HIPAA.

4) Care Coordination/Care Management Interoperability and Data Exchange

Suggested Outcomes: Because of interoperability by 2030, seamless exchange of standardized data relevant to care coordination and management, including SDOH data, will be available. Such exchange supports the expansion of value-based care programs, quality improvement, care coordination, cost effectiveness and pricing transparency. This outcome would mean that by 2030, uniform infrastructure and data format has enabled seamless health information exchange, and patients, their providers and their health plans have real time access to all of a patient's administrative and clinical data to manage and coordinate care. More specifically:

- By 2030, providers would improve access to health and support programs and quality of health outcomes due to more informed patient decision-making and care coordination from data accessibility.
- Because of interoperability, supplemental data files from providers are no longer needed for HEDIS and CMS quality, risk and accreditation reporting by or before 2030. Data would be exchanged through standard interoperable formats that meet audit integrity needs. In addition, because of interoperability, electronic attachments (insurance industry standard, the ANSI X12N 275 transaction with an HL7 document) and the attachment or information request (ASC X12 277RFI transaction) are standardized before 2030.

Issues: Lack of industry standards around data and ways to facilitate seamless exchange to achieve interoperability among various data systems are current barriers to achieving care coordination/care management interoperability and data exchange.

Recommendations:

The exchange of clinical and claims data through standards based APIs is recommended to enable secure interoperable data exchange across functional areas like care coordination/care management workflows and quality reporting. ONC should ensure that existing exchanges can connect to any plan or provider regardless of business affiliation or choice of EHR vendor, and most importantly, to all of the disparate actionable clinical and quality data found among the data systems. ONC can play a role in engaging providers, plans and EHR vendors to commit to the same standards and to follow through on adopting these tools once they are developed and vetted. Besides ONC's role in supporting standards, federal partners should consider

developing incentives particularly for providers to use digital infrastructure. Implementation of new requirements should be paced to match the availability of data standards, data security, and technical infrastructure. Real-world testing is needed to ensure data needs are met and systems can connect and move the data correctly between the FHIR and X12 standards.

BCBSA also recommends that the Department of U.S. Health and Human Services to evaluate and adopt the recommendations from Wedi, Council for Affordable Quality Healthcare (CAQH) CORE, and National Committee on Vital and Health Statistics (NCVHS) in mandating actual standards and operating rules for electronic exchange or transactions. Adopting these standards and rules has great potential to reduce complexity and administration burden (as well as cost).

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Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

July 30, 2021

Re: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

Dear Mr. Landen and Ms. Love,

Thank you for the opportunity to provide feedback on the National Committee on Vital and Health Statistics' (NCVHS) Request for Public Comment – "Healthcare Standards Development, Adoption, and Implementation." We appreciate your efforts to create a strategy for standards that will enable progress in the way the healthcare industry exchanges information.

The Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a leading nonprofit, national multi-stakeholder collaborative that drives the creation and adoption of healthcare operating rules that support standards, accelerate interoperability, and align administrative and clinical activities among providers, payers, and consumers. CAQH CORE Participating Organizations represent more than 75 percent of insured Americans, including health plans, providers, electronic health record (EHR) and other vendors/clearinghouses, state and federal government entities, associations, and standards development organizations. CAQH CORE is designated by the Secretary of the Department of Health and Human Services (HHS) as the author of federal operating rules for the HIPAA administrative healthcare transactions. Operating rules are developed by CAQH CORE Participants via a multi-stakeholder, consensus-based process.

The healthcare industry is moving towards a more interoperable ecosystem that includes the convergence of clinical and administrative data. X12 transactions remain the backbone of administrative data exchange, while momentum for application programming interfaces (APIs) continues to build. However, within this continuum of technology industry stakeholders are at varying levels of maturity – early adopters are already testing new API-based use cases while others have limited resources for innovation. This lack of alignment will quickly become an impediment to the industry's long-term vision of interoperability if not addressed.

Operating rules, defined as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications,"[1] can help bridge the gap between current and emerging standards to ensure ongoing interoperability between all stakeholders. The CAQH CORE Board is in the process of developing a longer-term strategy to support industry interoperability as technology continually advances. It is with this lens that we submit the following responses to your questions:

Question 1: How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Opportunities abound for enhancing data exchange between healthcare stakeholders as business needs and technology continually advance at a faster and faster pace. Greater industry alignment and collaboration, broad engagement and testing, and a standards-agnostic approach to transitions using the flexibilities within HIPAA are needed to drive improvements.

1. **Need for Alignment and Collaboration:** Given the current environment for healthcare standards, operating rules, and code sets, no one organization or government entity can solve the interoperability challenge. Feedback from CAQH CORE Participants has indicated the need for greater intra-industry alignment, collaboration, and leadership on a common vision for achieving true interoperability. CAQH CORE encourages NCVHS and HHS to promote industry alignment and collaboration to support the goals of interoperability through an ongoing, routine, and aligned process to establish expectations within the industry for annual transitional improvements. An aligned approach across government entities, standard development organizations, operating rule development, and code set maintenance would enable more purposeful industry progress and reduce confusion over priorities. One key aspect of this approach should include streamlining and simplification of the multiple industry committees, review processes, and use of regulatory authorities across HHS to demonstrate leadership, clarify priorities, improve communication, ensure broad industry applicability, and promote a more efficient and predictable process for continuous improvement.

   Additionally, NCVHS and HHS should consider the impact of their recommendations on innovation, pace of adoption, and return on investment (ROI). CAQH CORE Participants invest significant resources in the operating rule development processes during which criteria such as ROI, a strong business case, and cost to implement are used to evaluate potential requirements. A rule can only be approved via the CAQH CORE process if more than two-thirds of Participating Organizations support it. Similar criteria should be the key drivers for any successful collaborative efforts.

2. **Broad Engagement and Testing to Support Implementation:** Improving the adoption and updating of current standards, operating rules, and code sets is as important as developing new standards. To date, a lack of consolidated data related to adoption of HL7 FHIR-based technologies across the industry makes progress difficult to measure and muddles lessons

[1] Affordable Care Act.

learned. There is a need for research on the real-world adoption of new technologies, ROI, and best practices. In 2020, the annual CAQH Index started tracking industry readiness/use of HL7 FHIR. As industry gathers this data, it is critical that current standards continue to be updated (through newer versions or operating rules) to meet evolving industry needs and that clear roadmaps exist for transitions to new technologies supported by ROI research and best practices.

CAQH CORE has observed the importance of engaging all impacted stakeholders in this process. While technical experts can define the technical specifications, input is also needed from business, clinical, and operational staff who have greater insight into actual workflows and real-world challenges. Connectathons can only test the efficacy of new standards in an ideal environment but cannot unearth challenges that arise from issues like imperfect data, workflow disruptions, etc. For example, CAQH CORE has been engaged with the Cleveland Clinic and PriorAuthNow to study the impact of prior authorization standardization on the workflow resulting in practical, real world findings.

Clinical, business, operational, and technical expert engagement in the development and testing of new standards will mitigate implementation barriers and identify areas where operating rules are needed to further streamline the business use of technical standards, specifications, and options.

3. **Standard Agnostic Approaches:** Regardless of the standard used, industry needs consistency in the data content, infrastructure, and code sets supporting X12, HL7 FHIR, and other existing and emerging standards to support interoperability. Aligning data and infrastructure expectations across standards for the same business process via "standard agnostic" operating rules has the potential to accelerate interoperability by capitalizing on existing value built in backend systems, facilitating ease of technology transition, and supporting smaller entities with fewer resources. Whether a prior authorization is conducted using the X12 278 or via HL7 FHIR, it is critical the data and infrastructure of the transaction remain consistent. Industry cannot shift from a current to an emerging standard overnight, and therefore enabling common expectations regardless of the standard will keep backend data consistent and enable a more successful glidepath.

   Current prior authorization standards and operating rules provide an early example of how industry can align data across standards and exchange mechanisms. The CAQH CORE Prior Authorization Web Portal Operating Rule requires health plans use the 5010X217 278 Request / Response TR3 Implementation Names for web portal data field labels, which supports the HIPAA-mandated standard transaction. Additionally, if a web portal operator maps the data collected from the web form to an X12 278, it must conform with the CAQH CORE Prior Authorization & Referrals Data Content Rule. This ensures that regardless of the method of exchange, the same data elements are used across portals and EDI transactions, easing the burden of data collection for providers.

   Additionally, the new CAQH CORE Connectivity Rule vC4.0.0 has been updated to support protocols including REpresentational State Transfer (REST) and APIs for use with all existing

CAQH CORE Operating Rules for HIPAA transactions. This operating rule thus facilitates the use of X12 standards with new connectivity methods. X12 and the DaVinci Project are in the process of mapping the X12 278 to HL7 FHIR to support consistent prior authorization data exchange using HL7 FHIR APIs. The data content and infrastructure requirements in the CAQH CORE 278 Prior Authorization Operating Rules can be applied in a standard agnostic approach to help bridge and align industry use of other prior authorization exchange mechanisms like HL7 FHIR.

Beyond data content, there is value to ensuring a consistent set of exchange expectations, or infrastructure, for healthcare business processes. Regardless of the standard, common response times, system availability, error handling, acknowledgements, companion guide formats, etc. will improve interoperability.

CAQH CORE recommends that NCVHS and HHS consider the vital role that operating rules can play in continually improving interoperability through the integration and transition between standards and technology.

4. **Utilize Flexibility in HIPAA:** At CAQH CORE we see firsthand the critical importance of applying uniform standards and operating rules across the entire healthcare industry to enable consistent automation and interoperability, rather than a piecemeal approach by market segment. We encourage HHS to use its existing authority under the Administrative Simplification provisions in the Health Insurance Portability and Accountability Act (HIPAA) and expanded under the Affordable Care Act (ACA) to drive industry-wide adoption of new and modified standards to avoid fragmented industry adoption. Specifically, Section 1172 of the Social Security Act states:

> *The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for--(A) the financial and administrative transactions described in paragraph (2); and (B) <u>other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.</u>*

Additionally, language specified in Sections 1172 through 1176 of the Social Security Act permits the Secretary to establish different standards, new standards, and modified standards in consultation with public and private organizations. Given the growing connection and need for clinical information in administrative and financial processes, the use of HIPAA provides the opportunity to create the necessary integrations between these information sources in a more holistic way to support end to end workflows. Language specified under HIPAA also provides a tested and predictable timeframe for adoption by all HIPAA-covered entities and authorities to enforce compliance. The process is open to the public, includes an appeals process, can be enforced by CMS, and most importantly, moves the entire industry forward together.

HIPAA also provides the framework to maintain consistent support for standards and code sets that are working extremely well in our current healthcare ecosystem. More effectively using the authorities in HIPAA in a routine, annual process to update, change, create new standards and operating rules, or reaffirm well-functioning standards and code sets, would help the industry continually improve interoperability and proactively plan for resources and transitions.

5. **More Timely and Flexible Updates to Standards Based on Business Need:** Industry has been clamoring for more timely, incremental updates to standards and operating rules when there is a strong business case to support them, as NCVHS is aware from its work on the Predictability Roadmap. The Centers for Medicare and Medicaid Services has multiple ways of communicating and implementing policy changes at regular intervals, such as the annual payment rule notices and regular transmittals of guidance and policy updates. We encourage HHS to build on the success of these existing mechanisms to support transition and change management.

   In addition, CAQH CORE recommends NCVHS and HHS determine clear overarching benchmarks that must be met to justify advancing to a new standard, set of operating rules, or code set based on the extent of the change. This will provide transparency and certify a strong business case before a major change is required given the investment of significant resources to implement large system updates, while also providing a timelier mechanism for smaller changes to facilitate ongoing transitions.

Question 2: Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

CAQH CORE has tackled a number of industry challenges over the past year via operating rule development, leading industry efforts to drive efficient data exchange and automation. In our role as the HHS-designated operating rule authoring entity, CAQH CORE anticipates recommending a number of recently approved and upcoming operating rules to NCVHS and HHS for federal mandate in the Spring of 2022. The updated CAQH CORE Connectivity Rule and the new CAQH CORE Attachment Operating Rules serve as a bridge between existing and emerging standards. Additionally, the updated CAQH CORE Eligibility Data Content Rule, new Patient Attribution Operating Rules, and general Infrastructure Rules update will modernize current industry standards and support new business needs that have emerged since v5010 of the X12 standards was developed.

New Operating Rules Under Development/Newly Approved:

1. **CAQH CORE Connectivity Rule vC4.0.0:** Regardless of the standard, industry needs common methods of connectivity to drive interoperability. The CAQH CORE Connectivity

Rule establishes a national standard and safe harbor for how healthcare entities exchange data — a fundamental part of healthcare interoperability. The latest version, CAQH CORE Connectivity Rule vC4.0.0, has been updated to support protocols including REST and APIs. Like CAQH CORE Connectivity vC2.2.0 (which is federally mandated), the CAQH CORE Connectivity Rule vC4.0.0 is a Safe Harbor connectivity method and supports two connectivity standards; transitioning from SOAP/MIME in versions 2 and 3 to SOAP/REST in version 4. As such, payers and intermediaries must implement capability to support SOAP **and** REST in the CAQH CORE Connectivity Rule vC4.0.0 requirements. Providers must implement capability to support either SOAP **or** REST in the vC4.0.0 requirements. This version can be applied to all transactions addressed by existing CAQH CORE Operating Rules and other payload types, aligning with the CMS and ONC Interoperability Rules to move the industry closer to a single, uniform approach for administrative and clinical data exchange. This approach applied to connectivity is an important component of any change or update in technology or standards as it will create a transition with common expectations for organizations that may be at different stages of maturity. *Status: Rule approved for industry implementation.*

2. **Draft CAQH CORE Attachments Operating Rules:** Attachments are the bridge between clinical and administrative data. However, the current attachments workflow is primarily manual and a source of significant administrative burden. The goal of drafting CAQH CORE Attachment Rules is to develop a set of common specifications to support the exchange of attachments/additional documentation using the X12 transaction and/or other transaction types such as HL7 C-CDA, HL7 FHIR, .pdf, etc. CAQH CORE is currently refining and finalizing requirements for the CAQH CORE Attachments Infrastructure Rules and CAQH CORE Attachments Data Content Rules for Prior Authorization and Claims use cases. The Draft CAQH CORE Attachments Infrastructure Rules specify minimum system availability, maximum response times for acknowledgements, minimum supported file sizes, connectivity, electronic policy access requirements, and use of common Companion Guide formats. The Draft CAQH CORE Attachments Data Content Rules specify codes to reassociate X12 275 attachments to prior authorization requests or claim submissions, establish common reference data to connect X12 and non-X12 attachments, and require health plans to use appropriate codes to request the most specific additional information. *Status: Rules drafted and expected to be finalized in early 2022.*

3. **Draft CAQH CORE Eligibility Operating Rule Update:** CAQH CORE is currently working with an Eligibility & Benefits Task Group to draft updated and new requirements for the CAQH CORE Eligibility & Benefits Data Content Rule (which is federally mandated). These draft requirements support the following opportunity areas: telemedicine, expansion of required service type codes (STCs), remaining coverage benefits, tiered benefits, procedure codes, and authorization/certification. The delivery of robust and comprehensive eligibility and benefit information is supported by the CAQH CORE Connectivity Rule vC4.0.0 allowing essential coverage information to be exchanged quickly and securely over RESTful APIs. *Status: Rule update drafted and expected to be finalized in early 2022.*

4. **CAQH CORE Value-based Payment Attribution Rules:** In late 2020, the CAQH CORE Participants and Board approved a set of patient attribution rules developed to reduce the burden associated with the exchange of attribution information between plans and providers. Currently this data is shared via a range of formats outside the provider's workflow (spreadsheets, FTP files, etc.), using inconsistent data elements, at varying intervals (weekly, monthly, quarterly, etc.). The CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Rule is the latest addition to the Eligibility Operating Rule Set to enable provider notification of an attributed patient under a value-based care contract within the eligibility workflow. The rule requires health plans to return the patient attribution status (yes/no/partial) and effective dates of attribution in the X12 271 transaction.

   The Attributed Patient Roster Operating Rules support the electronic exchange of attributed patient rosters between health plans and providers via data content and infrastructure requirements using the X12 00510X318 834 transaction. The data content rule standardizes the minimum data elements a health plan must return to identify patients within the value-based population, including a contract name and effective dates of attribution. The infrastructure rule standardizes expectations for exchange and requires health plans to send providers an updated attributed patient roster (including updated dates of effective attribution) at least once per month. *Status: Rules approved for industry implementation.*

   Both attribution rule sets are supported by the CAQH CORE Connectivity Rule vC4.0.0 allowing information to be exchanged quickly and securely over RESTful APIs.

5. **General Infrastructure Rules Update:** In the Fall of 2021, CAQH CORE plans to launch a process to conduct a global update of the CAQH CORE Infrastructure Operating Rules, of which three are federally mandated. The purpose of this update is to modernize the rule requirements to align industry expectations across transactions and business processes for data exchange and drive continual progress. *Status: Rules update launching later in 2021 and expected to be finalized in early 2022.*

Question 3: How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

Healthcare is a complex industry to be sure, but lessons from operating rule implementation in financial services are applicable to healthcare and have been used as a model by CAQH CORE since our founding. Almost 50 years ago, the banking industry hit a turning point with the introduction of the ATM. The ATM's automated cash withdrawals and integrated global banking systems provided increased financial accessibility and streamlined everyday transactions between banks and customers. Today, the ATM is the backbone of online and mobile banking systems that enable customers to communicate with banks 24 hours a day.

The operating rules developed by Nacha, the Electronic Payments Association, and the Federal Reserve, act as the foundation of every automated clearinghouse (ACH) transaction. These

operating rules enable customers to authorize their banks to send bills or payments electronically — allowing huge amounts of data to be exchanged immediately and accurately. Although participation is voluntary, Nacha represents approximately 91 percent of all U.S. financial institutions, including the Federal Reserve. In 2018, Nacha convened the Afinis Interoperability Standards to advance API standardization and other financial services standards that enhance the efficiency and security of today's modern financial industry. We recommend HHS and NCVHS engage with Nacha to learn more detail about the testing, implementation, and certification components of this successful initiative.

Question 4: What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term Opportunities – Focus on Incremental Progress: NCVHS mentions a wide range of opportunity areas for industry in Question #2 and CAQH CORE encourages consideration of industry resources and a phased approach to enable success. It is important to learn from past successes and avoid trying to upend processes that are already working with a strong base of adoption for the industry such as claims, eligibility, and codes sets including the Current Procedural Terminology (CPT®) code set. HHS should prioritize the most pressing opportunities – those processes not currently working – and consider what incremental steps are needed to ensure all stakeholders, regardless of where they sit on the technology spectrum, can successfully exchange critical data electronically. For example, the draft CAQH CORE Attachment Operating Rules, expected to be finalized in early 2022, are a short-term opportunity for NCVHS and HHS to address a long-term industry challenge to support electronic exchange of medical documentation. Additionally, updating outdated requirements, such as updating federal operating rule mandates with the most recent versions of those operating rules, including the updated CAQH CORE Connectivity Rule that supports both SOAP and REST, will put the industry on a strong trajectory for success. In the short term, NCVHS and HHS should take the opportunity to make incremental progress while starting to lay out a roadmap to help the industry transition and prioritize resources.

Mid-term Opportunities – Provide a Roadmap and Drive Industry Alignment: CAQH CORE hears from industry stakeholders that feel they are in a holding pattern without clear direction from HHS on its plans for future standards and operating rules. The result is "implementation paralysis" whereby organizations focus on minimal compliance with little resources left for piloting and testing new opportunities. This lack of real-world implementation beyond simple connectathons means there is little supporting evidence to drive adoption of updated and emerging standards and operating rules. Transitioning the industry to updated and emerging standards cannot happen overnight. A future roadmap with expectations for transitions is needed to help organizations prioritize investments. In establishing this roadmap, it is important to note that technology is only one step toward automation and streamlined workflows. HHS should define its interoperability goals from both a technical and business perspective. Common expectations for when, what, and how data is shared is critical for true interoperability.

Once HHS sets industry expectations and priorities for transitions and common interoperability goals, it will be critical that standards development organizations, code maintenance groups, and

CAQH CORE be aligned in their efforts to optimize industry resources. CAQH CORE can lead as a trusted, standards-agnostic convenor to bridge existing and emerging standards working with standard development organizations and provide measurement support. The CAQH Index also measures industry use of both X12 and HL7 transactions.

Long-term Opportunities – Establish a Transparent and Predictable Annual Process to Make Continual Progress: Over the longer term, CAQH CORE recommends that HHS establish and maintain a transparent and predictable annual process with appropriate resources to make continuous improvements in interoperability. The pace of change will only increase over time and the industry will need clarity and alignment to continually adapt to support interoperability. A routine and timely process aligned across HHS initiatives to evaluate changes to standards and technology and communicate expectations for transitions is needed for effective change management and broad adoption across the industry. In addition to using the authorities in HIPAA, there are existing annual processes employed by HHS such as the annual payment notices for Medicare that are highly anticipated and followed by industry participants that should be used as models for routine industry communication.

The primary goal of interoperability should be to support the health of all patients regardless of their healthcare coverage in a way that is timely, accurate, complete, and straightforward for a patient and their caregivers. To achieve this goal, the industry needs to be aligned around routine, predictable processes that establish reasonable expectations for transitions to make continuous improvements in interoperability.

Thank you for considering our feedback to your information request. Should you have questions, please contact me at atodd@caqh.org.

Sincerely,

April Todd
Senior Vice President, CAQH CORE & Explorations

CC: Robin Thomashauer, President
CAQH Mark Pratt, Senior Vice President, CAQH Public Affairs
CAQH CORE Board Members

Amy Merlino, MD, FACOG
Enterprise Chief Medical Information Officer
25900 Science Park Drive, AC220
Beachwood, OH 44122

July 30, 2021

Re: National Committee on Vital and Health Statistics Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

Submitted electronically via: NCVHSmail@cdc.gov

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 18 hospitals with approximately 6,000 staffed beds, 21 outpatient Family Health Centers, 11 ambulatory surgery centers and numerous physician offices. Cleveland Clinic employs over 4,600 salaried physicians and scientists. Last year, our system cared for 2.4 million unique patients, including nine million outpatient visits and 273,000 hospital admissions and observations.

Cleveland Clinic appreciates the opportunity to share our thoughts regarding standards for exchanging electronic health information with the NCVHS.

(1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

- Providers both within our organization and among our partners have expressed frustration with the format of data that is shared via health information exchanges. The data are often displayed as one long document of text and cannot be easily navigated by documentation type or by date. The lack of ease of use discourages universal adoption of HIEs, leading providers to fall back on traditional means of obtaining patient information (i.e., manual transaction of paper between organizations).
- Other barriers particularly for smaller provider offices include cost of technology, fear of liability when sharing data, and lack of standardization. Standardization of result components, LOINC coding, and any other normalization would encourage apples to apples data sharing. Legal protection for good-faith information sharing would also reduce risk-averseness from hesitant providers. Resources must be made available to providers to encourage and increase utilization of HIEs.
- There is a lack of understanding among the patient population of what is and should be available to them in terms of health information and data sharing. Standards to ensure patient awareness, education, and technical assistance are essential for the success of data sharing. Updating the information as it changes is also crucial to include in the educational efforts. Targeted funding could be allocated for organizations to train patients on how to obtain information from HIEs. While patient education is important, patients should also be allowed to opt out of education efforts.
- A recommended allowable timeframe to unlink records from interoperability platforms while data are remediated/corrected would ensure patients records are eventually made available again via sharing platforms.

- Other recommendations to improve data sharing include:
    - supporting and encouraging electronic health records vendor development of robust automated solutions to enable greater information exchange with payers
    - enforcing FHIR and API standards to accelerate third party development
    - improving patient matching between organizations by standardizing the demographic matching requirements

(2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

- Given the increasing interoperability of different EHRs, erroneous data exchange needs to be considered along with establishing a mechanism for provider communication. For example, mandatory alerts or notifications of large scale data errors from organizations to their data sharing partners would improve information exchange systems.
- Promoting value-based contracts would establish minimum data standards and requirements for payors who provide essential information to electronic medical records for patient and contract management. This would allow organizations to link patients appropriately and allow for better matching of rates and risk adjustments.
- Health information exchanges can support the sharing of COVID-related data overall as well as new electronic standards for COVID vaccination cards and all vaccination data.
- Use cases should definitely include payors and electronic authorizations. Social determinants of health (SDOH) provide another opportunity, but systems should proceed with caution when working with community partners who are not part of the patient's health care 'team' but whose involvement impacts the overall health of the patient (e.g., food banks, shelters, job placement programs, etc.). Concerns about oversharing sensitive information should be factored into standards development.

(3) How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

- The Insurance Services Office, Inc. (ISO) serves as a centralized repository of statistical, actuarial, and claims data. ISO can facilitate member insurance companies' information access to support claims investigations and data discovery.

(4) What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

- Patient education campaign about information availability (short-term leading to long-term sustainability)
- Government and private industry incentives for comprehensive training programs for providers and data exchange use tracking to decrease manual data transactions (short-term leading to long-term sustainability)
- Standards for payors and organizations to be able to effectively exchange data bi-directionally (short-term leading to long-term sustainability)

- Establishment of a national group to review EHR vendor patient portals for the standardized ease of patient use. If all portals align with a standard look and feel, then all patients can access their information easily no matter where they get care. (long-term)

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Should you need any further information, please contact me at merlina@ccf.org or Marie-Joy Paredes at paredem@ccf.org.

Sincerely,

Amy Merlino, MD, FACOG
Enterprise Chief Medical Information Officer

Comagine Health

National Committee on Vital and Health Statistics

Public Comment on Healthcare Standards Development

Comments Submitted by

Comagine Health
10700 Meridian Ave N, Suite 300
Seattle, Washington 98133-9008

For Inquiries Please Contact

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Public Comment Response

Question 1.

How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Increase clarity on regulatory requirements and legal allowances for data sharing. Today, each entity which owns data (i.e. payers, providers, public health) interprets the regulatory and legal framework in slightly different ways leading to some entities being more, or less, willing than others to share data. The amount of time spent in engaging partners and building trust to create data governance and data use agreements acceptable to all parties is extraordinary and regularly creates barriers and delays in data sharing. The development of trusting relationship is currently a prerequisite for any data sharing, requiring large amounts of staff time and long runways to complete successfully. This includes clarity on HIPAA and HITECH provisions for non-Covered Entities such as All Payer Claims Databases (APCDs) and 3rd party applications. In today's landscape there are many parties actively working with and exchanging data related to patient's health and the current laws and regulations do not factor in all the pathways for data collection and exchange.

Create and maintain a federal patient identifier, or state-based master patient identifiers that can feed into a national system. This would address identity-related impediments to both data sharing and data use. While matching algorithms have come a long way and there are now many work arounds or one-off identifiers created by individual data owners, the lack of a singular identifier makes matching of exchanged data difficult and leads to duplication of effort.

Align public health and private health care data system standards. Many health-related data systems have been home grown and even with the implementation of FHIR standards, significant work is needed to transform those systems to meet the standards related to data exchange. In addition, FHIR and other standards are narrowly focused on the health care delivery space and largely exclude public health data systems and other systems outside of the traditional health care delivery space such as UniteUs and Aunt Bertha, both of which are platforms collecting social determinants of health (SDoH) data. To truly create a holistic data ecosystem that can respond rapidly to emerging needs and health threats such as a pandemic, is it imperative that public health data systems be required to follow the same standards as the private sector health care system (payers, providers, etc.)

Empower patients. Patients are largely unaware of what data is being collected about them and how they can access that information or restrict its use. Greater education to empower patients to be advocates for the exchange of their data would greatly benefit the entire data exchange ecosystem.

Question 2.

Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

Create standards and definitions for the collection and exchange of SDoH data. SDoH data standardization would greatly improve the current data ecosystem. This data is not regularly collected or consistently defined across data owners (i.e. payers, providers, and public health). A national consensus and standard on what data should be collected and how each data element is defined (e.g. is race based on OMB categories or is it collected at a more granular level) would greatly improve both the collection and reliability of this data. Additionally, several states have begun to mandate that certain race, ethnicity, language, and disability data is collected by state agencies. However, when those data systems (i.e. ALERT for immunizations) are built on national standards it is not possible to customize the data base to collect locally mandated information. Establishing a national standard, with allowances for the addition of locally-mandated data collection, could help resolve this issue.

Utilize All Payer Claims Databases (APCD). APCDs are an important data asset in understanding the health care system. As a central repository for data from all payers in a geographic region, they allow for a holistic look at the care provided to patients by providers and at a population level. To make their use as robust as possible both patient and provider identity resolution is necessary. As mentioned in earlier comments a master patient identifier is key to matching data from multiple sources. A provider directory affiliates individual providers with their practice locations, medical groups, and health systems as appropriate in a hierarchical manner. This information is valuable in understanding if better quality, lower cost care is delivered by providers working independently or if efficiencies are gained by being a part of a health system, for example. This information also allows for identification of specific areas which could benefit from quality improvement intervention. In addition, APCDs are a vital population health resource, whether that be Medicaid recipients, those in a particular age group regardless of payer, or individuals in a geographic region. The data collected and analyzed through these systems provide unique insights into the health care system which are not available from other sources and their adoption and implementation in every state should be encouraged.

Link and integrate data sources. Other use cases of importance include the ability to combine birth certificate data with claims (e.g. APCDs) and clinical data such as Health Information Exchanges (HIEs) to better understand drivers of birth outcomes, maternal risks, and predictive modeling to support targeted interventions addressing maternal and infant morbidity. Similarly, focus on the use of death certificates in combination with claims and clinical data to better understand drivers of maternal mortality, risks, and to support targeted interventions. If states or the federal government could establish singular master patient identifiers that persist across

data sources, linkage and integration of these data sources (e.g. vital stats + claims + clinical) would not be burdensome.

Question 3.

How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

Comagine Health does not have a comment on this question at this time.

Question 4.

What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term: Focus on removing barriers to data exchange that exist through regulation. Continued focus on implementation of standards such as FHIR, including penalties for non-compliance. Support for expanding the use of, or implementing, new APCDs, including adopting data submission standards such as the APCD Common Data Layout.

Mid-term: Standards for collection of Social Determinants of Health data. Repeal of the federal prohibition on the creation of a master patient identifier and/or encouragement of statewide identify resolution solutions. Closing gaps and loopholes in required data exchange between data owners in the health care system. Development of standards and/or best practices for data warehousing including privacy and security requirements that are as restrictive as necessary but not overly burdensome, and where the federal government is not implementing standards that are more stringent than industry. Review of disparate state requirements which may prohibit the sharing of data between state agencies and 3rd parties, across state lines, or with the federal government.

Long-term: Development of a federal master patient identifier for health data. Implementation of consistent standards across federal agencies for data collection, storage, and sharing including privacy and security requirements that are not unduly burdensome.

July 27, 2021

Richard Landen, MPH, MBA and Denise E. Love, BSN, MBA
Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782

RE: National Committee on Vital and Health Statistics: Notice of Meeting and Request for Public Comment

Dear Chairs Landen and Love:

The Confidentiality Coalition appreciates the opportunity to provide comments to the National Committee on Vital and Health Statistics (NCVHS).

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others founded to advance effective patient confidentiality protections. The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

The COVID-19 public health emergency (PHE) has highlighted the need to improve data sharing among public and private stakeholders. One of the greatest challenges to data sharing during the PHE has been the lack of a single data standard for health information. Creating harmonization among data standards will allow stakeholders to share information more easily with each other. We encourage NCHVS to evaluate how best to promote harmonization through existing recognized data standards. Leveraging a single standard will significantly improve public health efforts, including surveillance, preparedness, and response for public health threats, such as infectious disease outbreaks, natural disasters and other public health emergencies. Immunization infrastructure systems (IIS), in particular, have struggled with collecting and sharing information due to a lack of harmonized data standards. These systems collect a variety of information about vaccinations for children and adults, such as demographic information as well as more general health information. IIS that are harmonized are able to assist public health officials and healthcare providers in determining vaccination trends that would allow them to make community-level decisions to improve vaccination uptake.

Stakeholders have also had difficulties due to the lack of clear measurement data to collect and report upon during the PHE. Differing health data metrics among federal, state and local reporting requirements created confusion during the reporting period at the height of the COVID-19 pandemic. This lack of harmonized metrics resulted in contradictory and burdensome reporting situations that slowed the sharing of critical information. We encourage NCVHS to examine the data reporting process during the COVID-19 PHE so that the Department of Health and Human Services (HHS) can develop a common measurement framework at all jurisdictional levels. This will enable stakeholders to collect and share information more quickly during future PHEs.

While it is important to develop tools to allow for improved data collection and sharing, HHS must ensure that a baseline of privacy protections is in place before any personal data is shared. While protected health information is governed by the HIPAA framework, additional health data collected by entities outside of the HIPAA framework during PHEs may not be subject to robust protections. The Confidentiality Coalition has developed "Beyond HIPAA" principles to govern the sharing of information not covered by HIPAA. These principles emphasize the need to obtain patient consent for sharing of their health data not governed by HIPAA as well as prohibitions on the use of data beyond the expressed purpose for which consent was given. We encourage NCVHS to examine how to put robust protections in place before data is collected so that information is properly secured. Providing strong and workable privacy and security protections beyond the HIPAA framework will build patient trust around information sharing, resulting in greater access to important data for future preparedness and response efforts.

The Confidentiality Coalition looks forward to working with you on improving data collection and sharing. Please contact me at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council

SUBMITTED TO:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS SUBCOMMITTEE ON STANDARDS

August 25, 2021

Submitted By: Crystal Ewing, Director of Product, Waystar

Board Chair, Cooperative Exchange: *The National Clearinghouse Association*

Members of the Subcommittee, I am Crystal Ewing, Board Chair of the Cooperative Exchange (CE), representing the National Clearinghouse Association and Director of Product, Waystar. I would like to thank you for the opportunity to provide feedback on behalf of the Cooperative Exchange membership concerning the listening sessions on Health care Standards Development, Adoption, and Implementation.

Cooperative Exchange Background

Cooperative Exchange is the nationally recognized resource and representative of the clearinghouse industry for the media, governmental bodies and other interested parties

Cooperative Exchange's 22 member companies, represent over 90% of the clearinghouse industry and process annually over 6 billion plus claims representing $1.1 trillion, from over 750,000 provider organizations, through more than 7,000 payer connections and 1,000 HIT vendors. [1]

The Cooperative Exchange ***truly represent the healthcare industry EDI highway infrastructure*** and maintains hundreds of thousands of highways and the majority of the on and off ramp connections across all lines of healthcare business in this country.

[1] *Disclaimer: The Cooperative Exchange (CE) is comprised of 22 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions and positions expressed by CE.*

The Cooperative Exchange ***truly represent the healthcare industry EDI highway infrastructure*** and maintains hundreds of thousands of highways and the majority of the on and off ramp connections across all lines of healthcare business in this country.

Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of connection points
- Securely manage and move complex data content including administrative and clinical information
- Receive and submit both real time and batch transactions
- Provide interoperability by normalizing disparate data to industry standards
- Provide flexible solutions to accommodate the different levels of stakeholder EDI readiness (low tech to high tech)
- Actively participates and provides strong representations across all the national standard organization with many of our members holding leadership positions.

Therefore, we strongly advocate for EDI standardization and compliance within the healthcare industry. We are committed to promote and advance electronic data exchange for the healthcare industry by improving efficiency, advocacy, and education to industry stakeholders and government entities.

Response to Subcommittee Questions

1a: How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care?

Reduce the ambiguity of the implementation of healthcare regulations

- As new healthcare regulations are being developed greater collaboration early in the process across key industry stakeholder is needed to identify barriers, solution(s) available or not available, best practices for implementation, and risks with proposed mandates and timelines.
- Releasing a mandate without understanding if existing solutions exist or do not exist to solve the problem resulting in the industry scrambling find a solution and is not an efficient implementation strategy.
- The Cooperative Exchange strongly encourages this key industry collaboration to reduce stakeholder burden with resulting “hacked” or proprietary solutions increasing administrative burden for all stakeholders.
- A recent example of this is the No Surprise Act. Cooperative Exchange members have participated in many recent industry feedback sessions and expressed concern with amount of requirements, tight deadlines, and missed stakeholder concerns that could have been identified prior to the mandate to address specific use cases not defined clearly in the requirements.

- As indicated in prior testimonies and stakeholder feedback sessions, SDO's are working in silos which introduces even more complexity to implementation and slows down the regulation process. As indicated previously by WEDI, "*it is recommended that SDOs share roadmaps and work products with the other SDOs to improve harmonization and minimize overlap of work*". The Cooperative Exchange agrees with this statement.

Solve Critical Business Processes and Technical Workflow Inefficiencies

As previously presented by the Cooperative Exchange and multiple other industry stakeholders, and NCVHS recommendations to HHS we continue to have known gaps in the healthcare revenue cycle gaps despite years of advocacy, successful pilots, and ROI results.

Release an Attachment Regulation

- Despite multiple NCVHS Stakeholder Hearings, letters, and recommendation to HHS since 2005, recommending the adoption of updated electronic standards for attachments the industry is still burdened with this business problem. The lack of attachment regulations has resulted in increased payer portal usage, continued costly manual processes and administrative inefficiencies that has had significant impact across all stakeholders.
- What do we need to do to get this done? How can the Cooperative Exchange help?

Consider a pilot for 838 Electronic Enrollment

- EDI enrollment continues to be a challenge to healthcare industry stakeholders. The Cooperative Exchange's latest survey results identified that thousands of hours are spend each month by both providers and clearinghouses processing and managing outdated and manual processes for EDI enrollment that are unique for each health plan.
- Clearinghouses cannot perform all enrollment steps on behalf of provider, thus increasing the burden for providers. Most payers do not offer the option to perform bulk enrollment .
- The average time to complete enrollment is 30 days once the information is received. Manual workflow is often required to follow on up status of EDI enrollment and third parties managing enrollment on behalf of the payer do not always communicate with clearinghouse putting the burden of enrollment status back on the provider to manage.
- We must make this process more streamlined, reduce the administrative burden to providers, and increase the speed to implement EDI transaction adoption.

Adopt the Acknowledgement Transactions

- Per the October 15, 2016 letter to HHS, NCVHS recommended the adoption of the acknowledgement transaction stating: *The acknowledgment transaction is widely seen by the industry as a critical element in the end to-end healthcare administrative transactions lifecycle.*
- The recommendation from 2016 is still an outstanding business issue for the industry.
- The industry needs the 277CA and the 999. With so many variations of the standard this has caused industry burden which is outlined in the recommendations from 2016.

- What do we need to do to get this done? How can the Cooperative Exchange help?

Protect the Integrity of Administrative Simplification

- The proliferation of payer portals has been detrimental to the advancement of the foundational HIPAA Administrative Simplification goal of establishing national standards for electronic transactions to improve the efficiency and effectiveness of the nation's health care system.
- Proprietary payer portals create costly administrative burden for provider and facility entities that are required to distinctly navigate and access each payer's portal to conduct administrative transactions.
- Transactions via a payer portal are conducted outside of the providers practice management or hospital information system, and associated revenue cycle management systems create additional provider operational and fiscal burden and impact to data interoperability.
- The term "Operating Rule" should be reserved for use only as legally provisioned specific to federally mandated transaction standards. (Examples of concern: "Operating Rules" regarding payer portals)

Execute on Pilot Program Results

- The Cooperative Exchange supports the use of pilot programs to identify the return on investment including estimated cost, best practices for implementation, challenges with implementation and success results.

- Many members have participated in pilot activities for attachments, investing in technology and solutions, and presented ROI results however, as stated above the recommendations made to HHS have not been followed through with a federal mandate. **As an industry we are losing credibility in our boardrooms to request investments for future pilot programs**.

Operating Rule Optimization

- The Cooperative Exchange strongly encourages the Operating Rule Authoring Entity (ORAE) to partner and align efforts with their Standards Development Organization (SDO) peers more effectively.
- Data content rules created outside of and divorced from SDO guides/specifications create confusion and disparity in healthcare EDI standards deployment. Data content and enhancement needs should be formally submitted as timely as possible to the SDOs for consideration.

Missing Stakeholder Accountability

- As we have recommended in our previous testimonies, along with multiple other industry participants, Practice Management Systems and Electronic Medical Record vendors need to become covered entities to comply with the HIPAA EDI transaction sets which result in streamlined administrative simplification across all stakeholders. As noncovered entities they

have no obligation to comply with HIPAA EDI standards creating costly administrative workaround solutions that impedes interoperability.

1b: What are the barriers to these improvements?

Lack of HHS Response to NCVHS Recommendations

- Since 2005 as an industry, we have had presented the same business use cases to NCVHS. The questions being presented today are redundant to previous requests. The time, effort and cost associated in responding to redundant administrative simplification questions which have resulted in minimal results to resolving these issues is of serious concerns and has far reaching impacts to the credibility of the regulatory process.
- To continue to build trust with the current process this barrier must be resolved. The Cooperative Exchange highly recommends prioritizing focused efforts to expedite the need to publish regulations to adopt additional HIPPA standards based on previous recommendations.

Regulatory Guidance

- There are situations where existing regulations have barriers that have been raised, which are causing significant burden for providers and a decrease in adoption of the electronic transactions, for example situations where fees are charged for a provider to receive an EFT claim payment, and the No Surprises Act. Providing guidance in a timely manner when issues are raised will assist in alleviating these barriers and positively impact adoption of the electronic transactions.

Enhance Liaison Process Between NCVHS/HHS and Industry Stakeholders

- It is unclear to the industry that is providing valuable feedback to NCVHS who is accountable at HHS for reviewing these recommendations and the communication interface with NCVHS and industry stakeholders. As stakeholder we all need to be at the same table and collaboration and addressing the healthcare industry business needs of this country. HHS representatives should be a key stakeholder in this process.

- The lack of regulatory system accountability for the failure to resolve the industry business issues that have been repeatedly brought forward by NCVHS to HHS has significant impacts to us as stakeholders, the US Healthcare System, and delivery of patient care.

- Based on these results it is highly recommended we find a resolution to these issues before we can begin to discuss further administrative simplification opportunities. To mitigate historical repeated outcome failures, we need to move forward with solutions to resolve these industry business barriers.

- HHS is a critical stakeholder and must be involved in this process and held accountable to the industry to provide feedback and transparency as to why NCVHS and the industry stakeholders providing feedback to these recommendations are not being adopted and executed into actionable outcomes.

Are you aware of new standards or use cases in health care (for data exchange) that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification?

- Recognizing the health care industry standards advancement made over the past 20 years, the Cooperative Exchange welcomes opportunities for new and emerging standards to support the needs of the industry and our customers.

- Approved HIPAA Exception to test HL7 CRD and PAS IG standards
    - Some of the Cooperative Exchange members are also members of the HL7 Da Vinci Project. While we believe that the root cause barrier toward industry adoption of systematic and automated prior authorization workflow is not a "standards" issue, we look forward to supporting the exception testing and the outcome of the reported results and cost-benefit analysis.

- Predetermination
    - There is a unique opportunity to pilot the ASC X12 837X323 (837P) & ASC X12 837X324 (837I) v8010 standard to support the functionality of the Section 111 "Advanced Explanation of Benefits (AEOB)" functionality. The CLM19 data element can be used to designate the entire claim and services as "predetermination" to allow a payer to then return a "zero pay" remittance / explanation of benefits of the pre-d claim, which is supported by the current version of the ASC X12 835 transactions.
    - Leveraging 837 standards and existing network connectivity, the AEOB use case would be an excellent opportunity to pilot v8010 ahead of regulatory mandate. Without guidance, payers will (are) implementing proprietary and distinct solutions to meet the legislated statute.

Property & Casualty

- Bringing P&C into a HIPAA mandated status would reduce burden /costs for the healthcare industry stakeholders. Currently, many states have disparate and unique requirements/standards for P&C transactions which must be supported by providers and payers.

- Claim Status
    - Mandate the 277CA as a HIPAA named transaction to standardize and require a claim status update(s) in response to an 837-claim submission.

- Improve adoption use within payers. Many payers still do not support the 276/277 standard.

- Claims (837 P, I and D)

  - In general, the ASC X12 837 standards (P, I, and D) are well adopted and mature standards that are effectively supporting the industry needs. If there were a move to an alternative standard for the administrative transactions, there would be significant burden for the industry to migrate to a new standard. The same is true for the ASC X12 835 remittance advice transaction.
  - The Cooperative Exchange supports any regulatory rule making and/or educational initiatives toward migrating paper claim volume to EDI to further advance standardization and fully realize the initial HIPAA goal to reduce paperwork and streamline business processes across the health care system.

How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

- Property and Casualty since 2008 has adopted the HIPAA acknowledgement transaction sets that have been mandated in E-Bill states including California, Texas, Minnesota, Oregon, Tennessee, Virginia, North Carolina, Louisiana, Georgia, Illinois, New Jersey. Most of these states have adopted the IIABC National Workers Compensation Medical Billing and Payment Companion Guides that aligned with the National Standard Transaction Sets.

- Many of these states moved forward with adopting the acknowledgment transactions based on the 2005 NCVHS recommendations to HHS to adopt these standards.

- The business use case and ROI to adopt these transaction standards were based on bringing administrative simplification to automate an extremely paper based system.

- In addition to the acknowledgement transaction, Minnesota in 2009 adopted the attachment standard as it made good business sense to automate business processes and reduce administrative expenses.

- All of the same stakeholders involved with Property and Casualty are the same stakeholder engaged in commercial and government lines of business.

What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS in the next 5 to 10 years.

- The Cooperative Exchange highly recommends increased involvement with HHS and other industry stakeholders. Do we need to meet with HHS directly? Should they attend these hearings and listening sessions? Do we think this will help to move forward with our outstanding recommendations and decrease the regulatory challenges we continue to experience?

- How can we enhance the industry strategic approach and enhance outcomes?

- The Cooperative Exchange supports other industry stakeholders' recommendations to focus short term priority efforts on publishing critical outstanding regulations including the latest iteration of the X12 suite of healthcare transactions, naming new transactions as HIPPA standards as suggested above, including the pilot opportunity for the 838-enrollment transaction.

- The Cooperative Exchange further supports a focused, short-term effort to aid in efforts to comply with regulations from the No Surprises Act. As outlined above, there are multiple sections of this regulation that will require additional guidance for stakeholder compliance. The Cooperative Exchange welcomes the opportunity to provide further feedback for compliance options, concerns and best practices.

- The Cooperative Exchange supports a medium to longer term priority to increase collaboration efforts and reduce the silos with an oversight on SDO priority initiatives to avoid duplication or overlapping focus areas.

Conclusion

The Cooperative Exchange firmly believes as an industry we must first address the reasons **WHY** there is a lack of response and action from HHS and understand the continued disconnect with NCVHS and industry stakeholders to be able to move forward with a collaborative communication strategy which includes HHS that will yield administrative simplification outcomes that address the industry's business needs.

Respectfully Submitted,
Crystal Ewing, Board Chair
Cooperative Exchange

Electronic Healthcare Network Accreditation Commission

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July 27, 2021

Richard Landon and Denise Love
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SUBJECT: Response to Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

Dear Mr. Landon and Ms. Love:

The Electronic Healthcare Network Accreditation Commission (EHNAC) would like to thank the Subcommittee on Standards for your ongoing leadership to drive improvement to our Nation's healthcare system through the implementation of standards. Our industry needs leaders such as yourself who are familiar with healthcare data exchange, understand the importance of making this data is available to patients and clinicians when they need it, yet recognize the importance of maintaining the privacy and security of that data.

Founded in 1995, EHNAC is an independent, federally recognized, standards development organization and tax-exempt 501 (c) (6) non-profit accrediting body designed to improve transactional quality, operational efficiency, and data security in healthcare. EHNAC's accreditation programs also support industry-adopted standards, thus allowing for a more seamless information exchange between participants in health information networks.

EHNAC has 20+ healthcare stakeholder-specific programs available across the industry. These programs include ones that accredit Health Information Exchanges (HIEs), Health Information Service Providers (HISPs), and Electronic Healthcare Networks (EHNs). EHNAC also certifies Electronic Prescription of Controlled Substances (EPCS) programs for vendors. Newer EHNAC programs specifically address the interoperable exchange of data including a jointly administered program with HITRUST known as the Trusted Network Accreditation Program (TNAP). TNAP aligns with the draft ONC Trusted Exchange Framework and Common Agreement (TEFCA) requirements as well as the Trusted Dynamic Registration and Authentication Accreditation Program (TDRAAP), offered by EHNAC and UDAP.org. These programs are designed to facilitate the endpoint trust for industry interoperability and include non-HIPAA covered entities as well.

EHNAC serves in numerous ways to promote the industry's adoption of interoperable health care data exchange as defined under the 21st Century Cures regulations. This includes participating on the Office of the National Coordinator's FAST Executive Committee and co-leading the respective Testing and Certification Tiger Team; serving on the Board of the Sequoia Project/Recognized Coordinating Entity, co-chairing the Interoperability Matters Leadership Council and participating on the HHS 405(d) Cybersecurity Information Sharing Act (CISA) and the Health Care Sector Coordinating Council (HSCC). The HSCC effort involves a public/private partnership and collaboration to align industry awareness and preparedness facilitation in response to the exponential ransomware and cyber security attacks impacting

our world today. Further alignment and participation via ongoing feedback during policy making processes and other avenues occur with NIST, CMS, ONC, OCR and others regarding implementation of best practices, standards, and other industry guidance.

In order for the nation to achieve true "interoperability" of health data, EHNAC believes that healthcare organizations must be able to "trust" each other to appropriately share patient/individual data. Therefore, once going through a rigorous accreditation program, our candidates receive multiple and specific reports to "share" their status and demonstrate they can be "trusted" from a privacy/security and cyber-security perspective in addition to demonstrating they can provide operational/business stakeholder specific criteria in accordance with their program.

In specific response to the key issues noted in the request for public comment, please see the following:

1. ***How can data sharing be improved between patients, providers, payers, public health system and other actors in healthcare? What are the barriers to these improvements?***

As noted above, EHNAC believes the single most important barrier to the attainment of interoperable healthcare data exchange across all parties involved is the current lack of trust. We recommend that covered entities, business associates and actors be encouraged and/or required to undergo a third-party unbiased audit. This process would vet each organization's ability to meet standards and to secure and protect data. This may be accomplished by encouraging ongoing voluntary adoption of such accreditation/certification or by mandating such. One may have heard security being compared to a chain link and that overall, it is "only as good as its weakest link". Encouraging and/or requiring adoption of third party accreditation/certification in this manner assures the weakest areas must "raise the bar" and prove at least minimal privacy/security protections are in place.

2. ***Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases.***

EHNAC encourages this Subcommittee to review the wonderful work already conducted via the Office of the National Coordinator's FAST initiative. Specifically, we acknowledge the tremendous work that has been accomplished by the Regional Coordinating Entity, The Sequoia Project to promote interoperability across trusted Health Information Networks. The final TEFCA regulations and resulting implementation are expected to promote trust across such networks and their participants.

Additionally, the FAST work via Connect-a-thons, DaVinci and other initiatives continue to promote the use of Unified Data Access Profiles in order to allow for the needed security, efficiency and scalability for all endpoints to be able to move "credentials" across the ecosystem for dynamic registration and authentication. EHNAC has recently developed two programs which support these concepts: TNAP that is jointly offered with HITRUST certification and TDRAAP serves to test the technical use of UDAP standards in addition to vetting privacy and security. Lastly, use of a common Endpoint Directory such as that offered by CAQH to coordinate the various FHIR endpoints facilitates interoperability as well. Encouragement whether voluntary or required across the industry to establish, use and maintain compliance with such standards will support interoperability, promote burden reduction and administrative simplification.

3. ***How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?***

Traditionally, health care has looked to the financial industry for the recognition of the use of required standards. In particular, we urge the Subcommittee to review the deployment of effective security protocols by the financial industry for possible application to health care.

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

The following three key areas are recommended:

A. Continued development and promotion of standards especially in the area of the use of new technology, with emphasis on the emerging FHIR standards.
B. Promoting trust through the encouragement and/or requirement of accreditation/certification will build a greater belief in the reliability of all actors across the healthcare spectrum that basic privacy, security and cyber security can be met.
C. Continued work to assure regulations and authoritative requirements are integrated and consistent further promotes ease of adoption of such standards.

As new regulations and guidance are released across the healthcare industry, EHNAC will continue to participate by offering comment. As a federally recognized standards setting body, we welcome the opportunity to serve as a resource to the Subcommittee and further discuss health care privacy, security and cybersecurity issues and the role that EHNAC plays in facilitating effective and secure data exchange. Please feel free to reach out to me directly at lbarrett@ehnac.org.

Most respectfully submitted,

Lee Barrett
Executive Director and CEO

Cc:
EHNAC Commission

The Healthcare Information and Management Systems Society (HIMSS), Integrating the Healthcare Enterprise (IHE) USA, and Personal Connected Health Alliance (PCHAlliance)
Response to
National Committee on Vital and Health Statistics (NCVHS)
Request for Information on
Data Standards, Harmonization of Standards, and Code Sets
Submitted on: July 30, 2021

The Healthcare Information and Management Systems Society (HIMSS), Integrating the Healthcare Enterprise (IHE) USA, and Personal Connected Health Alliance (PCHAlliance) appreciate the opportunity to submit comments on the National Committee on Vital and Health Statistics' recent Request for Information (RFI). The work conducted collectively by our organization and our members is directly relevant to your review of data standards, harmonization of standards and code sets, new Fast Healthcare Interoperability Resources (FHIR®) standard application programming interfaces (APIs), and administrative and clinical standards that should be considered for adoption.

Overall, we believe that health information technology (IT) improves access to data from disparate sources and ensures that key data is consistently available to the right person, at the right place, and at the right time across the care continuum. A key building block to improving access to data is through greater use of technical standards, integration profiles, and implementation guides for exchanging health information. We generally recommend continuing to follow the established direction to name standards and specifications that are developed and maintained through Standards Development Organizations (SDOs), such as IHE International or Health Level Seven International (HL7®).

Our organizations also want to amplify the benefits of working in partnership with us on current standards-related activities, including the operating agencies of the Department of Health and Human Services (HHS), most notably the Office of the National Coordinator for Health IT (ONC) and Centers for Medicare & Medicaid Services (CMS), as well as the Department of Defense Health Agency and Department of Veterans Affairs.

A potential resource to HHS is the work of HIMSS, in partnership with HL7 and IHE International, through the creation of the Global Consortium for eHealth Interoperability. The principal work of the Consortium is to capitalize on FHIR—its focus is on engaging in and conveying real world testing guidance such as test plan development, sharing their roadmaps and interoperability vision for global community benefit, and developing online resources to share best practices, use cases as well as interoperability strategy planning.

Regarding the work of HHS, we support the steps taken thus far by ONC to adopt the United States Core Data for Interoperability (USCDI), by establishing a set of data

classes and constituent data elements that are required to be made available and accessible in support of nationwide interoperability. The Standards Version Advancement Process (SVAP) also plays a significant role by providing health IT developers with additional flexibility that allows them to voluntarily implement and use a new version of an adopted standard, such as those included in the USCDI, as long as the newer version is approved by the National Coordinator (through SVAP) for use in certification.

In addition, our organizations highlight the productive work undertaken by ONC to partner with IHE USA in a multi-year cooperative agreement to accelerate the adoption of FHIR-based IHE integration profiles to drive the adoption of the FHIR standard in compliance with the 21st Century Cures Act (Public Law 114-255).

The 21st Century Cures Act requires developers of certified health IT to publish APIs and adopt certification criteria that require standardized API access for single patient and population services using the FHIR standard. The objectives of the work being done by the IHE USA Cooperative Agreement project team focus on:

- Cataloging IHE Profiles that utilize the FHIR standard to enable cross community health information exchange
- Identifying and prioritize new profiling opportunities to leverage the FHIR standard
- Accelerating the development of robust, real world testing processes and adoption of the updated FHIR-focused IHE profiles and HL7 implementation guides
- Actively engaging with ONC, HL7, and IHE International on lessons learned through profiling improvements and real-world testing
- Strengthening and streamlining cross-organizational collaboration efforts between SDOs, interoperability test tool developers, FHIR champions, and other vital stakeholders

At their foundation, standards represent a shared agreement amongst multiple stakeholders on the optimal approach to a commonly agreed upon, standards-based solution in order to address a problem. It is critical to ensure that the healthcare community is continuously leveraging existing and emerging standards, data formats, and use cases to achieve greater health data interoperability in support of improved health outcomes. A comprehensive integrated approach to care can recognize and build upon the many mature, consensus-based standards and profiles already in place, while allowing innovation to pilot and incorporate new and emerging standards.

An important component of driving the successful implementation of interoperable systems is the education of implementers about existing standards and use cases relevant to their implementation goals. We want HHS and ONC to support and encourage efforts and convening opportunities for the health information and technology community, including SDOs, to provide such education.

The health community increasingly incorporates emerging and long-standing data sources into new methods of health data exchange and analytics (e.g., social determinants of health gathered from public health registries, social services agencies,

as well as genomic information, immunization information, quality reporting, environmental science, payer and billing components and other non-traditional stakeholders). As a result, standards-focused education is pivotal to ensuring that these data are based on known and adopted standards—standards that will continue to drive semantic interoperation and value for the broader healthcare community.

HHS should lead efforts to ensure appropriate standards are implemented, and used, consistently. The uniform implementation of standards achieves interoperability. Three of the biggest challenges limiting standards implementation revolve around quality, the level of consistency in the adoption of the standards, and the complexity of versioning for standards. HHS and its agencies should work with community stakeholders and other federal healthcare delivery organizations to articulate the value proposition and outcomes related to the use of these standards in how they improve aspects of care (e.g., preventing duplicative tests, medication errors, adverse events, incorporation/reconciliation of data, and data access).

In addition, HHS should facilitate development of, or identify, existing clear and comprehensive implementation guides (i.e., IHE technical frameworks) aligned with the standards for all healthcare domains; these guides should align with setting and clinical domain, and must address information exchange between entities that may have different levels of health information and technology sophistication. IHE USA, and its North American Connectathon, provides an in-person and virtual forum for national and international interoperability implementers to test the interoperability of their systems to improve the adoption of consistent, standards-based implementation guidance.

Overall, the efforts of NCVHS are a positive step toward greater interoperability as well as the broader recognition and use of standards in supporting open and secure data exchange. With these factors in mind, HIMSS, IHE USA, and PCHAlliance offer the following thoughts on these topics and how our organizations can continue to help in standards adoption and implementation:

(1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

The development of a National Patient Identification Strategy would help improve data sharing across the health ecosystem as our country lacks a national strategy to accurately match patients to their health information. This inability to match patients with their records can lead to serious quality and safety issues, from medical errors to lost diagnoses, duplicate testing, adverse drug events, and other poor outcomes, all at a significant financial cost to our healthcare system. Public health data linkages are also hampered between immunization information systems (IIS) and disease surveillance systems, as well as core "cradle to grave" national health statistics such as linkage of a birth record to the Centers for Disease Control and Prevention's (CDC's) Vaccine for Children program.

Although the Health Insurance Portability and Accountability Act (HIPAA) called for the creation of a unique patient identifier to address this issue in 1996, for nearly two decades since then, Congress has banned federal dollars from being used to promulgate a unique patient identifier. A narrow interpretation of this archaic ban has prevented HHS from leading on efforts to advance a national patient identification strategy, to the health and financial detriment of patients, providers, and public health.

The COVID-19 crisis has made clear just how important this issue is—without the ability to match patients accurately to their health information, critical information is lost and individual and public health suffers. The success of our nationwide response to COVID-19 hinges on sharing accurate patient information. We want to move forward with developing a National Patient Identification Strategy that is committed to improving patient matching in support of secure information sharing as part of a broader effort to improve interoperability as well as care quality, effectiveness, affordability, and safety.

From a technical perspective, data sharing can also be improved by enabling *any* device to securely and automatically communicate universally understood health data to *any* health record system on a global scale.

The ONC and CMS Interoperability Regulations call for open APIs, and although this is an important and very practical step, it only provides connectivity. This move still requires costly integration at scale. Industry adoption of *one open API* will dramatically reduce the cost to implement and maintain compatibility across innumerable platforms at global scale.

Since its founding, PCHAlliance has leveraged a modern, open, standards-based software implementation providing this one open API. It addresses many of the challenges of product development allowing a diverse collection of manufacturers to quickly implement products that will automatically communicate with each other.

Software is presently available for collecting observation data via Bluetooth Low Energy, the upload of observations using FHIR, and receiving those observations by a FHIR server. The software also provides a pathway for proprietary devices to participate in and evolve towards modern open standards.

To help ensure the software has been properly implemented in products, PCHAlliance, in collaboration with IHE International, provides a validation and implementation framework that supports continuous integration testing, including tests that employ the use of the physical Bluetooth interface and the cloud interface. A test tool is freely available to demonstrate conformance to industry standards.

Moreover, data sharing can be improved by CMS, and HHS more broadly, endeavoring to push healthcare delivery in the direction of value-based care. Such a system will not only produce better outcomes for patients, and minimize the burden issues that are inherent in a fee-for-service care environment, but also promote more sharing of patient information across the ecosystem. CMS should push for the continued development of demonstration and pilot programs to test different value-based service delivery and alternative payment models (APMs) in order to determine how to deliver

high-value care to every community in America and ensure that quality measures align with goals that matter to patients and with a patient's values.

Health data interoperability works to make the right information more accessible at the right place and time so it is more meaningful and impactful to patients and providers. Overall, working in a system that focuses on delivering value-based care promotes enhanced data sharing for its role improving health outcomes and driving down healthcare costs.

(2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

There are two use cases under development to demonstrate the practical application of Patient Generated Health Data (PGHD) and Remote Patient Monitoring (RPM) to reduce burden in clinical workflows. The first one is to automatically link PGHD to Patient Reported Outcome Measures (PROM). The second is to employ Self-Measured Blood Pressure to treat hypertension. These use cases specifically target reduction in the clinical burden of collecting and digesting volumes of health data to provide the right information, to the right place, at the right time to support clinical decisions.

An Automated Insulin Delivery demonstration is under development to illustrate how significant medical value is delivered using standards-based software, implemented in a complex, multi-component & vendor, high-risk regulatory class system.

To further simplify the cost to implement and maintain one open API, PCHAlliance and IHE International are working with:

- The IEEE 11073 Personal Health Devices to define a standard for a simplified information model independent of transport
- The Bluetooth SIG Medical Devices Workgroup to create a Generic Health Sensor (GHS) service and profile standard based on the simplified model that enables communication of a wide range of health-related observations from sensor devices to collectors
- Internet of Things (IoT) service providers to define a uniform implementation of these new standards to deliver sensor data over cellular Direct-to-Cloud

IHE Integration Profiles are also being leveraged to move FHIR Standard adoption forward. These profiles are guides that provide a common language for purchasers and vendors to define the integration needs of healthcare settings and the integration capabilities of health IT products. IHE profiles provide healthcare professionals seeking to acquire or upgrade systems a convenient, reliable tool that reduces the complexity, cost, and anxiety of implementing interoperable systems by offering a way to specify a level of compliance to standards sufficient to achieve truly efficient interoperability.

The ONC/IHE USA Cooperative Agreement project team is engaging stakeholders across the health IT industry to update and drive adoption of the following IHE Integration Profiles to achieve interoperability in support of the 21st Century Cures Act:

Profile Name	Description
International Patient Summary (IPS)	A minimal, non-exhaustive set of data elements defined by ISO/EN 17269 and realized by HL7 in both clinical document architecture (CDA) and FHIR. The IPS is a snapshot clinical document that can be used for planned or unplanned care of a person locally or across borders
Mobile Access to Health Documents (MHD)	Defines one standardized interface to health documents (a.k.a. an API) for use by mobile devices so that deployment of mobile applications is more consistent and reusable
Mobile Care Services Discovery (mCSD)	Supports discovery of care services resources using a RESTful interface in interrelated, federated environments
Patient Identifier Cross-Reference for Mobile Integration (PIXm)	Provides a transaction for mobile and lightweight browser-based applications to query a Patient Identifier Cross-Reference Manager for a list of patient identifiers based on the patient identifier in a different domain and retrieve a patient's cross-domain identifiers information into the application
Paramedicine Care Summary (PCS)	Provides the structures and transactions for sending the patient's paramedicine encounter information to the receiving facility
Quality Outcome Reporting for EMS (QORE)	Uses a query and a SEND transaction to move quality measurement data across several EHR entities that will allow for these data to be used for quality and registry measurement for Hospitals and emergency medical system (EMS) companies

Referral Interfacility Patient Transport (RIPT)	Provides a methodology for a standard approach to share post-discharge documentation to the EMS transport team that informs them of important patient care information

(3) How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

The telecommunications industry has developed standards and certification programs that have enabled the explosive growth of cellular communications, with handsets and data devices automatically connecting and exchanging voice and data on networks worldwide. As the value proposition moves up the protocol stack, the telecommunications industry has standardized the lower-level protocols to enable the interoperability of devices in order to deliver reliable data on which to provide value-added services. To ensure this interoperability, the telecommunications industry has developed and implemented uniform test and certification programs.

The telecommunications industry is currently defining protocol standards to provide low cost and efficient exchange of data for IoT devices. PCHAlliance and IHE International are working to leverage these new protocols for use by the healthcare industry.

(4) What short term, mid-term, and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term opportunities should focus on:

- Promoting *one open API* to enable *any* device to securely and automatically communicate universally understood health data to *any* health record
- The practical application of PGHD to existing clinical workflows to provide evidence of the promised efficacy and efficiencies
- Demonstrating how significant medical value is delivered using standards-based software, implemented in a complex, multi-component & vendor, high-risk regulatory class system
- Increased industry collaboration on test tooling development to support FHIR-based testing
- Active engagement in the Global Consortium for eHealth Interoperability

Mid-term opportunities may include:

- Designing workflows to fundamentally change the way healthcare is provided; from a hospital-centric focus to a more consumer/patient-centric, prevention and an anywhere-care approach through the appropriate use of sensor-enabled technology
- Developing standards, implementation profiles, and test solutions to demonstrate and measure efficacy and efficiencies of these new workflows

- Working with Health Information Exchanges to support regional interoperability testing and Implementation Guide development for eCase reporting and other public-health focused IHE profiles

Long-term opportunities may include:

- Developing and demonstrating a Patient Home Resource Kit that includes a suite of devices and applications that can be used to monitor chronic diseases and offer a method for people to proactively monitor their health condition(s) at home during outbreaks with fair warning if/when their condition worsens and warrants admitting to a hospital
- Improved governance and implementation best practice sharing to support consistency in standards adoption

Please do not hesitate to contact Jeff Coughlin, HIMSS Senior Director of Government Relations, at 703.562.8824, with questions or for more information.

Thank you for your consideration.

Background on HIMSS, IHE USA, and PCHAlliance

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision. Established in 1961, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 105,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations.

IHE is an International Standards Profiling Organization, founded in 1999 by HIMSS and the Radiological Society of North America (RSNA). IHE's vision is to enable seamless and secure access to information whenever and wherever it is needed, and its mission is to improve healthcare by providing specifications, tools and services for interoperability. IHE USA is a 501.c.3 not for profit entity founded in 2010 as a national deployment committee of IHE International. Other deployment committees include IHE Europe, IHE Canada, IHE Japan, etc.

PCHAlliance, a membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies. PCHAlliance is working to advance patient/consumer-centered health, wellness and disease prevention. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected

health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

HL7 International

July 26, 2021

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Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted electronically to:
NCVHSmail@cdc.gov

RE: NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation

Dear NCVHS Subcommittee on Standards Chairs Love and Landen:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation. HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

The NCVHS Subcommittee on Standards asks for critical and timely input and "seeks to understand the extent to which current and emerging standards for exchanging electronic health-related data under Health Insurance

Portability and Accountability Act (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the health care system." HL7 offers its input below categorized by the four organizing questions contained in the NCVHS Request for Public Comment.

Key themes in these HL7 comments include:

Successful Interoperability Transitions

- Successfully transitioning from the current state to a new state of standardized interoperability requires focused programs that involve both human and financial resources to facilitate the transition with an extended period of simultaneous support for multiple sets of standards for substantially similar purposes.

- Patients should become more aware of the importance of standards-based interoperability and increasingly request it from their providers and apps. Health systems, researchers and other service providers should request standards-based interoperability from vendors. And, lawmakers/regulators should use their tools to encourage or mandate standards-based interoperability when other market forces are insufficiently comprehensive or fast.

- Providers and researchers should be educated and engaged more effectively at the right times in the standards development process, and in the piloting and implementation of standards-based systems.

- All standards mentioned in the ONC's Interoperability Standards Advisory (ISA) should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction, or administrative simplification.

Health Equity and SDOH

- Development and adoption of common data standards is foundational to identifying inequities, identifying potential interventions, coordinating interventions across agencies, measuring progress, and conducting research and evaluation.

- Requiring that health systems collect standardized data elements indicative of social determinants of health, and report these data, are key to improving the ability to share data that helps our society address inequities.

Privacy and Security

- Creating a better awareness of why data sharing matters and how to protect, secure, or release patient information as part of personalizing one's care delivery experience is critical. It is also important to ensure that people from various demographics can validate approaches, reaching as many as possible.

- Consents need to be electronic, and obtained in the clinical workflow, so that sharing is not delayed due to inefficiencies in collecting consent.

Global Issues and Governance

- As humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding data represented in USCDI, US Core, and specialized Implementation Guides (IGs).

- The principle: "No aggregation without representation" – represents a desire for collective governance of digital rights for patient groups and communities that should be considered.

These comments include the combined perspectives of HL7's leadership, Policy Advisory Committee, multiple HL7 Work Groups, and FHIR Accelerators. In addition to focused comments on public health and patient empowerment, specific perspectives on cancer data and related interoperability were gathered by CodeX leaders. CodeX is an HL7 FHIR Accelerator building a community to accelerate interoperable data modeling and applications based on a common, standard language for cancer data - mCODE™, the minimal Common Oncology Data Elements, with supplemental Implementation Guides for particular use cases.

Should you have any questions about the attached, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to HHS.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Walter G. Suarez, MD, MPH
Board of Directors, Chair
Health Level Seven International

HL7 Responses – NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation

HL7 offers comments below categorized by the four organizing questions contained in the NCVHS Request for Public Comment.

Organizing Question #1 -How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Overarching Perspectives – Standards, Interoperability and the Digital Divide

- The HHS Secretary should allow the Standards Development Organizations (SDOs) that are responsible for the specific standards to update adopted health care standards to newer versions without rulemaking in order to encourage innovation, and to implement new functionality that can improve interoperability and promote patient safety.

- Transitioning from the current state to a new state of standardized interoperability is difficult without focused programs that involve both human and financial resources to facilitate the transition with an extended period of simultaneous support for multiple sets of standards for substantially similar purposes.

- Funding of pilot projects is critically important to enable adoption and broader implementation. There is a chicken and egg issue of testing and adoption that can interfere with large-scale adoption. Many vendors and other organizations cannot adopt new standards until there is general acceptance of the standard and pilots have been completed, but it is hard to gain that necessary level of acceptance because no one is able to engage in early testing and feedback, as the standards aren't generally accepted. For example, it can be difficult to add profiles to HL7 FHIR US Core before there is widespread adoption of them, but it can also be problematic to get vendors and other groups to test and pilot standards that aren't in US Core.

- The Federal Data Strategy, Practice 20 calls for the federal government to "Leverage Data Standards: Adopt or adapt, create as needed, and implement data standards within relevant communities of interest to maximize data quality and facilitate use, access, sharing, and interoperability." Continuing to take a primary role in orchestrating the development and adoption of standards is a key role the federal government can play. Participating in and supporting the HL7 communities developing standards with human and financial resources are investments the federal government should make to speed and scale standards development and adoption.

- The benefit of advancing the development and adoption of common data standards, which will enable data to be interoperable among patients, providers, payers, public health system, and other actors in health care, is foundational to identifying inequities, identifying people for interventions, coordinating intervention across agencies, measuring progress, and conducting research and evaluation. Requiring that health systems collect standardized data elements indicative of social determinants of health and collect these data are also key to improving the ability to share data that helps our society address inequities.

- As our society becomes more attentive to prioritizing health equity, significant barriers in the form of the digital divide – along with gaps in digital and health literacy – continue to prevent populations from having equitable access to their health data and tools of communication with their providers. Barriers also exist in the form of the ability (funding, staff resources) of parts of the health safety net to invest in technology

implementation that will enhance connectivity and data sharing while also ensuring privacy and security of data.

- Lack of standard electronic health records in key settings for certain vulnerable populations (e.g., those in long-term care settings) results in difficulty for providers, beneficiaries, and caregivers accessing the most current data. Furthermore, data frequently do not travel with the person from setting to setting effectively/efficiently. This may lead to medical errors or duplicative screening, diagnostic workups, and care.

- Trust – in understanding why data are being collected, how it will be used, and by whom – is an ongoing barrier to data sharing among organizations and by the people whose data is desired.

- Providers and researchers who focus in areas outside of IT sometimes do not understand the importance of data standards to patient care and research, so it is harder to engage them. More effective ways should be sought for educating and engaging providers and researchers at the right times in the standards development process (not all the time), and in the piloting and implementation of standards-based systems.

- Federal agency hesitancy to embrace a single standard in some of its new payment models perpetuates heterogeneity in standards used and adopted in the field and can become a barrier to data sharing.

Public Health Perspectives

- The limited scope of data elements called out by the USCDI and supported by the US Core FHIR Profiles means that key Public Health reporting data elements are inaccessible via standard FHIR APIs related to EHR implementations. Access to data relating to pregnancy, delivery and maternal and child health are particularly inaccessible despite the critical roles these elements play in a wide variety of Public Health reporting requirements.
- Public Health programs lack sufficient resources (time, personnel and funding) to develop, test and implement the tools and processes necessary to onboard reporting providers and health care organizations at scale.
- Due to limited resources and competing priorities EHR systems often don't support standards not part of certification requirements or regulations.
- Neither Public Health programs nor Health IT vendors have the resources necessary to regularly participate in HL7 FHIR Connectathon activities or otherwise review and test emerging standards.

Patient Empowerment Perspectives

- Provide a complete patient-centered longitudinal record that is both accessible by the patient and can be shared by patient-mediated exchange.

- Consents need to be electronic and obtained in the clinical workflow so that sharing is not delayed due to inefficiencies in collecting consent.

- Ability to appropriately segment or partition data is enhanced to allow individuals with concerns about privacy for some of their data to participate in data sharing.

- Where blockchain is used for data sharing there should be consideration of standards harmonization

- Create a better awareness of why data sharing matters, how to protect, secure, and release patient information as part of personalizing one's care delivery experience, and ensure that people from various demographics can validate approaches, reaching as many as possible.

Organizing Question #2 - Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

Overarching Perspectives – Standards, Interoperability and the Digital Divide

- We request that the United States Core Data for Interoperability (USCDI) continue to be implemented in FHIR as "US Core". Clarifying this relationship to a broader community would be helpful.

- As humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding data represented in USCDI, US Core, and specialized Implementation Guides (IGs).

- On top of US Core, specialized Implementation Guides will need to be developed in a coherent manner for specific applications across health. This will foster improvements in care and research and reduction of burden and cost. mCODE (https://confluence.hl7.org/display/COD/mCODE) is an example of a specialized IG focused on data that should be collected for every cancer patient. mCODE is being tested and improved with the CodeX HL7 FHIR Accelerator against several use cases (RWD clinical trials, finding trials, registry reporting, etc.). The "mCODE approach" is also being considered for other areas, including cardiovascular disease and Alzheimer's/related dementias.

Public Health Perspectives

- All standards mentioned in the ONC's Interoperability Standards Advisory (ISA) should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification. Important examples include:
    - Newborn screening (EHDI, CCHD, DAR and DBS use case in LOI and LRI)
    - Birth Defect Reporting (CDA and draft FHIR)
    - Cancer Reporting (CDA and draft FHIR)
    - Immunization Decision Support
    - Occupational Data for Health

Patient Empowerment Perspectives

- The HL7 International Patient Access (IPA) specification will extend the reach of US Core to the international level.

- The principle: "No aggregation without representation" – represents a desire for collective governance of

digital rights for patient groups and communities that should be considered.

- Consider support for emerging network topologies to enable patient mediated exchange of health data.

- The HL7 Patient Empowerment Workgroup is working on an Implementation Guide for Patient Request for Corrections - providing a standard way to communicate and support this request would help improve the quality of health care information.

- The HL7 Patient Empowerment Workgroup is also working on a white paper to define the field of patient *contributed* data. Note that this is much more than PGHD (patient *generated* data, e.g. data from a fitness watch) - it includes any types of information that the patient and family say are important, whether or not those data types are currently modeled in health data systems. This is an essential aspect of the shift to patient-centered care.

- The Advance Directive Interoperability (ADI) Community is working on improving data sharing by allowing people to create, update, and make their goals, preferences, and priorities for treatment - which will drive data sharing from the main user of health care services, the patient themselves. This work should be considered.

Organizing Question #3 - How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

Overarching Perspectives

Successful, open standards systems provide value to most players in an ecosystem, and remove waste (burden, cost, delay, middle-players who profit on chaos). Successful standards are also developed with input from stakeholders and with the benefit of real-world testing. Standards are implemented widely when they address motivations of actors in an ecosystem. Related to this, patients should become more aware of the importance of standards-based interoperability and increasingly request it from their providers and apps. Health systems, researchers and other service providers should request standards-based interoperability from vendors. And, lawmakers/regulators should use their tools to encourage or mandate standards-based interoperability when other market forces are insufficiently comprehensive or fast.

Six examples follow, of other industries that have effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care are below that are successful in terms of interoperability.

- Global Financial System in the Internet Age: Increasing transparency, less burdensome/costly currency flow, etc. depends on data standards (like SWIFT https://en.wikipedia.org/wiki/Society_for_Worldwide_Interbank_Financial_Telecommunication, FIX https://en.wikipedia.org/wiki/Financial_Information_eXchange, etc.) as well as practice standards and regulatory oversight/coordination.

- Global Logistics Automation: Starts with data standards for unique identification of things using unique IDs, barcodes, RFID, descriptions of things, locations, business entities, data exchange formats and protocols, practices etc. On a less technical level, standards for the dimensions of shipping containers have been important to increasing efficiency. https://en.wikipedia.org/wiki/Logistics_automation.

- Telecommunications: Standards for equipment, frequencies, hand-off between towers/networks/countries, and data exchange, coupled with regulations https://en.wikipedia.org/wiki/Interoperability#Telecommunications.

- World-Wide Standardized Seismographic Network: For decades, seismologists needed practice and instrumentation standards to share data between institutions in order locate earthquakes and understand the interior of the earth. Early seismographic observations were exchanged on paper, telegraph, and telephone. The WWSSN, implemented in the early 1960s, was a major step forward. The WWSSN was primarily funded to monitor global underground nuclear testing. The network also substantially increased our understanding the structure and tectonics of the Earth. The WWSSN included advanced standards for seismometers, global timing, measuring signals, formatting and exchanging data, and using the data to detect, locate and identify seismic events https://en.wikipedia.org/wiki/World-Wide_Standardized_Seismograph_Network Subsequent implementations for global geophysical monitoring have built upon the WWSSN standards-based model. E.g., https://www.ctbto.org/verification-regime/background/overview-of-the-verification-regime/.

- Internet and World Wide Web: Starting with US-based projects and standards, ANSI (https://www.ansi.org/), ISO (https://www.iso.org/), IETF (https://www.ietf.org/) and the W3C (https://www.w3.org/) evolved international standards such as TCP/IP, HTTP, URL, HTML, and others that power and make more accessible the internet and World Wide Web. There are useful lessons here regarding what led people to demand an open Web, over its predecessors on the Internet (Prodigy, Compuserve, AOL, etc.). There are also useful learnings regarding challenges posed by widespread interoperable data systems, value, and abuse.

- Airline Schedule and Reservation Sharing: E.g. https://www.iata.org/en/publications/store/standard-schedules-information/ The SSIM is the official set of standards, guiding the industry with recommended practices, messaging formats and data processing procedures that are to be used by all IATA member airlines and their business partners for the exchange of airline schedules, communication of airport coordination information and minimum connect time data. Airlines also share standardized data to help travel agents and applications present travel options to travelers, help travelers book trips, etc.

Organizing Question #4 - What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

HL7 recommends:

Short-term:

- Leverage standards for demographic concepts like Social Determinants of Health https://commons.wikimedia.org/wiki/File:Social_Determinants_of_Health_Infoviz.jpg to prioritize work based on potential to improve health and research, reduce inequities, and reduce cost and burden. The United States Core Data for Interoperability now includes SDOH and SOGI data elements: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v2. Resources such as the SDOH-focused HL7 Gravity Project should be maximally consulted and leveraged.
- Review and leverage existing strategies, like the draft National Strategy for Digital Health and the Federal Data Strategy to prioritize actions and propel momentum to key milestones.
- Continue to clarify and coordinate roles of government agencies.
- Increase financial support for open consensus health IT standards development organizations, and clarify which organizations are responsible for which standards.

- Ensure the new National Institutes of Health Advanced Research Projects Agency for Health (ARPA-H) has as one of its foci standards-based interoperability and its impact on health. ARPA-H and all agencies should require researchers to use standards, where applicable. More information on ARPA-H can be found at: https://www.nih.gov/arpa-h.
- Expand the USCDI to include core data elements crucial to Public Health reporting.

Mid-term:

- Focus on gathering stakeholders to collaborate to demonstrate in real-world settings the value of proposed standards before they are finalized. Provide funding and resources for pilot projects on emerging standards. Implementation and testing fora like the HL7 Accelerator Program are proving to be effective in this regard.
- Develop a strategy to ensure that code/terminology systems required for interoperability are easily available for implementers and users. Consider a national licensing scheme, or direct funding to the code system custodians to lower financial barriers to adoption, implementation, and use of these standards.
- Work with patients and other stakeholders to develop a strategy for patients and caregivers to control their health data from birth to death and beyond.
- Develop a strategy for appropriate worldwide collection and sharing of health data.

Long-term:

- Finalize implementation of strategies, measure progress, update as needed.

From: Bonner, Patrick
To: NCVHS Mail (CDC)
Subject: Ideas and Improvements
Date: Friday, August 6, 2021 3:33:42 PM

Hello,

My name is Patrick Adam Bonner, and I work as an Operations Analyst at Washington University Physicians Billing Service in St. Louis, MO. I am replying to NCVHS's request for ideas and improvements for the year ahead. Here are my thoughts:

1. How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Standardization *and enforcement* of electronic codes (be they ANSI, Rejection, Remark, PLB, etc.) across all payers would cut down on a significant amount of unnecessary work. One payer uses code 72 to mean they will be taking back a payment in the future, another uses 72 to say this is a reconsideration, and so on. It does little good to tell everyone they have to use the same codes, but not regulate *how* those codes should be used.

Many providers find it so complicated to get payments from certain payers that they simply give up and write-off any charges they would send to those payers. This is great for the payers who get to keep that money, but it puts an unnecessary burden on the industry as a whole because those costs must be mitigated somehow.

Electronic Remittance and Electronic Payments (ERA/EFT) enrollment is also a convoluted mess. Everyone follows a completely different process. One payer requires you to go to a third party website (CAQH Enrollhub), while another requires email requests for Registration Codes, that must be received by the provider and manually entered on their website, while another requires all enrollments be submitted on paper via mail. The unnecessary complexity of the process, coupled with the poor training payers and vendors provide their Provider Service Representatives makes enrollment literally impossible sometimes. We have had enrollments outstanding for years because every representative who reviews an enrollment request comes up with a different reason to deny the request.

As an example, I used the CAQH EnrollHub to enroll one our departments in ERA/EFT. My request was denied. When I called to ask why, I was told it was because the company letterhead was on the upper right hand side of the page, and it needed to be in the upper left. I corrected the letter and resubmitted it. It was denied. When I asked why, I was informed it was because the letter head was in the upper left hand corner and it needed to be in the upper right. I resubmitted the original letter. It was denied. When I called to ask why, I was informed it was because the Bank Representative signed his name above his phone number and it had to be below the number. I made the changes and resubmitted. It was denied again, this time because the signature was supposed to be above the phone number. I have literally dozens of examples of this same problem across the board. CAQH may be the worst, but I encounter this issue with everyone from Illinois Public Aid to Medicare to

PaySpan to Optum.

So-called 'Verification Processes' implemented in the name of security are also out of control. Taking CAQH as an example, they require the following information every time you contact them:

Position and Title
Username
User email address
NPI
TIN
Bank Routing Number
Bank Account Number
List of all payers submitted for enrollment
Re-confirm Position and Title

Along with a battery of questions:
Did you submit this enrollment
Did you know your enrollment was submitted
Did you authorize the submission

Etc. etc. etc.

Some security measures are reasonable, and necessary, but the above level of detail is inhibitive and only slows down an already tedious, time-consuming process. In the above example, the fact that I can give the username and email address means I already have access to the website, and I can find all of the other information on the website, so what additional security does asking those questions provide? Once I'm in the site, I can verify whatever they want, but it doesn't make the account more secure. The necessary safety measures, such as regular password resets, dual authentication, and so on already cost our staff enough time. Piling more and more requirements on the verification process may allow the vendor/trading partner/payer the ability to say "We have 12 levels of security," but all of those 12 levels can be accessed with one password, so it doesn't add any *actual* security.

2. Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

3. How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Enforcement of the governmental standards, and giving the providers a means of reporting infractions and holding the payers/vendors/trading partners accountable for meeting the standards that are already in place would make great strides in fixing this problem. Even if only a few core principles were applied across the board, to all payers, this would greatly improve efficiency and cut down on waste and loss.

For example, A payer has so many days to submit the remit that matches a particular payment. Many payers do not meet these requirements, they hold the remits for an extended period of time, or they require a person to get on the phone and call them and ask them to fax or mail or email or resubmit the remit electronically. This delay in receiving the remit causes a delay in the posting of payments. This results in patients being billed erroneously for outstanding balances their insurance company is responsible to pay. People's accounts get sent to collection agencies not because they refuse to pay their bill, but because the payer refuses to meet the requirements for remit submission.

As providers, we have no recourse or way to hold the payer accountable for not meeting the standards. It does little good to put standards in place if there are no means in place to enforce the adoption of those standards. Nor does it do any good to fine someone for an infraction and charge them less than the cost of fixing the infraction. Paying a penalty every couple months is probably cheaper than hiring and training and providing benefits for the staff required to fix a problem and/or speed up a workflow. If the payer sees it is cheaper to pay the fine, why would they ever change the process?

Thank you for your time.

Contact me with any questions.

Thank you,
Patrick Adam Bonner

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From: Christopher Gracon
To: NCVHS Mail (CDC)
Cc: Jonathan Fox
Subject: Comment on 8/25/21 Standards Subcommittee meeting
Date: Wednesday, October 27, 2021 1:58:42 PM

I know this is coming 2 months after the Standard Subcommittee meeting, but I had an additional thought in regards to a new use case the NCVHS should consider for recommendation to HHS o adopt. It has to do with the 835.

The new use case would be an extension to the comments I submitted in July in regards to submissions to state All Payer Claims Databases (APCD). One of the challenges covered by the Department of Labor's recent State All Payer Claims Databases Advisory Committee (SAPCDAC - State All Payer Claims Databases Advisory Committee Report with Recommendations under Section 735 of the Employee Retirement Income Security Act of 1974 (dol.gov)) final report was with the absence of non-claims payments data being submitted. In almost all cases, submissions from payers to state All Payer Claims Databases are tied to claims and encounters. This leaves out all non-claims based payments from being submitted. Since this is covers an increasing portion of health care services its absence is presenting a challenge to have a complete view of health care spending in a state.

The X12 835 is currently used by payers to explain payments, including non-claim based payments, to providers. This same transaction could be used by payers to submit non-claims based payments to states without any changes. With the next version of the 835, the code list which explains these sorts of payments in the PLB segment has been moved to an external code set which means that as new reimbursement methodologies are adopted, they can be quickly added to the list and used.

I would like to ask that you please recommend an extension to the uses of the 835 as a standard transaction to include reporting non-claims based payment to state APCDs. This is in addition to my prior suggestions about naming the PACDR 837, NCPDP Post Adjudication History, Plan Member Reporting 834 and the 277DRA (Data Reporting Acknowledgement) transactions for purposes of submitting data in a standard format to state APCDs (see below).

Thank you for your consideration of my suggestions.

Christopher Gracon

From: Christopher Gracon
Sent: Tuesday, July 27, 2021 12:02 PM
To: ncvhsmail@cdc.gov
Cc: Jonathan Fox Jonathan.Fox@independenthealth.com
Subject: Comments for August 25 Standards Subcommittee

I am offering my personal comments to the questions the NCVHS Standard Subcommittee requested feedback on:

1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

a. Barrier – Having payers be the source of truth does not bode well for the health records going forward. Payers receive copies of data from the providers, and possibly not updates to those same records. Since they receive copies, the current model does not appear to have a way for payers to validate the data (such as is weight within 'valid' range, or blood pressure reading make sense) and push back to the provider to share 'clean' data. The health records providers keep, while sharable, are not really captured for the purpose of sharing. It is captured for the purposes of the provider and administering care. Current, and proposed, final rule on interoperability seem to assume the payers are to receive the data and treat it as being 'clean' and 100% accurate.
b. Barrier – Currently many providers share records in HL7 V2.x formats. These will need to be mapped by the payers into FHIR to be able to be shared further. Many payers are not used to working with FHIR let alone HL7 V2.x, so they will have to map data between formats they are not fluent in. This could introduce mapping errors in the data
c. Barrier – HL7 allows extensions. Extensions present a challenge in that data is not part of the standard and for many payers they might not be able to use/store the data.
d. Barrier – Absence of an Attachments rule. This limits the data which can now be shared electronically as there is no requirement for all parties to be able to do this.
e. Barrier – FHIR Implementation Guides are immature. The DaVinci ones are only a STU (Standard for Trial Use). Any requirement to use these guides should ensure that they are at a more normative level.

2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

a. All Payer Claims Database submissions (claim/encounter and membership) should be Standard Transactions. The NCPDP Post Adjudication History, X12 PACDR 837, and X12 Plan Member Reporting 834 should be the named transactions. If Acknowledgements are named as Standard Transactions, then the X12 277DRA (Data Reporting Acknowledgement) should be included as it is the PACDR equivalent to the X12 277CA. By naming these, it will standardize submissions to state APCDs. New York currently uses these transactions for its All Payer Database. The NCPDP and PACDR 837 transactions mirror the Standard Transactions which the payers use for receiving claims and sending remittances. This simplifies the payers understanding of the data to submit to APCDs and matches the data rules & requirements the payers are already familiar with.
b. Consideration should be made to having sponsors of healthcare insurance, and their agents who help them with enrollment, to become Covered Entities so that they would be required to use the X12 834 transaction, and to use it as the TR3 specifies.
c. State APCDs should be named as Covered Entities so that HIPAA rules apply to them. By doing this the industry will not have happen the challenge of the HIPAA 834 where

the senders are usually not covered entities so the Standard Transaction rules do not apply

d. Acknowledgement should be named as Standard Transactions. This will facilitate the exchange of current Standard Transactions.
e. Hospital Discharge submissions should be Standard Transactions so the 837R Health Care Reporting guide should be named. Similar to the PACDR 837, if Acknowledgements are named as Standard Transactions, then the 277DRA (Data Reporting Acknowledgement) should be included as it is the 837R equivalent to the 277CA. The use of Hospital Discharge submissions could be an extension of the All Payer Claims Database mentioned above, as in New York this data is also loaded into their APCD.
f. HIPPS Codes should be named as a Medical Code set so that they are valid based upon date of service and not the date of the transaction. There have been challenges we have faced when we receive a HIPPS Code and then when we need to submit it to an APCD or to a reporting agency after the expiration of the code, that the code is seen as being invalid even though it was at the time of the service and probably the time of the claim submission.

3) How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

a. I am not aware of any.

4) What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

a. Short term – issuing an Attachments rule to encourage attachments and to standardize the processes
b. Short term – upgrading the HIPAA Standard Transactions to 8010 while providing a roadmap to future version changes with X12 now updating the guides every year. Having a predictable schedule will ensure that the changes between versions is smaller than what has been happening, and allows all parties to be able to plan with certainty.

Christopher Gracon

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July 30, 2021

Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Via: NCVHSmail@cdc.gov

Re: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

Dear Mr. Landen and Ms. Love,

MGMA is pleased to offer this letter in response to the Request for Public Comment (RPC) from the National Committee on Vital and Health Statistics (NCVHS) entitled "Healthcare Standards Development, Adoption and Implementation" which was published on June 18, 2021. The movement of data and information between the numerous, disparate entities within healthcare is crucial for an efficient and high-functioning healthcare system. MGMA commends NCVHS for this latest RPC and looks forward to being a close partner in this process to modernize the infrastructure linking patients, providers, payers, the public health system, and other actors in healthcare.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical groups comprising more than 350,000 physicians. These groups range from small independent practices in remote and other underserved areas to large regional and national health systems that cover the full spectrum of physician specialties. MGMA continuously strives for administrative simplification so that medical groups can provide efficient and effective care to America's patients. MGMA applauds NCVHS in taking these next steps to identify improvements in the healthcare data exchange system.

Key Recommendations

- MGMA believes that the successes of the present data exchange system aren't fully being realized and that more can be done to implement currently mandated standards. We assert that successful data exchange is possible with present-day standards, operating rules, and code sets and believe more should be done to encourage their utilization.
- As NCVHS undertakes this endeavor, MGMA emphasizes the need for full involvement from all stakeholders in a transparent development process and that any changes to standards or processes have minimal impact to the current system of data exchange.
- MGMA recommends NCVHS study and provide evidence of Return on Investment (ROI) for any new or revised standard. Specifically, all stakeholders should be fully apprised by the Committee

on how any new or revised standard will improve the status quo in terms of administrative time and money saved, and, specific to providers, how practice operations and patient care will be improved.

Comments to NCVHS Question #1: *How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?*

MGMA comment: As NCVHS takes steps to identify needed improvements to healthcare data exchange, MGMA recommends the Committee also support efficiencies already in place.

Data interoperability enables providers to coordinate care among institutions and act based on comprehensive and current information. The scope of data interoperability has expanded to encompass social and behavioral services, public health, cost and quality assessment, and research, in addition to administrative uses. Data standards, therefore, must be multifaceted and meet the needs of several stakeholders. Providers require data standards that are credible, comprehensive, and that are developed using a rigorous and evidence-based process. The Current Procedural Terminology (CPT®) code set is a foundational code set for describing medical services and procedures and is universally trusted by the health care system.

CPT codes are evidence-based, timely, and reflect current clinical practice in a common medical language. The CPT Editorial Panel is an independent body of expert physicians and qualified healthcare professionals convened by the American Medical Association (AMA) with the unique ability to manage an open, transparent, consensus-based, and stakeholder-driven editorial process. The AMA and the CPT Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of health data standards across disparate health-related data systems. While NCVHS casts a wide net in terms of scope and invites a complete re-envisioning of the administrative and clinical electronic standards and code sets used in the US health care system, we encourage NCVHS to consider a more moderate, realistic path that fully considers the overwhelming success of many electronic transactions and code sets used today. The CPT code set plays a vital role in data sharing among providers, patients, payers, public health systems, and other actors in health care. As health care evolves, reliable and trusted data, coding, and terminologies—such as the CPT code set—must continue to receive support.

The CPT code set already is an adopted standard for HIPAA purposes. In its recommendations to the Secretary, we urge NCVHS to continue to support the foundational role that the CPT code set, and the CPT Editorial Panel play in the efficient and effective exchange of electronic health related data under HIPAA.

MGMA comment: Compliance with current standards remains a problem. NCVHS should recommend that the Department of Health and Human Services (HHS) and the Center for Medicare & Medicaid Services (CMS) put in place a stronger program for assessing penalties for actors who violate current mandates. Education programs can also be strengthened for actors who are unaware of currently mandated standards.

Since 2014, as part of the Affordable Care Act (ACA), it has been required health plans are required to offer physician practices the option of receiving their reimbursement via a standardized electronic funds transfer (EFT) method. This standard uses a set of ACA-mandated EFT business operating rules which are incorporated with existing HIPAA-directed electronic remittance advice (ERA) operating rules. In concert together, these standards and operating rules streamline the flow of reimbursement and revenue

cycle management, a bedrock healthcare administration process vital to the efficient management of patient care.

MGMA is becoming increasingly aware of entities within the healthcare data exchange infrastructure that are taking advantage of vague guidance from the federal government and have put in place financial roadblocks that deter providers from making use of electronic remittance advice (ERA) and EFT standards and operating rules. These actions go against the spirit of administrative simplification and add needless cost and burden to healthcare administration. More work needs to be done to recommit to the idea of administrative simplification by issuing enforcement and assessing penalties on actors who violate current mandates.

MGMA comment: As NCVHS, in partnership with the industry, takes new steps in the standards development process, it is important that impacted stakeholders have the required information needed to buy into and fully implement any potential new standard.

Information on ROI specific to each stakeholder category. Healthcare providers and medical practices operate on narrow margins and every financial decision is made first and foremost with the financial viability of the practice in mind. The implementation of electronic health data exchange standards has a ripple effect across practice administration from retooling workflow processes to the update or purchasing new technology platforms. As new standards are being discussed, NCVHS needs to provide information on how the adoption of any new potential standard will impact ROI for each specific healthcare stakeholder category.

Information on the process used to develop new standards. It will be imperative for there to be full access to the standards development process from all impacted stakeholders in concert with Standards Development Organizations. NCVHS should take every opportunity to reach out and engage with not just stakeholder associations and societies, but also specific healthcare entities who will ultimately implement any new potential standards. A clear path on the standards development process should be created by NCVHS and shared with the industry.

Information from testing and pilot projects with stakeholders. When a potential new standard is formed, volunteers from industry need to have time to test the standard and the opportunity to report back to the Committee and the industry on costs, benefits, and important lessons learned from using the new standard. This piece is crucial before any decision is made on mandating the standard.

Information to educate stakeholders on implementation and compliance. Once a standard has been appropriately vetted and is chosen to be mandated, NCVHS with HHS should use every outreach tool available to inform stakeholders on how to appropriately use the new data exchange standard and how to remain compliant with any mandates.

Comments to NCVHS Question #2: *Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification?*

MGMA comment: MGMA is aware of HL7 Fast Healthcare Interoperability Resources (FHIR), including the incubation projects such as Da Vinci and CARIN. MGMA believes more can be done to educate the wider healthcare industry of the potential and ROI of FHIR.

When deciding whether to adopt standards currently being developed within the industry, MGMA believes NCVHS should still ensure that impacted stakeholders have the required information needed to buy into and fully implement any potential new standard. Furthermore, we caution NCVHS from a

wholesale adoption of a standard(s) under development within the industry, and instead encourages the Committee to look at ways in which the standard(s) could be applied in a targeted manner to address current gaps and deficiencies in health data exchange (prior authorization as an example). We stress that incubator demonstration projects within closed-loop systems will face unique challenges when deployed among the healthcare industry's disparate entities.

Comments to NCVHS Question #4: *What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?*

MGMA comment: MGMA offers the following timeline of priorities.

Short-term: Complete a full inventory of gaps and deficiencies in the current system of health data exchange. Identify wherever telephones, faxes, and single, proprietary web portals are being used as a starting point to address these gaps. NCVHS should issue regulations adopting the CPT Guidelines under HIPAA. The Committee should also assemble a plan, with stakeholder buy-in, for the necessary steps to develop new standards. Finally, NCVHS should seek to grow the use of current HIPAA-mandated standards.

Mid-term: NCVHS should compile a plan for how it will look to consider new standards (either internally or externally developed) for implementation and potential mandate. The Committee should explain, with stakeholder input, how it will test potential new standards and how it will measure ROI as it pertains to each specific stakeholder category.

Long-term: Moving forward, it will be important for NCVHS to put in place a clear, agreed upon system and process for standards development in the future. Additionally, the Committee should develop and put in place a system and process for revisiting currently adopted standards to assess if any changes or updates should be made.

We thank you for your consideration of these comments and recommendations. We look forward to continuing to work with the Committee to identify opportunities to improve and streamline the flow of electronic health data between patients, providers, payers, the public health system, and other actors in healthcare. Should you have any questions, please contact Drew Voytal, Associate Director, Government Affairs, at 202.293.3450 or dvoytal@mgma.org.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs, MGMA

July 30, 2021

National Committee on Vital and Health Statistics
Subcommittee on Standards
Via email

Re: Request for Comment on Healthcare Standards Development, Adoption and Implementation

Dear NCVHS Members,

Nacha appreciates this opportunity to comment on Healthcare Standards Development, Adoption and Implementation. We appreciate the work of HHS, NCVHS, and the entire industry in the movement toward electronic transactions and administrative simplification.

Nacha fully supports the NCVHS goal of understanding the extent to which current and emerging standards for exchanging electronic health-related data under Health Insurance Portability and Accountability Act (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the health care system.

While we offer these comments in good faith, Nacha and other stakeholders remain frustrated that many previous recommendations on administrative simplification, and the use and enforcement of existing standards, remain un-acted upon.[1]

Nacha, the ACH Network, and the Nacha Operating Rules[2]

Nacha is the financial services industry's governance and administrative organization for the Automated Clearing House (ACH) electronic payments system. Nacha is responsible for the development, adoption, and maintenance of the *Nacha Operating Rules* that govern the use of ACH payments. In addition to the healthcare EFT standard, the ACH Network is commonly used for the Direct Deposit of payroll and benefit payments and tax refunds; recurring and online electronic bill payment; and business-to business payments. Nacha estimates that in 2021 there will be 29 billion ACH payments, transferring $72 trillion.

The Healthcare EFT Standard

Since the designation of the Nacha "CCD+Addenda" as the healthcare EFT standard on January 10, 2012, the adoption of this standard transaction by the industry has been robust. Measured by the number of payments, its use has more than doubled since 2014 (the first full year of use after the effective date) to more than 360 million payments in 2020, and transferred approximately $1.9 trillion in value in 2020. (See chart below.) According to the 2020 CAQH Index[3], 68 percent of medical claim payments were made using the standard EFT, although the same CAQH Index shows that only 23 percent of dental claim payments were made using the standard EFT.

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[1] For example, see Nacha Comment Letter of December 7, 2018 to NCVHS on Predictability Roadmap at https://www.nacha.org/sites/default/files/2019-04/NACHA%20Comment%20Letter%20on%20NCVHS%20Predictability%20Roadmap%20Recommendations%20-%20December%207%202018.pdf

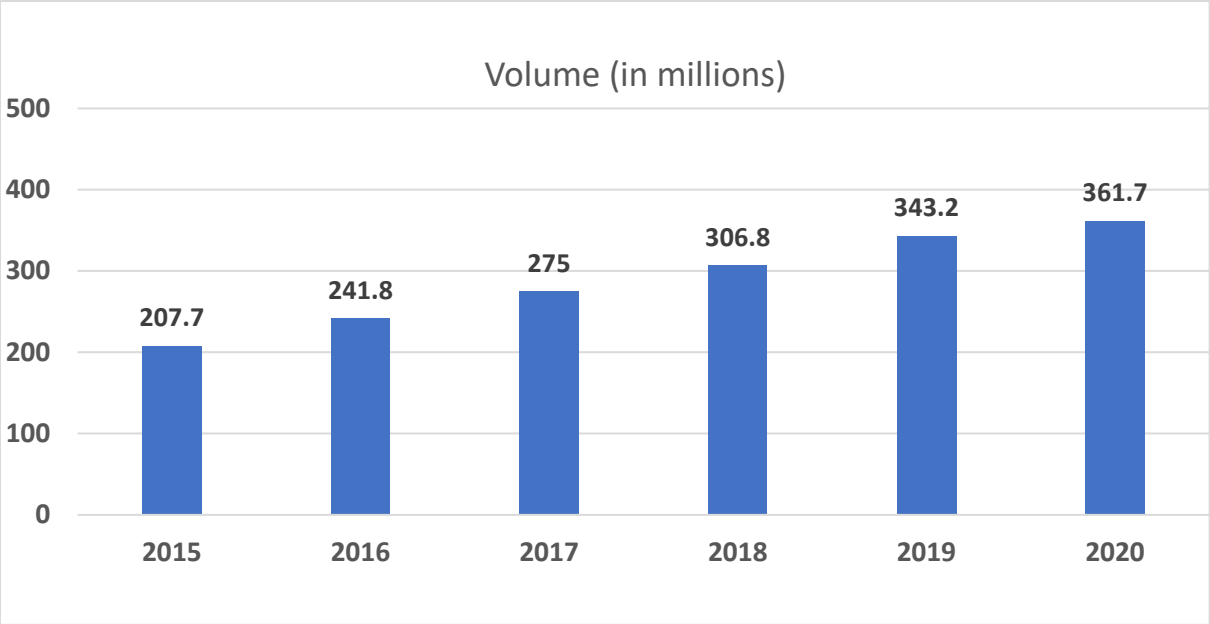
[2] A comprehensive overview of Nacha, the ACH Network, and Nacha's rulemaking process for the Nacha Operating Rules was given in testimony to the NCVHS Subcommittee on Standards on July 20, 2010 - https://healthcare.Nacha.org/sites/healthcare.Nacha.org/files/files/20100709%20NACHA%20Testimony%20on%20Operating%20Rules%20NCVHS%20Hearing.pdf

[3] See https://www.caqh.org/sites/default/files/explorations/index/2020-caqh-index.pdf

The value proposition for greater adoption of EFT is the tremendous cost savings to Providers and Plans. According to the 2020 CAQH Index, even with 68% adoption rate of Medical EFT, there is still an opportunity for Plans to save $79 million industry-wide by converting to 100% EFT and $347 million in savings for Providers. On the Dental side, Plans can save $34 million, and Providers can save approximately $438 million, with full adoption of EFT for claim payments.

A significant pain point experienced by some providers regards business practices by some payers or their vendors. In many instances, providers have experienced difficulties in enrolling in EFT; that payers or their vendors are charging fees to use the standard transaction; or that they are paid involuntarily by virtual credit cards. Addressing these existing pain points could go a long way toward increasing adoption of the standard EFT transaction.

Chart - Healthcare EFT Standard Transactions (in millions)



Industry Standards for Data and Data Exchange

In 2018, Nacha convened a new financial services industry standards group - Afinis Interoperability Standards. Afinis works to advance standardization of Application Programming Interfaces (APIs) among financial service industry stakeholders. API standardization helps the financial industry achieve objectives such as improved safety and transparency of payments, increased communications speed, and overall efficiency. To date, Afinis has completed twelve standards for payment-related APIs that address common functions among financial institutions and with business customers.[4]

Afinis is a prime example of an industry collaboration that has achieved success in bringing diverse parties together to develop and promote industry standards for data exchange.

[4] Recent Afinis news with a description of the twelve standard APIs is at https://www.nacha.org/news/afinis-interoperability-standards-releases-new-apis-help-businesses-cash-management-decisions.

Enforcement

Nacha would like to reiterate our strong support of a previous recommendations regarding enforcement. In our experience with the governance of electronic payments, clear and consistent enforcement is inherent to compliance with standards, operating rules and other business practices. The knowledge and expectation of scrutiny provides an incentive for compliance. We have direct experience of this with the *Nacha Operating Rules*, in which compliance is achieved via adherence to contracts, a requirement to audit compliance with the Rules annually, and a Nacha-administered enforcement process.

* * * * *

Nacha appreciates the opportunity to provide comments in response to the Request. If you have any questions regarding our comments, please do not hesitate to contact me at (703) 561-3916 or bsmith@nacha.org.

Sincerely,

Bradley W. Smith, AAP
Senior Director, ACH Network Administration

July 30, 2021

Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Submitted via email: NCVHSmail@cdc.gov

Re: National Committee on Vital and Health Statistics Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

Dear Mr. Landen and Ms. Love,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to submit comments and looks forward to further discussion on ways we can assist the subcommittee. NCPDP is concerned with the current rulemaking process which impedes innovation, interoperability and industry speed to implementation. We offer the following comments to questions posed by the subcommittee and request NCVHS recommend revisions to the current processes to enable standards development organizations (SDOs) to name standards in a timelier manner and work with the industry to speed implementation of such standards.

NCPDP Comment Question #1: ***How can data sharing be improved between patients, providers, payers, public health systems, and other actors in health care? What are the barriers to these improvements?***

NCPDP standards can be used to improve data sharing among patients, providers, payers, and public health systems. NCPDP standards support real-time communications between providers (prescribers and pharmacies), payers, public health systems and intermediaries. These standards include patient demographic, eligibility and specific clinical information as well as details related to the product and services provided to the patient. Real-time communication protocols and the use of shared code list terminology allows for expedited processes to be coordinated between the prescriber and the pharmacy, the pharmacy and the payer, and the payer and the prescriber. NCPDP standards are

available to support the communication of similar information between the provider and an intermediary or regulated agency such as Prescription Drug Monitoring Programs (PDMP) and state Health Information Exchanges (HIEs). As the industry moves forward in integrating the patient into the healthcare continuum, existing NCPDP standards can be used to create synergies in the development of new standards that provide interoperable solutions that include the patient.

The industry continues to merge clinical and administrative data for both pharmacy and medical services to achieve improved patient outcomes. This merged data provides an opportunity to streamline processes to achieve interoperability. There are, however, multiple barriers to reaching these goals resulting in increased healthcare costs and patient care risks. Below are examples of current barriers to interoperability and recommendations on how to improve the data sharing process.

Barrier	**Recommendation**
• Inconsistencies in patient matching processes	• Explore implementation of a patient matching solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries • Support the use of a universal healthcare patient identifier • Harmonize data standards to support the use of a universal patient ID similar to the way the NCPDP standards are harmonized
• Disparate standards and the lack of harmonization of data dictionaries and code lists	• Involve all healthcare standards in the United States Core Data for Interoperability (USCDI) data harmonization process • Support language translation and recognize specific situations of use by the impacted entities
• Inability to pilot new solutions for HIPAA mandated standards without risk of being non-compliant • Rigid structure and extensive timeline of the HHS rulemaking process inhibits technology innovation and ability to address current business needs	• Update HIPAA regulations and if necessary, legislation, to support SDO determination of updated version implementations. • Align the United States Department of Health and Human Services, (HHS) with the Office of the National Coordinator for Health Information Technology (ONC) Standards Version Advancement Process (SVAP) structure • The Secretary should allow the SDOs that are responsible for the specific standards to update to newer versions of standards without rulemaking in order to encourage innovation and the adoption of new functionality that can improve interoperability and promote patient safety
• Federal and state regulations impacting healthcare processes and standards lack consideration of interoperable technical and operational workflows, creating costly administrative barriers and compromising patient care, for example: o RxNorm to NDC	• Leverage the Health Standards Collaborative (HSC) as a consultative forum where federal and state business cases would be proactively reviewed to determine the applicable standards' optimal solution(s)

Barrier	Recommendation
○ ICD-10 utilization ○ Consolidated Appropriations Act of 2021 (CAA) requirement for ID cards	
• Data reporting format inconsistency across states compromises efforts to leverage healthcare data at the patient level regardless of the patient or service location, creates unnecessary administrative costs, and leads to data integrity risks due to data duplication • Lack of standardization, simplification and interoperability across PDMPs, HIEs and immunization data repositories. • State data sharing restrictions based on certain disease states (e.g., mental illness, HIV) and sharing outside of entity jurisdictions compromise provider access to critical clinical data necessary to coordinate patient care.	• Influence state agencies with specific data reporting requirements to adopt the use of the specific standard as recommended by the applicable SDO, and/or SDO Collaborative, for example: ○ NCPDP PDMP Reporting Standard ○ NCPDP SCRIPT MedicationList ○ NCPDP State Medicaid Provider File • Harmonize federal and state regulations related to information blocking, to establish the necessary data transparency across provider systems.

NCPDP Comment Question #2: ***Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.***

NCPDP has been waiting since NCVHS made their recommendation to HHS on April 22, 2020 to name the Telecommunication Standard Version F6. NCPDP requests NCVHS' support in expediting the rulemaking process for NCPDP's Telecommunication Standard Version F6. This version includes multiple enhancements to improve interoperability across standards by harmonizing field formats, field lengths, and patient demographic information. The ability to link data at the patient and product/service level is critical to achieving interoperability advancements.

NCPDP has many other existing standards published and ready for use, supporting interoperable communication between the designated stakeholders. Similar to the ONC SVAP, NCPDP recommends NCVHS endorse new standards as needed and allow the SDO of each standard to support pilots and implementation of new versions of previously named standards.

NCPDP recommends that NCVHS support the advancement and endorsement of these standards. Such support could be through demonstration projects or rulemaking that facilitates piloting of these standards and messages.

The list below includes examples of the most recent developments.

- Specialty Medication Enrollment Implementation Guide
  - NCPDP worked with HL7® to improve the enrollment process associated with the prescribing and dispensing of specialty medications.
  - The resulting Specialty Medication Enrollment Implementation Guide will reduce current administrative barriers and delays in patient access to care.
- Real Time Prescription Benefit Standard (RTPB) Version 12
  - This standard provides prescribers and pharmacists access to plan benefit coverage rules and, where applicable, alternative options for the patient.

    - The RTPB Standard is a critical tool in reducing workflow barriers and patient care delays, as it provides the necessary transparency at point of care, mitigating retrospective actions that cause care delays.
- State Medicaid Provider File Standard
    - This standard provides practical guidelines for state Medicaid agencies or entities producing federal and state required provider enrollment files used in the pharmacy industry to leverage a standardized file layout.
    - The standardized layout allows for interoperable implementation and use of the data between the Medicaid agency, Managed Care Organizations (MCOs), Pharmacy Benefit Managers (PBMs), pharmacies and prescribers, enabling consistency in communication to the patient.
- Post Adjudication Standard
    - Enables processors/payers to supply the qualified receiving entity, in a consistent format, detailed drug or utilization information post claim adjudication.
- Prescription Drug Monitoring Program Reporting Standard
    - Provides a consistent format for providers to report prescription data to PDMPs.
- NCPDP SCRIPT 2019071 and higher
    - MedicationList Message
        - Enables pharmacies to communicate dispensed medication lists to HIEs and other entities.
    - Referral Message
        - Enables providers and payers to request referrals electronically from other providers.

NCPDP Comment Question #3: ***How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?***

NCPDP cannot speak to the standards process and business needs of non-healthcare related industries reliant on interoperability of data. NCPDP can, however, emphasize the broad number of stakeholders and processes that are supported within the healthcare industry and how the current regulatory process often hinders advancement. NCPDP recommends regulators replace the current HIPAA/HHS rulemaking process with a method similar to ONC's Standards Version Advancement Process (SVAP). SVAP allows developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use approved newer versions of standards that are adopted in regulation so long as certain conditions are met. This supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

NCPDP Comment Question #4: ***What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?***

Short-term: As noted under the response to question #2, NCPDP stresses the immediate need for HHS to complete the HIPAA rulemaking process for NCPDP Telecommunication Standard Version F6.

Mid-term: While COVID has hindered many timelines and initiatives, the industry is eager to establish new mechanisms to expedite the HHS rulemaking process to allow the use of current versions of named standards. NCPDP recommends the HIPAA/HHS rulemaking process be modified to better support the implementation speed necessary to address business needs and regulatory requirements.

The combination of eliminating or reducing rigid regulations and establishing SDOs as the industry experts for proactive solutions will allow the industry to pilot innovation more quickly. Government program incentives that support these pilots will further increase stakeholder participation to validate viability and expected outcomes.

Long-term: The past 20 years of experience has made it evident that the current rulemaking process for HIPAA Transactions and Code Sets needs to be streamlined. This process and the associated Transaction Standards rule no longer support the speed of change happening in the healthcare industry.

NCPDP looks forward to working with NCVHS to streamline the current rulemaking process and improve the advancements of standards for the industry.

For direct inquiries or questions related to this letter, please contact:

Margaret Weiker
Vice President, Standards Development
NCPDP
mweiker@ncpdp.org

Sincerely,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

August 6, 2021

Richard Landen
Denise Love
Co-Chairs
National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Via: NCVHSmail@cdc.gov

RE: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

Dear Mr. Landen and Ms. Love,

The National Uniform Claim Committee (NUCC) is pleased to submit the following comments on the National Committee on Vital and Health Statistics (NCVHS) "Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation."

The NUCC is a Data Content Committee, Designated Standards Maintenance Organization (DSMO), and advisor to the Secretary of Health and Human Services (HHS) for the adoption of new and modified standards under the Health Insurance Portability and Accountability Act (HIPAA). We have a diverse membership of health care providers, health plans, designated standards maintenance organizations, public health organizations, and vendors. Our goal is to promote the development of a uniform claim "form" for use by the professional health care community to transmit related claim and encounter information to and from all third-party payers. As such, we provide a broad perspective on professional data reporting and claims processing needs impacting the industry.

The NUCC is committed to the work of administrative simplification. Our member organizations see first-hand the burdens that come from manual, outdated processes. While the health care industry has made significant progress since the passage of HIPAA to standardize and automate administrative transactions, we also see a continued need to improve the standards and operating rules development, adoption, and implementation processes. We strongly support these efforts by the NCVHS to identify opportunities to improve the nation's health care infrastructure.

1. How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Gaps in Current Electronic Capabilities

While there has been much work with developing and implementing data exchange standards, there remain gaps in the current versions of standards that inhibit the ability to fully automate data exchange. The main issue with the gaps is the speed at which updated versions of the standards can be adopted and implemented as part of the regulatory process. The NCVHS should look at the Office of the National Coordinator for Health Information Technology's (ONC) Standards Version Advancement Process (SVAP) as a potential model for adopting updated versions of standards. Additionally, the failure to issue a regulation for the electronic attachments standard, which was recognized as a business need 25 years ago in HIPAA and again 11 years ago in the Patient Protection and Affordable Care Act (ACA), is an ongoing gap that needs to be addressed.

The NUCC recommends that HHS, the standards development organizations (SDO), and other industry stakeholders focus on the gaps that currently exist in being able to share data electronically. Every instance where a phone, fax, or web portal is used to send or receive health care information should be examined as a potential function that can be replaced by a more automated solution.

The CAQH Index[1] is a resource the NCVHS can leverage for identifying opportunities to address ongoing gaps in the use of the current versions of HIPAA standards. The 2020 report shows consistent and high adoption, greater than 80 percent, of the Health Care Claim and Eligibility and Benefit Verification electronic standards for medical services. Conversely, Prior Authorization, Attachments, Claim Payment, and Remittance Advice all have low adoption rates of the electronic standards and high reliance on manual process. Further work and resources should be invested in understanding why these transactions have not reached higher adoption rates, especially considering the volume at which they are used. We suspect the reason for lower adoption is the need to fix issues within the standards, which emphasizes the need for a more flexible process, such as the ONC SVAP, for updating standards.

Compliance with Mandated Standards

One pivotal component of data sharing is compliance by the sending and receiving partners with the standard being used. The goal of standards is to standardize the information that is sent and received between organizations, which provides an efficient and cost-effective system for the exchange of information. Despite the many years of experience with the HIPAA-mandated X12 transactions, the NUCC continues to hear of situations of noncompliance with the Health Care Claim: Professional (837P) Technical Report Type 3 (TR3). For data exchanges such as the 837P and other administrative transactions, the burden of being compliant falls more heavily on the senders. If the sender does not follow the standard, the receiver can reject the transaction, leading to additional rework for the sender. Similarly, if the receiver requests data be sent in a transaction despite them not conforming to the standard's requirements, the sender must do so, or the receiver will not accept or process the transaction. Tolerance for allowing noncompliant data in transactions is counter to the efficient and cost-effective system the industry is striving to attain.

The NUCC is aware of the work that has been done by the Centers for Medicare & Medicaid Services (CMS) to educate the industry on compliance with the mandated standards and manage the complaint-driven

[1] https://www.caqh.org/sites/default/files/explorations/index/2020-caqh-index.pdf

process. The Administrative Simplification Enforcement and Testing Tool (ASETT) is a helpful resource for the industry to test their compliance and file complaints. We also appreciate CMS' new report of its Compliance Review Program findings, most recently released on July 15. The new report provides greater detail on the transactions and common violations. We are hopeful that these reports will educate other organizations on their violations and encourage noncompliant organizations to become compliant. **The NUCC recommends that HHS continue its Compliance Review Program and assess penalties to violators of HIPAA.**

Standards Must be Standardized

A related concern to compliance with mandated standards is the allowance for variations in the use of the standards, which might be framed as innovation or a proprietary business need of an entity. Variations can be found with the data content within the standard or with a version other than what is currently mandated. The unintended consequence is that organizations are required to support multiple variations of data content or standard versions. The result is a loss of efficiency and increased costs and administrative burden.

While there is a need for innovation, variations to data reporting should not be allowed within an existing mandated standard. CMS has established an exceptions process that permits covered entities to apply to use a different standard than what is currently mandated. Innovation should be limited to scenarios where an existing mandated standard does not exist. Allowing early adopters to implement new, nonmandated standards will provide real-world experience and information on the costs and benefits of implementation.

One specific example that has resulted in variations with a standard is the failure to adopt the Current Procedural Terminology (CPT®) Guidelines and Conventions (CPT Guidelines) under HIPAA. The CPT Guidelines are critical to the correct use of the CPT codes. The lack of stakeholder uptake has resulted in some organizations creating their own instructions for how to report the CPT codes, thus imposing a burden on the entire health care system in the claims and coordination of benefits processing.

Keeping Pace with Industry Needs

Effective and efficient data sharing require standards that meet the current business needs, which in turn means that the development and adoption processes for newer versions of standards must also keep pace with the industry's needs. **The NUCC continues to support previous recommendations by NCVHS for a more predictable schedule for the development and publication of updated versions of standards and the ability to address incremental updates to standards.** We continue to believe that having predictability with the development and adoption processes will give the industry more confidence in the process and facilitate the appropriate and timely allocation of resources. Again, we encourage the NCVHS to look at the ONC SVAP as a potential model.

Costs and Benefits

The NUCC believes it is essential for the industry to have a true understanding of the costs and benefits to implement newer versions of standards and strongly supports a requirement to undertake a cost-benefit analysis for all proposed new or updated versions of standards. We also recommend that these

analyses be done on a periodic basis following implementation to understand optimal timing to move to updated versions of standards. Since the first implementation of HIPAA-mandated standards, industry stakeholders have been told they will receive a return on their investment in the form of faster processing times, more data for decision making, less rejections and rework, and less need to submit additional clinical information, and other benefits. While a portion of these have been achieved, it is only a fraction of the opportunity that remains to improve the transactions and bring meaningful reductions in costs and increases in benefits.

Comprehensive, Real-World Testing

Comprehensive, real-world testing and piloting of new and updated standards are essential for ensuring that the standards truly meet the business requirements of the industry. The current implementation approach is to adopt the standards and then address any necessary fixes in a subsequent version. This process might be sufficient if the next version of the standard could be developed and implemented in a timely manner, but that is not the case today. Currently, when an adopted standard is not meeting business requirements, workarounds must be employed, which are manual and burdensome for all organizations. It is clear that the industry needs a process to test or pilot standards prior to national implementation, yet the industry currently lacks the infrastructure to conduct real-world testing.

The primary drawback to completing comprehensive testing is the cost. Both sending and receiving organizations must program their systems to accommodate the updated or new standards being testing, which is time and resource consuming and outside the normal workflow. Implementing the necessary programming changes must be done in blind faith not knowing if the new standards will be adopted and implemented. **The NUCC recommends that HHS provide federal funding and resources necessary to have comprehensive, real-world testing.**

Industry Participation

There is an immediate need to increase the membership and diversity of membership in the standards development process. The success of standards is dependent on fully understanding all aspects of the industry's business requirements and building the standards to meet those needs.

Terminology Standards

Data interoperability enables providers and payers to coordinate care among organizations and act based on comprehensive and current information. The scope of data interoperability has expanded to encompass social and behavioral services, public health, cost and quality assessment, and research, in addition to administrative uses. Terminology standards, therefore, must be multifaceted and meet the varied needs of the industry. They must be credible, comprehensive, and developed using rigorous and evidence-based processes.

The CPT code set, International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) are terminology standards that are pivotal for describing medical services, procedures, and diagnoses. Additional critical terminology standards are the Current Dental Terminology (CDT) for describing dental

services and the National Drug Codes (NDC) for describing drugs and biologics. They are all evidence-based, flexible, reflect current clinical practice, universally used, and trusted by the health care system.

The terminology curators for these standards continually demonstrate successful coordination in the development, adoption, implementation, and conformity of the standards across disparate health-related data systems. The code sets will continue to play a vital role in data sharing among providers, patients, payers, public health systems, and other actors in health care. **The NUCC recommends that NCVHS continue to support these trusted terminology standards.**

Consumer Friendly Terminology

Patients are widely recognized across all stakeholders as playing an increasingly integral role in the care they are receiving. To better inform and empower patients, they must have improved access to their health information as well as tools to assist them in interpreting the medical terms they will find in their clinical records, related administrative documentation, and other care delivery and treatment resources.

One specific resource for patients is the CPT Consumer Friendly Descriptors. Each CPT code has a CPT Consumer Friendly Descriptor that is a more easily understandable version of the medical procedure. Their use in records and documents for patients provide for better understanding of the clinical information allowing the patient to be more informed of their care. **The NUCC asks that NCVHS recommend that HHS promote the use of the consumer-friendly terminologies for use in patient materials and resources.**

2. Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

The NUCC has not tracked new use cases for data interoperability and has not received any recent requests to revise or add new data elements in the claim transaction.

3. How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

The NUCC does not have the necessary experience or expertise with other industries' implementations of electronic data standards to propose what might be applicable to health care.

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

The above comments on today's systems and processes are all recommendations for necessary changes to improve the standards development, adoption, and implementation. Ideally, these changes should be made expeditiously. The following are recommendations for how HHS should stage our recommended changes.

Short-term (0 – 12 months)

- Identify the gaps in the current electronic capabilities and develop a plan for eliminating them.
- Continue to conduct compliance audits and publish the findings.
- Encourage stakeholder uptake of the CPT Guidelines.
- Develop and publish a proposal for conducting cost-benefit analyses for new and updated versions of standards.
- Develop and publish a plan to increase participation in standards development work.
- Issue recommendations supporting current HIPAA-mandated terminologies.
- Develop and publish a plan to provide more consumer-friendly resources.

Mid-term (13 – 24 months)

- Implement the plan for eliminating the gaps in the current electronic capabilities.
- Develop and publish a proposal for how standards can be tested, analyzed, adopted, and implemented in a timely manner and solicit public comment.
- Develop and publish a new process for comprehensive, real-world testing of new and updated versions of standards, including funding resources.
- Implement the plan to increase participation in standards development work.
- Implement the plan to provide more consumer-friendly resources.

Long-term (25 – 60 months)

- Implement the new process for how standards are tested, analyzed, adopted, and implemented in a timely manner.
- Implement the new process for conducting cost-benefit analyses of new and updated versions of standards.
- Implement the new process for comprehensive, real-world testing of new and updated standards.

The NUCC appreciates the opportunity to comment on this request for public comment. If you have any questions, please contact me at (312) 330-2953 or nancy.spector@ama-assn.org

Sincerely,

/s/

Nancy Spector
Chair, National Uniform Claim Committee

July 30, 2021

National Committee on Vital and Health Statistics
Subcommittee on Standards
Washington DC

Re: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

To Whom it May Concern,

On behalf of the 4,100 U.S. hospitals and health systems and more than 200,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to your Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost.

Utilizing data from multiple sources is integral to every aspect of healthcare and is needed for timely and robust data for multiple use cases, including care delivery, care coordination and transition, public health, population health, performance improvement, and government reporting. There is an increasing need to integrate and leverage administrative, financial, and clinical data. Intrinsic to data collection, access and use is the need for data standards (content, transport, messaging) to ensure the ability to share, exchange and understand data from disparate data sources and across health IT systems.

Below we provide a summary of our recommendations and then further describe approaches to address ongoing challenges and barriers.

SUMMARY OF RECOMMENDATIONS

- **Develop a comprehensive national strategy for standards development, deployment, and adoption.** We urge NVCHS to help develop a national strategy for standards development and adoption across rulemaking authorities and Federal Programs. The strategy should address use of standard clinical terminologies, vocabularies, and data formats in addition to agreed-upon data exchange, transmission methodologies and data standards.

- **Prioritize the need for enhanced and accelerated development and adoption of data, transmission, and interoperability standards**. It is critical to have a robust, consistent, inclusive, and compliant approach to standards development. However, innovations in health and healthcare along with technology innovations are significantly outpacing the ability of standards development organizations to create and implement new standards or to update existing standards.

- **Consider standardization of electronic data capture and measurement.** Ongoing efforts to leverage EHRs and other data sources illustrate the need for a holistic approach developing and adopting standards for use across care settings. It is critical to leverage resources currently available and accessible to providers and to streamline administrative burden across Federal reporting programs.

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- **Address the need for public health data standards.** The COVID-19 public health emergency highlighted significant challenges to connect heath care and public health information systems. Among the contributing factors was inconsistent data and data definitions and incompatible standards. Interoperability between heath care and public health requires data standards.

- **Ensure health IT innovation and a competitive marketplace.** Additional actions are needed to further ensure a dynamic, competitive, and innovative healthcare information technology (IT) ecosystem that minimizes provider administrative, implementation and reporting burdens.

- **Inform the national strategy for patient matching and identification.** COVID 19 highlighted the urgent need to implement a national strategy around patient identity. NCVHS should address the need to improve patient identification and matching as part of its work on data and interoperability standards

Additional Discussion and Comments

Develop a comprehensive national strategy for standards development, deployment, and adoption.
We urge NVCHS to help develop a national strategy for standards development and adoption across rulemaking authorities and Federal programs. The strategy should consider terminology standards, content/format standards, data exchange/transport standards, and privacy and security standards and needs to identify more predictable, timely, transparent, and collaborative processes to accelerate, enhance, and expand standards development for administrative, public health, and clinical data. The strategy should also address how to ensure that a wider array of providers can more easily participate in standards development, testing, and adoption. It is critical to consider the inter-relationship and impact of standards across Federal agencies, such as the Center for Medicare and Medicaid (CMS) programs for quality, public health, and Promoting Interoperability reporting and the Office of the National Coordinator for Health Information Technology (ONC) roll out of the Trusted Exchange and Common Agreement (TEFCA).

A national strategy for standards development, deployment, and adoption is consistent with recommendations included in the recent Health Information Technology Advisory Committee (HITAC) Intersection of Clinical and Administrative Data Task Force (ICAD) report to ONC.[1] The ICAD recommended that ONC, working with CMS and other relevant Federal agencies establish a consistent process for standards advancement for relevant standards for health care interoperability, including transactions, code sets, terminologies/vocabularies, privacy and security used for conducting the business of health care, irrespective of whether that business is clinical or administrative.

Harmonizing and aligning regulatory rules and timelines (such as those required by CMS and ONC), as well as common standards, terms and terminology will help improve compliance and reduce the operational, implementation and reporting burdens on stakeholder subject to a myriad of new rules, each with its own different scope, definitions, and requirements. Ongoing disparate approaches to standards development adoption, and implementation risks misalignment of standards or versions of standards and adds complexity to efforts to achieve nationwide interoperability.

[1] https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

Standards development and adoption is complex, and standards may pertain to security, data transport, data format or structure, or the meanings of codes or terms.[2] [3] Various laws and regulations cover how administrative and clinical data are defined, recorded, standardized, and shared. A significant challenge is the sheer number of (health) standards development organizations (SDOs) each with disparate processes and sometimes overlapping areas of focus.

Across the many SDOs are numerous clinical data and health information technology standards and implementation specifications in various stages of finalization for industry piloting, use, and adoption to fulfill specific clinical health IT interoperability needs.[4] These clinical standards are in addition to the disparate standards and operating rules required for administrative transactions by HIPAA and subsequent legislation.[5] [6] All this makes the sharing, exchange, understandability and use of information more complex and cumbersome. However, the historically disparate standards development workstreams governing administrative and clinical data may no longer be appropriate, necessary, or relevant.[7] [8] We urge NVCHS to address these multiple and separate processes.

We urge NCVHS to address the need for enhanced and accelerated development and adoption of data, transmission, and interoperability standards to drive open data access across clinical, financial, public health, and administrative health IT systems. The healthcare eco-system is moving beyond simply recording data in EHRs and submitting data on claims toward integrating and combining data for multiple use cases to streamline analytics for evidence-based decision-making. The movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as accountable care organizations (ACOs) and bundled payments involve participation by multiple providers, suppliers and payers who are at risk for coordinating the care of patients, requiring the ability to access, integrate, and aggregate information from different EHRs, health IT applications and across multiple facilities and care settings. Yet clinical systems (EHRs), public health information systems and claims systems do not uniformly or consistently collect, define, or present data.[9]

Information that is electronically exchanged from one provider to another or one payer to another and from payers to providers should adhere to the same standards, and these standards should be implemented uniformly (within EHRs, practice management and billing systems) for the information to be understandable and usable, thereby enabling interoperability and robust data uses. Standards-based EHRs, practice management and claims processing systems that are consistently implemented will help minimize costs and service disruptions during systems' implementation and maintenance. We recommend that NCVHS build on the HITAC ICAD[10] recommendation that ONC and CMS jointly establish relevant certification criteria and urges ONC to establish a certification process for practice management system (PMS) software, in addition to the current EHR software certification process.

[2] https://www.healthit.gov/topic/standards-technology/health-it-standards
[3] https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/StandardsSettingandRelatedOrganizations
[4] https://www.healthit.gov/isa/
[5] https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA
[6] https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/StandardsAdoptionProcess
[7] https://journal.ahima.org/a-pathway-to-clinical-and-administrative-data-integration/
[8] https://www.ahrq.gov/talkingquality/measures/understand/index.html
[9] https://www.healthit.gov/sites/default/files/facas/2021-04-29_ICAD_TF_Findings_and_Recommendations.pdf
[10] https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

Providers' real-time access to robust claims and electronic health record (EHR) data is limited. We recommend that NCVHS efforts help accelerate adoption and consistent implementation of data and interoperability standards to support seamless and unfettered provider data access at the point of care and within the workflow including standardized (public and private sector) claims data. NCVHS should explore improvements to identifying and adopting new and revised standards and explore mechanisms for reconciling, aligning, and harmonizing administrative and clinical data standards.

We also urge NCVHS to recognize the need for accelerated progress on standards for multiple administrative, public health, and clinical use cases, including open APIs, Bulk Data on FHIR, CDS hooks, and standards for read-write, bi-directional data flows. We recommend that NCVHS advance efforts to align and optimize existing standards and approaches while considering emerging standards and technologies.[11] **NCVHS should also explore alignment and standardization of claims data and formats across payers**. We believe that CMS' projects (such as the Beneficiary Claims Data Access (BCDA) and the Data at the Point of Care (DPC) are a good first start toward availability and access to standardized claims data but not sufficient. Similar efforts are needed to include a broader array of providers and additional public sector (I.e., Medicare Advantage) and commercial payers.

Develop standards for electronic data capture and measurement**.** A holistic approach is needed for data standards whereby standards are developed and adopted for use across care settings. NCVHS should include efforts to advance the adoption and consistent implementation of data and interoperability standards so that provider data collection and reporting requirements are enabled by health information technology. **We strongly encourage NCVHS to focus efforts on driving toward standardization of electronic data capture and measurement, leveraging resources currently available and accessible to providers, and streamlining administrative burden across programs**.

Health systems are currently capturing sociodemographic data, but this information is not easily adaptable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the Centers for Disease Control and Prevention (CDC) to the Office of Management and Budget (OMB),[12] race and ethnicity codes captured in the EHR cannot be consistently mapped.[13] This is a result of lack of use of standard taxonomies—in part by the EHRs and in part by the providers to allow the category selections to align with how their populations would like to report information. Similarly, there are an abundance of tools to screen for social determinants of health with underlying definitions for certain social risk factors (e.g., food insecurity) significantly varying even when the same tool is used by different providers. Standardization is vital to providers' success in driving towards health equity, as it will foster the development and sharing of best practices within and among clinical settings, health systems, and delivery system designs.

Reports indicate[14] [15] [16] [17] that barriers health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve, addressing the needs of

[11] https://www.healthit.gov/sites/default/files/facas/2020-06-09_Premier_Presentation_508_0.pdf
[12] https://www.cdc.gov/phin/resources/vocabulary/documents/CDC-Race-Ethnicity-Background-and-Purpose.pdf
[13] https://www.ahrq.gov/research/findings/final-reports/iomracereport/reldata3fig3-3txt.html
[14] Kirst, M., Shankardass, K., Bomze, S. et al. Sociodemographic data collection for health equity measurement: a mixed methods study examining public opinions. Int J Equity Health 12, 75 (2013). https://doi.org/10.1186/1475-9276-12-75
[15] https://www.ahrq.gov/research/findings/final-reports/iomracereport/reldata5.html
[16] Williams-Roberts, H., Neudorf, C., Abonyi, S. et al. Facilitators and barriers of sociodemographic data collection in Canadian health care settings: a multisite case study evaluation.Int J Equity Health 17, 186 (2018). https://doi.org/10.1186/s12939-018-0903-0
[17] Office of the Assistant Secretary for Planning and Evaluation (ASPE). Second Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. 06/29/2020. (https://aspe.hhs.gov/pdfreport/second-impact-report-to-congress, a

these populations, and monitoring improvements over time. Findings note that the principal challenges in obtaining race, ethnicity, and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected. **We recommend that NCVHS help advance standards for the collection of sociodemographic and social risk factors data, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and Fast Healthcare Interoperability Resources (FHIR) standards.**

Another example is CMS exploring using FHIR for electronic clinical quality measures (eCQMs) and designing software solutions for digital quality measures to be compatible with any data sources that implement standard interoperability requirements. There are a limited number of common data elements across inpatient, outpatient, and post-acute care, however, these elements could serve as a starting point for cross-continuum patient assessment.[18] [19] A critical component to using FHIR for eCQMs is the adoption of bulk FHIR transactions to simplify and speed transmission. In the absences of bulk FHIR transactions, providers will be unable to support FHIR implementation. We urge NCVHS to recognize the need for CMS to work with ONC to advance the adoption and consistent implementation of data and interoperability standards so that provider data collection and reporting requirements are enabled by health information technology.

Address the need for public health data standards. One of the greatest challenges during the COVID-19 pandemic has been exchanging and sharing data between healthcare providers and public health authorities, as well as submitting data to meet federal and state reporting requirements. Current public health processes often rely on non-standardized data collection systems that are inadequate—data sets are often not consistent across states, or not harmonized with clinical care data standards. There are obstacles to connect public health information systems including incompatible standards. For example, data and interoperability standards facilitating providers' EHR connections for health information exchange do not align with public health use cases for transport and semantic interoperability.[20] [21] **We urge NCVHS to address the need for harmonized and consistent data and interoperability standards across the health care continuum and with public health,** including approaches to facilitate the interoperability, data sharing and exchange needs of providers not previously included in HITECH considerations for adoption and use of certified EHRs (such as for long term and post-acute care providers). The HITAC ICAD report[22] also discussed the benefit of harmonizing standards to create a consistent set of standards for Code Sets, Content and Services that are evolved together to address multiple workflows, both clinical and administrative.

Address the need for health IT innovation and a competitive marketplace. **We urge NCVHS to help ensure a dynamic, competitive, and innovative healthcare information technology (IT) ecosystem that minimizes provider administrative, implementation and reporting burdens**. NCVHS should consider issues related to end-user licensing of adopted standards, code sets and vocabularies. Costs related to licensing fees for HIPAA required standards, code sets and vocabularies contributes significantly to provider burdens. NCVHS should consider options to increase the participation of

[18] https://www.cms.gov/files/document/blueprint-codes-code-systems-value-sets.pdf
[19] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf
[20] Brian E. Dixon, Daniel J. Vreeman, Shaun J. Grannis, The long road to semantic interoperability in support of public health: Experiences from two states, Journal of Biomedical Informatics, Volume 49, 2014, Pages 3-8, https://www.sciencedirect.com/science/article/pii/S1532046414000781 https://doi.org/10.1016/j.jbi.2014.03.011.
[21] Connecting Public Health Information Systems and Health Information Exchange Organizations LESSONS FROM THE FIELD Published September 2017 https://stewardsofchange.org/wp-content/uploads/2018/03/FINAL_ONC_PH_HIE_090122017.pdf
[22] harmonize standards to create a consistent set of standards for Code Sets, Content and Services that are evolved together to address multiple workflows, both clinical and administrative

providers in the standards development process. Current time and resource constraints may be a limiting factor for some providers and clinicians.

We recommend that NCVHS consider the need for EHR platforms with open APIs for third party applications and new data sources. This is critical to fostering a robust and innovative health information technology and third-party application marketplace, allowing for easy-to-use applications for clinicians, and ensuing more efficient data reporting for public health and quality improvement. Open platforms are needed so that providers can improve care delivery, patient safety and performance, drive operational efficiencies and facilitate data sharing and exchange from new data sources, including patients and remote monitoring devices.

Inform the national strategy for patient matching and identification. COVID 19 highlighted the urgent need to implement a national strategy around patient identity. **We urge NCVHS to address the need to improve patient identification and matching as part of your work on data and interoperability standards**.[23] Accurate identification of patients is one of the most difficult operational issues during a public health emergency, including the gathering of patient demographic information (e.g.—address, phone, email, etc.) and ensuring such information remains attached to the correct patient. Temporary testing and vaccination sites in parks, convention centers, and parking lots have exacerbated these challenges.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to inform NCVHS discussion on healthcare standards development, adoption, and implementation. We look forward to working with NCVHS and other stakeholders to ensure interoperability to help transform care delivery and improve patient outcomes, especially as the U.S. health system transitions to value-based care and payment and embraces innovations for health information technology and personalized healthcare, and discovers new cures, therapies, and products.

If you have any questions regarding our comments or need more information, please contact me at blair_childs@premierinc.com or 202.879.8009 or Meryl Bloomrosen, Senior Director federal Affairs at 202.879.8012.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance

[23] http://patientidnow.org/wp-content/uploads/2021/04/Patient-ID-Now-Framework-Executive-Summary.pdf

Thursday, 29, July 2021

Dear NCVHS Subcommittee on Standards,

SNOMED International values the critical role the National Committee on Vital and Health Statistics (NCVHS) plays in providing the recommendations that lead to administrative and clinical data efficiency across the United States health data ecosystem. As a founding Member of SNOMED International (via the US National Library of Medicine), the United States continues to be an active part of our 41 Member organization.

As the owners of SNOMED CT, the most comprehensive, multilingual clinical healthcare terminology in the world, that is used in more than 70 countries, we appreciate this opportunity to provide feedback on your *Standardization of Information for Burden Reduction and Post-Pandemic America* project. As SNOMED CT is widely used in the United States in electronic clinical and dental systems and in other domains such as drugs, devices, etc., and a recognized standard for use in USCDI, we look forward to engaging with the United States on how SNOMED CT can continue to meet needs in clinical, administrative, public health, research and more.

SNOMED International appreciates the opportunity to provide feedback on the NCVHS Request for Public Comment on Healthcare Standards Development, Adoption and Implementation. Additionally, SNOMED International thanks the Subcommittee for the opportunity for Dr. James Case, SNOMED International Chief Terminologist, to provide a verbal testimony at the August 25th NCVHS Listening Session. We appreciate and welcome any questions or comments from the Subcommittee which can be addressed to Dr. Case (jca@snomed.org) or Suzy Roy (sro@snomed.org), the Customer Relations Manager for the Americas.

Sincerely,

Don Sweete
CEO
SNOMED International

SNOMED International Leading healthcare terminology, worldwide

SNOMED CT The global language of healthcare

SNOMED International responses to NCVHS request for public comment

1. **How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?**

Rooted in the organization's product and service strategy, SNOMED International has positioned its approach regarding Member and stakeholder needs to provide SNOMED CT as an integrated hub-and-spoke model for clinical terminologies with SNOMED CT as the the hub, or clinical reference terminology. This 'terminology integrator' approach provides opportunities for collaboration with other governments, regulators, clinical professional bodies, standards development organizations and many others. This helps to reduce the burden on governments and end users by providing links where it is most critical for data interoperability - at the terminology standard foundation.

Continued support for the harmonization of standards with SNOMED CT as the clinical reference terminology will help to facilitate interoperability. A product of our formal program of collaborating with partners, we provide crucial mapping files to key standards for the benefit of our users internationally. For example, in collaboration with the WHO, we have produced a SNOMED CT to ICD-9 map and more recently a SNOMED CT to ICD-10 map. As the WHO creates a new classification for countries to implement, SNOMED International is developing a mapping artifact to ensure the US and other SNOMED International Members will be able to fully encode and collect clinical data with SNOMED CT and with a map that allows for administrative reporting and billing with classification codes. The map helps to reduce end user burden by allowing for the technology to provide the mapping or the link from the SNOMED CT clinically enriched data to the statistical classification code. SNOMED International is also in the process of working with the American Medical Association on creating a bi-directional map between SNOMED CT and CPT (Current Procedural Terminology) for those customers that use both standards. These types of maps and collaborations amongst standard groups alleviates the need for users to remove the standards they have implemented and instead allows interoperability without incurring significant re-work costs.

More recently, SNOMED International participated in the WEB RADR 2 project resulting in SNOMED CT/MedDRA bidirectional maps. Through these efforts, users are now able to provide pharmacovigilance via the SNOMED CT encoded electronic health record data, which can be converted to MedDRA for the purposes of adverse event reporting for regulatory purposes or for epidemiological research. Conversely, the mapping files also provide clinical care decision support by notifying healthcare providers when prescribing, dispensing, or administering a

product that has a MedDRA coded adverse event, warning or other regulatory notice. Mappings such as these significantly help to improve interoperability by providing crucial patient-centered safety links between areas of the health data ecosystem that were previously decoupled.

In addition to the many collaborations that result in beneficial products for Members to use for interoperability solutions, SNOMED International also participates on the Joint Initiative Council for Global Health Informatics Standardization (JIC). As one of 10 participating standards development organizations (SDO), SNOMED International strives to work collaboratively to align the standards across the SDOs to help to reduce the burden on end users and facilitate conditions for interoperability. The JIC was created to provide a vehicle for SDOs to identify opportunities to collaborate with another and to engage in a manner that will help the international digital health community. Demonstrable progress on initiatives such as the International Patient Summary (IPS) continue to provide a way to help to further align standards to improve interoperability across the health data ecosystem.

There are some challenges of migrating existing local terminologies to a standard terminology; such as technical challenges of implementing a hierarchical and ontology based terminology in existing "flat" terminology structures in EHRs. SNOMED International has created the Global Patient Set (GPS) which can be used as an entry point for standard terminology use in the EHR. The GPS is a collective set of SNOMED CT Freesets, licensed under the Creative Commons Attribution 4.0 International License, allowing for free use by Members and the international community for the capture and exchange of health data. By including the IPS, content related to social determinants of health and COVID-19, and SNOMED CT Freesets such as general dentistry, nursing activities and health issues, DICOM, IHE Clinical Profiles and more, the SNOMED GPS is a good starter set for use in minimal datasets and ensures that interoperability between Members who utilize the full SNOMED CT terminology, and non-Members who utilize the GPS, will be able to exchange data.

2. **Are there any new standards or use cases available or under development that should be considered byby NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.**

While not new to the world of healthcare analytics, the ecosystem benefits of integrating and utilizing SNOMED CT in clinical information systems and health data and analytic platforms for interoperability are now being embraced. This is in large part because the use of SNOMED CT allows for the facilitation of electronic exchange of clinical data and documents among Care

Providers across the ever increasing continuum of care. SNOMED CT can be used to provide individual historical summaries and point-of-care reporting or clinical decision support as well as population analytics through trend analysis and pharmacovigilance. SNOMED CT encoded data also supports management analytics with comparative analysis as well as health system value analysis and clinical, laboratory and scientific research.

The breadth of SNOMED CT's clinical content continues to be enhanced through the inclusion of new terminology domains. This is made possible by our strong partnerships and collaborations with other standards development organizations and professional societies and domain experts. Content enhancement is critical for the ability to share data across disparate areas of health. SNOMED International has continued collaborations with the Academy of Nutrition and Dietetics (AND) with the incorporation of NCPT (Nutrition Care Process Terminology), a terminology used to describe the Nutrition Care Process into SNOMED CT. As well as new partnerships such as with the International Council of Nurses (ICN) on the inclusion of the International Classification for Nursing Practice (ICNP) so that the terms used by nurses to record observations and interventions are now included in SNOMED CT for use in the EHR. Other content integration with collaboration partners include areas such as rare diseases, digital imaging, and much more. The alignment with specialized areas of health with the SNOMED CT reference terminology will facilitate the ability to interoperate with many actors across health for the ultimate benefit of patients and citizens.

The recent release of Version 2 of the US Core Data for Interoperability (USCDI) from the Office of the National Coordinator for Health IT (ONC) highlights new strategic areas of interest that will help to reduce health inequality. The inclusion of sexual orientation and gender identity (SOGI) data elements help to move towards more equitable healthcare. SNOMED CT terminology was federally adopted for the 'Gender Identity' and 'Sexual Orientation' data elements within the 'Patient Demographic' data class.

Additionally, work by the Gravity Project, an HL7 Accelerator Project, has taken a consensus-driven method to discover the needs of social determinants of health data. The highly successful project has completed and balloted the 'food insecurity' domain and additional areas such as housing instability, transportation insecurity, and more continue. These efforts have led to the inclusion of USCDI data elements for social determinants of health. SNOMED International has been participating in Gravity since the project launch in 2019 and taken steps to ensure that content in-scope of SNOMED CT are included in the terminology and can be used for encoding, collecting, exchange and analysis of social determinants of health data. 5455 concepts related to social determinants of health are currently in SNOMED CT terminology and added to the SNOMED GPS to ensure global free use. Going forward, social determinants of health continue to be a feature domain in the SNOMED International strategy and roadmap.

SNOMED International applauds the NCVHS in their action to help to reduce health inequality both through the support of Gravity and also recognizing the importance of SOGI. The new USCDI and other initiatives from ONC and other HHS agencies align with SNOMED International's commitment to health data interoperability and also healthcare equality and safety for all.

3. **How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?**

Agile methodology has become the preferred approach for technical development. Every technology organization today practices a version of an iterative and incremental approach to providing a solution. Many other terminology standards publish annually with only a few publishing more frequently. SNOMED International has published the SNOMED CT International Edition every 6 months (31st January and 31 July) each year. But to ensure that the needed SNOMED CT technical design, content architecture, and terminology are available in the quickly evolving and agile industry, SNOMED CT will be moving to a more frequent delivery schedule. This will allow for less down-time between release cycles and enable faster turnaround of content. This will also provide improved time-to-market for important content changes - such as for vaccinations and diseases as just experienced with the COVID-19 pandemic. This will also provide a way to deliver the published terminology to key stakeholders at more frequent intervals - especially important as we continue to integrate or map with other terminologies and standards. And this more frequent, agile approach will benefit as we move to a more advanced, FHIR-exchange and AI-assisted health care world. Agile methodologies should be considered for artifacts, such as standards, in order to provide for the fast-moving and constantly evolving health care needs to ensure for patient safety and health. The move to more frequent releases allows flexibility for users who wish to move quickly with new content; however, this change still allows our more cautious users to continue at a pace that suits their requirements.

Additionally, use of new technology for the maintenance of terminology standards should be considered. Ensuring clinical quality is essential for patient safety. One recent employment of new technology for SNOMED CT terminology clinical quality is the use of a term validation service. This tool highlights potentially erroneous preferred terms and tags content for SNOMED CT terminologists to review. This balance of providing the content quickly with more frequent releases but also utilizing technology for maintenance will allow SNOMED International to continue to provide scientifically validated clinical content for users.

4. **What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?**

The iterative approach the US has taken for healthIT priorities has proven to be successful in many ways. For example, in the United States, SNOMED CT has been included as a required clinical standard since the enactment of Meaningful Use and now with USCDI. In addition to promoting the use of standards in electronic health records, HHS agencies have already taken steps to utilize health terminology standards that will prove beneficial for data interoperability, and their recipients, in the long-term. Examples include the FDA use of SNOMED CT in new biologic forms, NLM use of SNOMED CT in RxNorm, and NLM/FDA use of SNOMED CT in the Global Unique Device Identification Database (GUDID and Access GUIDID) for links to device information. These multiple points of SNOMED CT inclusion provide longer-term opportunities to have interoperability between dispersed areas of health information.

Long-term opportunities that build on current data captured at the point of care include use of clinical data analytics. Analytics may be used to describe, predict or improve clinical and business performance, to recommend action or guide decision making. Use of analytics can enhance the care of individual patients (via the retrieval of information for clinical care, integrating guideline and decision support, and retrospective searches for follow-up), populations (via epidemiological monitoring and reporting, research of causes and management of disease, and patient cohort identification), and provides cost-effective delivery of care (via guidelines to minimize risk of costly errors, reducing duplication of investigation and interventions, auditing delivery of clinical services, and in planning based on emerging health trends). The US is positioned to achieve opportunities for analytics based on previous and current healthIT initiatives due to the use of standards. SNOMED CT has a number of features which makes it uniquely capable of supporting a range of powerful analytics functions which can be achieved from inclusion of the terminology standard in the clinical record.

Continued iterative additions of data classes and elements to USCDI, and in other HHS initiatives, will help to advance the data collection and exchange. SNOMED International encourages NCVHS to keep data analytics as a goal and to expand beyond data collection for billing and reporting. Being able to provide decision support and public health surveillance will benefit the patients, care providers, and population health. Continued support of standards such as SNOMED CT will help these long term goals.

For more detail on the information provided by SNOMED International, please contact Dr. James Case (jca@snomed.org), or Suzy Roy (sro@snomed.org).

surescripts

July 30, 2021

Submitted by electronic mail to:
NCVHSmail@cdc.gov

Rebecca Hines, MHS
Executive Secretary, NCVHS
National Center for Health Statistics, Centers for Disease Control and Prevention
3311 Toledo Road
Hyattsville, Maryland 20782

Re: Request for Public Comment

Dear NCVHS Committee Members:

Surescripts appreciates the opportunity to respond to the National Committee on Vital and Health Statistics' (NCVHS') request for public comment. We believe NCVHS plays a very important role in steering HHS's priorities with respect to the collection and exchange of health data. We have responded to NCVHS' four questions below, and welcome efforts by the Committee to streamline the health IT standards-making process to promote interoperability.

Surescripts serves the nation with the most trusted and capable health information network, built to increase patient safety, lower costs, and ensure quality care. Founded in 2001 to enable electronic prescribing, today we are drawing on that experience to exchange many other kinds of actionable patient intelligence—including medication histories, prior authorizations, and other complex clinical messages. The Surescripts Network Alliance includes virtually all electronic health record (EHR) vendors, pharmacy benefit managers (PBMs), pharmacies and clinicians, plus health plans, long-term and post-acute care organizations and specialty hubs and specialty pharmacy organizations. In 2020, we transmitted 17.5 billion secure health data transactions—including 1.91 billion e-prescriptions and 1.95 billion medication histories—and connected 2 million healthcare professionals, who rely on a master patient index covering 95% of the U.S. population. Additional information about Surescripts is available at surescripts.com. For more data on how we're advancing nationwide health information exchange, please see our National Progress Report, available at https://surescripts.com/report.

(1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

One current barrier to the exchange of health information is the lack of a uniform process or standard for patient matching. For e-prescribing transactions, Surescripts has deployed its own master patient index, which allows health care providers to uniquely identify and securely access prescription data of over 324 million patients. However, we understand that matching patient data that is not connected through a master patient index can be more difficult. We applaud ONC's efforts through @ProjectUS to standardize the collection of mailing addresses by health IT developers, but we believe further efforts to improve patient matching are needed to facilitate data sharing and instill trust in health information exchange. Surescripts

would be happy to offer NCVHS additional information on the lessons it has learned from development of a leading master patient index.

(2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

Surescripts asks that NCVHS review the "Referral Certification and Authorization Transaction" under 45 C.F.R. § 162.1201 and recommend that HHS either: 1) clarify that electronic prior authorization transactions for prescription drugs are not covered by this transaction; or 2) adopt NCPDP SCRIPT 2017071 as the required standard for all electronic prior authorization transactions involving prescription drugs.

Under 45 C.F.R. § 162.1201, HIPAA defines the "Referral Certification and Authorization Transaction" as "a request from a health care provider to a health plan for the review of health care **to obtain an authorization for the health care**." (emphasis added) Under this transaction, HIPAA requires the use of ASC X12 278 for "dental, professional, and institutional request for review and response". There is no reference in the regulation to the use of the transaction for obtaining prior authorization for a prescription drug, which, unlike a professional or institutional request for prior authorization, is essentially a justification for a *pharmacy* to distribute health care to the patient (not the dental, professional or institution itself to distribute medical care). Extensive due diligence by the industry has shown that **the ASC X12 278 standard is not sufficient for ePA workflows for prescription drugs**. NCPDP began standards development work to create the NCPDP SCRIPT ePA transactions as a result of an ePA pilot conducted in 2006 that evaluated the efficacy of the ASC X12 278 and ASC X12 275 transactions for ePA. The pilot found that ASC X12 transactions were sub-optimal for the support of ePA for medications and did not offer improvements in administrative efficiency. **It is clear from studies and research that the ASC X12 prior authorization transactions named under HIPAA are for *medical benefits* and are not effective for the exchange of information related to prior authorizations of products covered under a pharmacy benefit.**

WEDI stated the following in a white paper produced in 2019 on the prior authorization process:

> "Electronic prior authorization (ePA) transactions for drugs covered under the pharmacy benefit have been developed as part of National Council for Prescription Drug Programs' (NCPDP's) SCRIPT e-prescribing standard. **The NCPDP ePA transactions have achieved significant penetration in the marketplace and have had a meaningful effect on administrative burden placed upon providers by medical policies developed to ensure the appropriate use of pharmaceutical therapies**." (emphasis added)

WEDI's endorsement of NCPDP SCRIPT for ePA, and recognition of NCPDP SCRIPT's significant penetration in the industry should give NCVHS and HHS pause about interpreting the "Referral Certification and Authorization Transaction" to encompass electronic prior authorization transactions. When viewed in combination with CMS's recent naming of the NCPDP SCRIPT standard for electronic prior authorization transactions for drugs prescribed under Medicare Part D, prescribers and EHR vendors would potentially need to adopt and use two different transaction standards depending on whether or not the patient is covered under a Part D prescription drug plan. **NCVHS should therefore push HHS to clarify the "Referral Certification and Authorization Transaction" to eliminate any industry confusion about the**

permissible use of NCPDP SCRIPT 2017071 for prior authorization transactions with prescription drug plans outside of Medicare Part D.

(3) How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

The majority of health care standards development is currently dependent on HHS conducting notice and comment rulemaking to require implementation of standards or new versions of standards. While this process has spring-boarded adoption of health IT standards by the industry, it has also unintentionally stalled innovation – as HHS cannot conduct notice and comment rulemaking quickly enough to keep up with industry advancements.

For example, under the Medicare Modernization Act, CMS has the sole authority to update the NCPDP SCRIPT standard through notice and comment rulemaking. Prescribers and pharmacies cannot participate in Part D plans unless they use the version of NCPDP SCRIPT selected by CMS, so under the current law industry cannot even pilot new standards until CMS advances the standard through notice and comment rulemaking. Since CMS first adopted the NCPDP SCRIPT standard for electronic prescribing in 2005, CMS has only updated their selected version of the SCRIPT standard through regulation two times. As a result, **the standard that is currently effective under CMS rulemaking contains technology that is more than a decade old.** Meanwhile, NCPDP has published 39 versions of the standard in the same period of time. Importantly, the requirement for CMS rulemaking prior to testing or movement to a new version of the SCRIPT standard has not resulted in *any* substantive changes to the consensus recommendations of NCPDP.

As a result of this time-consuming and valueless process, the industry has not been able to implement in a timely manner the technological innovations contained in NCPDP-approved additions to the SCRIPT standard, such as new fields for prescribers to communicate allergy and substance use history to pharmacies, and to send certain specialty and compound prescriptions electronically. What is most concerning about the current requirement for CMS to use notice and comment rulemaking to approve any changes to the SCRIPT standard is that patients and their prescribers and pharmacies are unable to timely benefit from innovations in electronic prescribing technology.

In other industries, government agencies have allowed standards development organizations to play a more direct role in setting standards. For example, the Securities and Exchange Commission (SEC) requires public, private, and not-for-profit organizations to follow “Generally Accepted Accounting Principles” or “GAAP” when providing financial reports to investors and potential investors. GAAP is a standard established by the Financial Accounting Standards Board (FASB), an independent, private-sector, not-for-profit organization that the SEC has delegated the responsibility to the FASB to establish and modify GAAP. FASB has a very deliberate stakeholder process when it considers any changes to GAAP. When FASB approves changes to GAAP, the SEC does not need to engage in notice and comment rulemaking to ratify the changes. Rather, once FASB approves the changes, industry must adopt them.

The Internet is another example where the United States and other governments of the world have largely deferred to independent standards development organizations to dictate content and transport standards. Although the initial infrastructure for the Internet was created by a government agency (i.e., DARPA), now the Internet Architecture Board and Internet Engineering Task Force (IETF) provide long-term technical direction for the evolution of the Internet and related standards. The IETF’s unofficial motto is “we believe

in rough consensus and running code", emphasizing that *implementation experience* provides critical feedback to the standardization process.

Even within the health industry itself, HHS has more fully delegated the development of certain content standards without the need for further notice and comment rulemaking to ratify updates. The American Medical Association (AMA) updates Current Procedural Terminology (CPT), the code set used to bill outpatient and office procedures. CMS incorporates the latest CPT code set into the Healthcare Common Procedure Coding System (HCPCS), which CMS has established as part of the HIPAA standard transaction requirements. The development of new CPT codes occurs within the AMA's well-defined and organized process and is not subject to the regulatory notice and comment process.

We ask that NCVHS consider and recommend more direct processes in health IT standards development that would allow consensus-based ANSI accredited SDOs to lead the adoption and advancement of standards.

(4) What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

In the short term, we would like to see HHS improve the processes for adopting new versions of e-prescribing standards and allow industry greater leeway to pilot advancements in standards. The Standards Version Advancement Process – developed by ONC under the 21st Century Cures Act Final Rule – is a step in the right direction. Under this process, industry stakeholders may ask ONC to recognize a newer version of a standard required under the Health IT Certification Program, allowing health IT developers to voluntarily adopt the new version without jeopardizing their compliance with ONC's certification criteria. We believe that e-prescribing standards, such as NCPDP SCRIPT, are prime candidates for the voluntary adoption of newer standards through the SVAP.

Surescripts notes, however, that under the current regulatory framework ONC would be unable to apply the SVAP to the NCPDP SCRIPT standard unless CMS first issued an interim final rule to recognize a version of the NCPDP SCRIPT standard as backwards compatible, or CMS engaged in notice and comment rulemaking to advance the NCPDP SCRIPT standard. We believe the SVAP would be considerably more effective for e-prescribing if it could be used to allow voluntary adoption of a new version of the NCPDP SCRIPT standard by prescribers, pharmacies, and Part D prescription drug plans *without CMS rulemaking*. As a result, **we ask that NCVHS recommend that HHS re-delegate the authority to name the standard for e-prescribing, medical history and electronic prior authorization transactions for Part D prescription drug plans from CMS to ONC. This would create a paradigm similar to the Promoting Interoperability program, where CMS would be responsible for outlining the required functionality for a Part D e-prescribing program, and ONC would be responsible for identifying the standards and implementation specifications for the required functionality.**

We also hope that HHS will take steps in the near term to eliminate barriers to health information exchange posed by health privacy rules that are more stringent than HIPAA. For example, 42 C.F.R. Part 2 prevents substance use treatment providers from sharing substance use disorder medical records for treatment, payment, and health care operations purposes without a very specific type of written consent from patients. This limitation has jeopardized patient safety, preventing primary care providers and specialists that provide concurrent care to see vital information about the patient's substance use disorder treatment. Under the CARES Act, Congress directed HHS to engage in notice and comment rulemaking by March 2021 to modify

42 C.F.R. Part 2 to allow sharing for treatment, payment, and health care operations under an umbrella patient consent at the beginning of substance use disorder treatment. HHS has not yet published a proposed rule to implement Congress's direction. We hope HHS will act quickly on this, and that it will look for other ways to streamline state and federal privacy laws for the easier exchange of health information between providers.

Thank you for the consideration of our views. Please do not hesitate to contact me with questions or for further information.

Sincerely,

Mary Ann Chaffee

Vice President for Policy and Federal Affairs
Surescripts
maryann.chaffee@surescripts.com

TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

July 30, 2021

Richard Landen, Co-Chair
Denise Love, Co-Chair
National Committee on Vital and Health Statistics
Subcommittee on Standards
3311 Toledo Rd.
Hyattsville, MD 20782-2002

Via: NCVHSmail@cdc.gov

RE: Comments NCVHS Standards Subcommittee | Federal Register Notice

Dear Co-Chairs Landen and Love:

On behalf of the Texas Medical Association (TMA) and our more than 55,000 physician and medical student members, thank you for the opportunity to provide input ahead of your Aug. 25 stakeholder listening session.

TMA offers the following feedback on the questions posed to stakeholders:

1. How can data sharing be improved between patients, providers, payers, public health systems, and other actors in health care? What are the barriers to these improvements?

Improving interoperability: More than a decade after the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, there are still many significant barriers to true interoperability that meets one of the Office of the National Coordinator's (ONC's) goals of "a learning health system where individuals are at the center of their care and providers have a seamless ability to securely access and use health information from different sources."[1] The following are suggested improvements:

- **Data available for exchange must be focused and clinically relevant to the recipient.** Rather than the intended focused set of data that is useful for clinical care, consolidated clinical document architecture (CCDA) documents frequently are a hodgepodge created to meet government requirements. We have seen examples of these documents missing problem lists, medications, allergies, and other key data as each organization creates its own approach without any feedback from clinical recipients. We also have seen examples of "CCDA bloat" where the problem list and imaging reports, as examples, contain reams of clinically useless data.

[1] HealthIT.gov; www.healthit.gov/topic/interoperability; accessed July 28, 2021.

An example using a typical lab (bilirubin) that is done on virtually all normal newborns might be illustrative. Should every single bilirubin value be reported to the follow-up clinician? Most would answer resoundingly "no" in virtually all cases. Then what is the clinically relevant data? Is it the rate of rise? The most recent bilirubin value and the hour after birth it was obtained? Is it the infant's risk factors for kernicterus presented clearly and in a standard format? Currently, there is no guidance from professional societies as to what's important and what's not, so each hospital creates its own approach to this. Some put the risk factors in notes. Others put the risk factors in the problem list. Others don't include them at all. The result is that follow-up clinicians are often confused, ill-informed, and frustrated. The simple bilirubin case is just one small example. Follow-up of pediatric and adult diabetics admitted for ketoacidosis are equally challenging in terms of deciphering what was done and what needs to be done. The number of use cases is enormous but not infinite. TMA recommends that NCVHS encourage quality measure development reflective of TMA's policy[2]:

> Evidence-based quality-of-care measures must be the primary measures used in any program.
>
> 1. All performance measures used in the program must be defined prospectively and developed collaboratively across physician specialties.
> 2. Practicing physicians with expertise in the area of care in question must be integrally involved in the design, implementation, and evaluation of any program.
> 3. All performance measures must be developed and maintained by appropriate professional organizations that periodically review and update these measures with evidence-based information in a process open to the medical profession.
> 4. Performance measures should be scored against both absolute values and relative improvement in those values.
> 5. Performance measures must be subject to the best available risk adjustment for patient demographics, severity of illness, and comorbidities.
> 6. Performance measures must be kept current and reflect changes in clinical practice. Except for evidence-based updates, program measures must be stable for two years.
> 7. Performance measures must be selected for clinical areas that have significant promise for improvement.

Interoperability isn't just about creating the pipes to move data. It's also not just programming computers to "read" what is received. It *is*, and perhaps most importantly, the usability of the data received. The approach taken to date is that it's the recipient's responsibility to make sense of the flood of data, rather than having standards that focus the flow to what's needed, relevant, and appropriate at the point of care. TMA strongly supports efforts to foster this approach using Fast Health Interoperability Resources (FHIR). We also recommend support for professional organizations to develop what data should be available for use cases and how these data should be communicated. This isn't a simple or quick approach, but it's necessary.

[2] TMA Policy Compendium; 265.017 Pay-for-Performance Principles and Guidelines; www.texmed.org/Policy; accessed July 28, 2021.

- **Data available for exchange must be ubiquitously available and easy to access.** Unfortunately, competing proprietary electronic health record (EHR) vendors and the patchwork of local health information exchanges (HIEs) have made it difficult for physicians to purchase off-the shelf tools that quickly connect to the data they need. **In most cases, it is a capital expense in physician budgets to connect to external sources. This causes undue financial burden to physicians who are continuously challenged with increased expenses and often-declining revenues.** In addition to interface fees, physicians must pay ongoing monthly fees to maintain the interface. If we are serious about interoperability, EHRs must come with it preinstalled and working immediately. It should no longer be viewed as an add-on.

  This "built-in" data-sharing should require local and national HIEs and EHR vendors to develop and test the needed connections for seamless bidirectional exchange in advance of product general availability so that physicians are not burdened with the expense of "connecting the pipes." Physicians want to be able to securely, with minimal extra effort, and within their normal workflow, send, receive, and use relevant patient information.

  The NCVHS subcommittee on standards should consider the example set by Appriss, the prescription monitoring program (PMP) vendor for more than 42 states. Appriss built the interface with the vendors so that when it is installed and updated, physicians automatically, within their workflow, have access to PMP information on a patient when launching a prescription for that patient. This did not require additional effort or cost by the physicians. In fact, since the state of Texas funded the integration for the state PMP, Texas physicians did not even need to make the request to have access to the PMP. It just appeared one day and worked – to the satisfaction of physicians needing access to the PMP.

  In contrast, TMA recently heard from practices working to comply with the 21st Century Cures Act by giving patients access to their information immediately upon request. In attempting to put radiology reports on the patient portal, practices are having to concoct an arduous workaround. A radiology report should be easily uploaded to the patient portal. According to the EHR vendor's technical guidance, practices have to take the EHR vendor's default .tif file, which cannot be published to the vendor's portal, and convert it to a .pdf file, which the portal supports. To accomplish this, *for each image*, staff must exit the secure EHR and complete the transformation by printing and scanning. Staff then have to log back into the EHR, upload the .pdf and publish it to the portal. **This task repeated many times over is an enormous undue burden and expense to the practices and is fraught with safety and security issues.** Sadly, the EHR used by these practices is one of the largest ambulatory vendors in the country. EHRs, as part of certification, are required to perform certain functions, but those functions do not have to performed efficiently. TMA urges the common-sense implementation of requirements that efficiency must be part of certification.

- **Additional regulations and standards need to be evidence-based rather than consensus-driven and should have meaningful post-implementation evaluation.** Technology in most other aspects of life such as banking, travel, and shopping have improved exponentially over the past decade. EHRs are a glaring exception, with many physicians still expressing frustration and experiencing burnout. A recent (2020) survey of TMA physicians indicated that 33% are either

somewhat or very dissatisfied with their EHR.[3] Perhaps more important, 58% reported that data entry at the point of care interferes with their diagnostic thought process, and 68% reported that use of the EHR interferes with communication and attentiveness to the patient.

As the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services, and ONC place more regulatory requirements on physicians requiring technology components for interoperability, TMA pleads for thorough development and testing of those new requirements prior to widespread deployment.

2. Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

TMA is not aware of any additional technical standards that should be considered. However, as outlined in the answer to the first question, an enormous number of use cases need to be defined and standardized – much like the many different situations that pilots may experience in flight.

In creation of new requirements, TMA strongly urges consideration of data formats that minimize the effects of artifacting, as file types such as .jpg can lead to loss of image quality across multiple file transfers, which may prove detrimental to the long-term preservation and use of an image.

3. How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

While health care is unique regarding data exchange, privacy, and security, it is not unique in terms of having use cases that need standard data and standard display for appropriate care. Just as aviation has slowly developed use cases and standard data requirements for the large number of situations that can occur in flight, medicine needs to do the same at warp speed to catch up. While aviation is the industry best known to have defined use cases and requirements, many other high-reliability industries have done this.

4. What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Short-term: HHS should reevaluate ONC's implementation of the 21st Century Cures Act as related to information blocking. TMA supports the concepts of making sure patients have access to their health information, but as health care works towards compliance, we find nuances that were not considered. The recent requirement that significantly abnormal test results must be released before they are finalized with a physician review, while noble in intent, is generating underreported problems that are damaging to patients and physicians. As examples, patients in emergency departments (EDS) are now seeing radiology and lab reports before the treating ED physician and coming to their own conclusions,

[3]Survey of Texas Physicians: Health Information and Technology; www.texmed.org/uploadedFiles/Current/2016_Practice_Help/Health_Information_Technology/2020%20HIT%20Survey%20Final%20Report.pdf; deployed August 2020.

sometime incorrectly, about whether additional care is needed. There are multiple examples of issues in pediatrics, especially regarding adolescent privacy and newborn records in the case of divorced parents. For example, the newborn chart may contain sensitive health information about the mother that would be available to the father requesting the child's record. These are just a few examples of use cases that need evidence-based professional society guidance as to how they should be handled in a standard way across the country.

Short-term: Greatly increased cyber security support, with a national approach is needed. Expecting each physician practice to have to figure out how to protect against international cyber villains is not feasible.

Mid-term: HHS should use policy levers that require certified vendors to develop and test interfaces with HIEs that can easily be deployed to physicians with little effort and at no cost to physicians. HHS should also support professional societies in the creation of the data use cases, tools, and filters to provide clinicians with focused, meaningful information, not tsunamis of data.

Mid-term: It is extremely costly for physicians to convert from one EHR to another. The ability to switch vendors quickly and easily would bring rapid improvements in EHRs. TMA supports the development and enforcement of standards and systems that allow ALL data to be efficiently, accurately, inexpensively, and quickly migrated to a new EHR just as smart phone users can switch data providers and have all applications, contacts, photos, and other data seamlessly and completely moved across platforms. TMA has requested and advocated for this for nearly a decade, and there's little evidence of progress towards this goal.

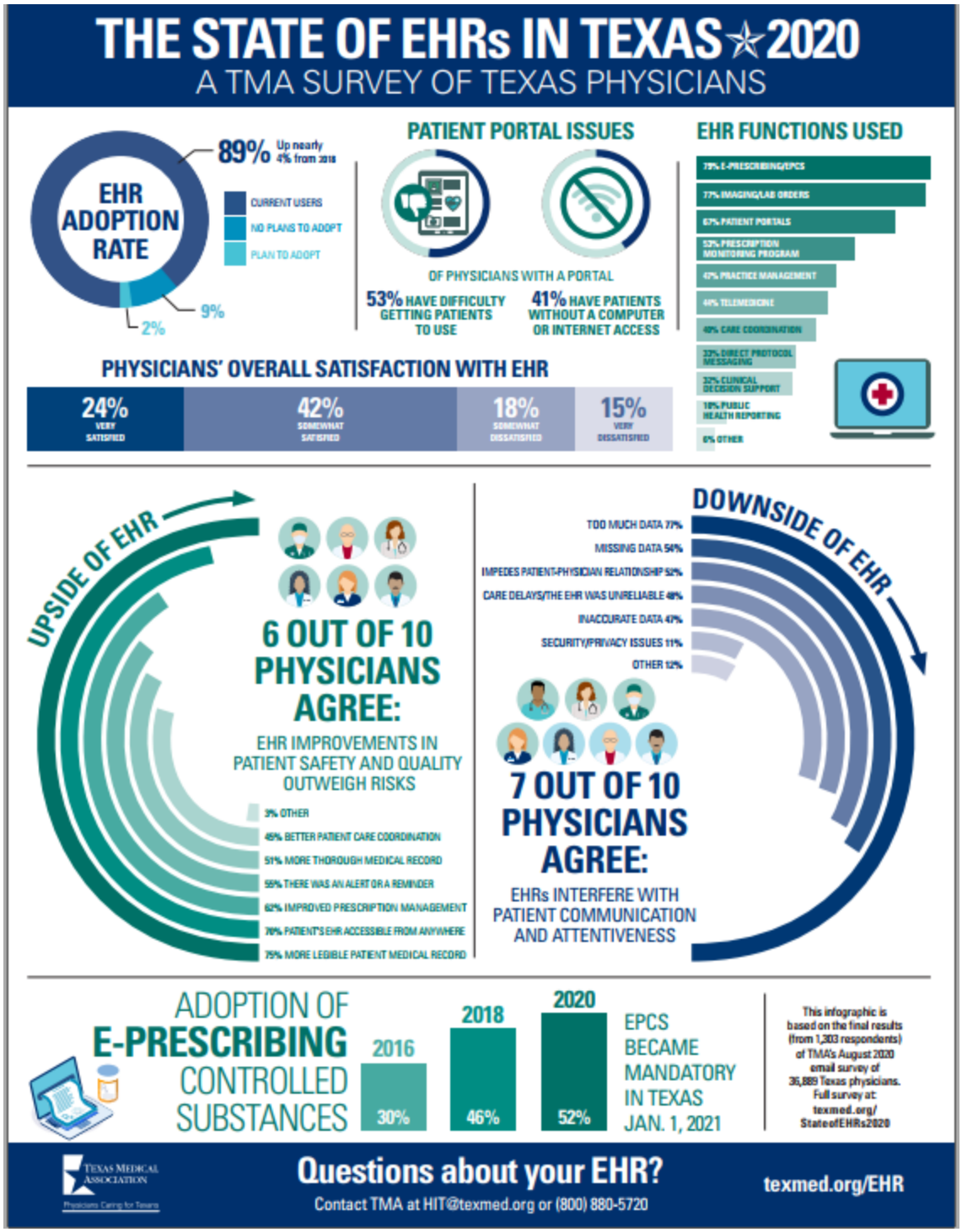
Mid- to long-term: HHS must reconsider patient portals. Currently patients under the care of multiple physicians have multiple portals with separate log-ins, passwords, and platforms. While this works for banking, it doesn't work for health care to have a patient's health history spread across multiple computer systems. Clinical decision support and artificial intelligence tools have to be made enormously more complex when the data is in multiple places, with the potential for data conflicts. Patients' portals must be combined into one easily accessible portal containing all necessary health information for the patient. This should be combined with a "patients should share responsibility for their own medical records" awareness program.

TMA appreciates the opportunity to provide this important feedback to NCVHS. Any questions may be directed to Shannon Vogel at TMA by emailing shannon.vogel@texmed.org or calling (512) 370-1411.

Sincerely,

Ogechika Alozie, MD, MPH
Chair, Committee on Health Information Technology
Texas Medical Association

Attachment: Infographic | The State of EHRs in Texas 2020


THE STATE OF EHRs IN TEXAS ★ 2020
A TMA SURVEY OF TEXAS PHYSICIANS
EHR ADOPTION RATE
89% Up nearly 4% from 2018
CURRENT USERS
NO PLANS TO ADOPT
PLAN TO ADOPT
9%
2%
PATIENT PORTAL ISSUES
OF PHYSICIANS WITH A PORTAL
53% HAVE DIFFICULTY GETTING PATIENTS TO USE
41% HAVE PATIENTS WITHOUT A COMPUTER OR INTERNET ACCESS
EHR FUNCTIONS USED
79% E-PRESCRIBING/EPCS
77% IMAGING/LAB ORDERS
67% PATIENT PORTALS
52% PRESCRIPTION MONITORING PROGRAM
47% PRACTICE MANAGEMENT
44% TELEMEDICINE
40% CARE COORDINATION
33% DIRECT PROTOCOL MESSAGING
32% CLINICAL DECISION SUPPORT
10% PUBLIC HEALTH REPORTING
6% OTHER
PHYSICIANS' OVERALL SATISFACTION WITH EHR
24% VERY SATISFIED
42% SOMEWHAT SATISFIED
18% SOMEWHAT DISSATISFIED
15% VERY DISSATISFIED
UPSIDE OF EHR
6 OUT OF 10 PHYSICIANS AGREE:
EHR IMPROVEMENTS IN PATIENT SAFETY AND QUALITY OUTWEIGH RISKS
3% OTHER
45% BETTER PATIENT CARE COORDINATION
51% MORE THOROUGH MEDICAL RECORD
55% THERE WAS AN ALERT OR A REMINDER
62% IMPROVED PRESCRIPTION MANAGEMENT
70% PATIENT'S EHR ACCESSIBLE FROM ANYWHERE
75% MORE LEGIBLE PATIENT MEDICAL RECORD
DOWNSIDE OF EHR
TOO MUCH DATA 77%
MISSING DATA 54%
IMPEDES PATIENT-PHYSICIAN RELATIONSHIP 52%
CARE DELAYS/THE EHR WAS UNRELIABLE 48%
INACCURATE DATA 47%
SECURITY/PRIVACY ISSUES 11%
OTHER 12%
7 OUT OF 10 PHYSICIANS AGREE:
EHRs INTERFERE WITH PATIENT COMMUNICATION AND ATTENTIVENESS
ADOPTION OF E-PRESCRIBING CONTROLLED SUBSTANCES
2016 30%
2018 46%
2020 52%
EPCS BECAME MANDATORY IN TEXAS JAN. 1, 2021
This infographic is based on the final results (from 1,303 respondents) of TMA's August 2020 email survey of 36,889 Texas physicians. Full survey at: texmed.org/StateofEHRs2020
TEXAS MEDICAL ASSOCIATION
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National Committee on Vital and Health Statistics
Subcommittee on Standards
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

July 30, 2021

Via: NCVHSmail@cdc.gov

Re: Request for Public Comment on Health care Standards Development, Adoption and Implementation

Dear Mr. Landen and Ms. Love:

WEDI is pleased to submit the following letter in response to the Request for Public Comment (RPC) from the National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee entitled "Healthcare Standards Development, Adoption and Implementation" published on June 18, 2021. We believe this RPC process is an important step toward improving the identification and implementation of standards that will streamline communications between patients, providers, health plans, and other health care stakeholders.

WEDI, formed in 1991, is the leading authority on the use of health information technology (health IT) to enhance the quality of care, improve efficiency, and reduce the costs of our nation's health care system. WEDI's membership includes a broad coalition of organizations, including hospitals, providers, health payers, vendors, government agencies, consumers, not-for-profit organizations, and standards development organizations (SDO). WEDI was designated in the 1996 Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the U.S. Department of Health and Human Services (HHS).

There are significant opportunities to improve the current process for identifying, developing and adopting new and revised health care standards, deployment of new workflows, encouraging wide-spread use of the standards, and enforcing compliance with mandated standards. We note that transitioning from one set of X12 standards to a new version has been needlessly protracted with a number of federally mandated standards still waiting to be promulgated. For example, the X12 275 electronic transaction has yet to be published, despite two statutory requirements and four separate letters sent by the NCVHS to the Secretary of HHS calling for its release. Many of the currently mandated standards are being underutilized and industry stakeholders are increasingly leveraging proprietary web portals instead of

taking advantage of electronic data interchange. In addition, future standards and regulations are vital to further promote secure and timely bi-directional data exchange. We encourage the sharing of data between payers and providers, as well as other appropriate health care stakeholders, as we believe this will lead to increased efficiency, support the transition to value-based care, and improved clinical outcomes.

Summary of Key Recommendations

- Implementation of new or revised standards should promote a transition that facilitates seamless, automated data exchange through mature, clear, and unambiguous standards that have been thoroughly tested and demonstrate meaningful and positive change for the health care community.
- Any new or revised standard must have the ability to be integrated easily within the provider and payer workflows.
- A direct improvement to the care delivery process and a return on investment (ROI) must be established prior to the mandating of any new or revised standard.
- As new or emerging standards are being developed, Social Determinants of Health (SDoH) data elements must be incorporated by applicable SDOs.
- The current lengthy time periods between mandated standards must be replaced with a process that identifies and implements innovation with an accelerated timeline.
- Where there is limited industry experience with a standard, expedited real-world testing and piloting, should be conducted prior to mandating.
- A reasonable and achievable implementation glidepath must be developed to ensure a seamless transition to any new or revised standard and to minimize industry disruption.
- Once an ROI or business need is established, HHS should expeditiously release regulations establishing national standards for electronic attachments, electronic acknowledgements, prior authorization automation, and regulations supporting the No Surprises Act.
- Achieving administrative automation should be viewed as a "public good" as it will benefit patients and other health care stakeholders. As such, government funding should be made available to support industry efforts to develop and implement new and revised standards.

NCVHS Question: 1a: How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care?

Standards Development Process

- Demonstration of ROI: We strongly support the expedious completion of a cost-benefit analysis of a new or revised standards or operating rules to demonstrate ROI prior to adoption. Understanding the economic impact that a new or revised standard will have on stakeholders is critical. Standards should not be required prior to a demonstrable clinical improvement for the patient or economic value to the system. In addition, we recommend that an economic and clinical impact analysis be completed on a periodic basis following adoption of a standard to better understand of the costs and benefits to industry stakeholders. Rather than create a new organization to undertake these types of studies, we encourage the NCVHS to look to existing entities, such as WEDI, to perform these tasks. HHS should fund these studies as an integral component of the standards development process.

- Ensure stakeholder access to the standards development process: Any new or revised standard must work for practicing physicians, inpatient facilities, other providers, health plans and vendors. As such SDOs

should augment engagement efforts to ensure that all stakeholder groups, especially smaller organizations, are consulted during the standards development process.

- Appropriate timing for release of regulations: HHS should expedite the publishing of regulations for a new or revised standard or operating rule once a recommendation has been made by the NCVHS and agreed to by the Secretary, but we disagree with putting a specific time frame on publication of regulations for new standards. At the same time, there is a need for increased speed and predictability in the development and implementation of standards and operating rules. We understand that requiring the publication of regulations within one year of receipt and acceptance of a recommendation for a new or revised standard or operating rule may not always be appropriate, as factors such as other regulations that would compete for stakeholder resources may necessitate use of an alternative timeline for the industry. However, the current lengthy time periods between mandated standards must be replaced with a process that identifies and implements innovative solutions that solve business challenges with an accelerated timeline.

- Consider adopting individual transaction standards: HHS should consider the option of adopting a single transaction standard as opposed to implementing a full version set (i.e., X12 008010). For example, there may be a business need and clear ROI for an update to a specific standard (i.e., 006020 X12 278) but less clear value for other transactions. We encourage the NCVHS to consider, when appropriate, recommending the adoption of a specific standard and not be forced to incur the lengthy process required to evaluate and implement a full suite of a new version.

- Patient care must be at the center of the standards process: The underlying foundation for deploying any new standard must be the improvement of patient care. This could be a standard that has a direct impact on clinical care, such as a new standard that improves data exchange, or one that decreases administrative burden and cost during the care delivery process.

- Implementation guides: Implementation guides (IGs) cited as references to mandated standards must have a sufficient level of maturity. Adequate time and multi-stakeholder input is needed for IG development and to incorporate feedback from early adopters. IGs should also offer sufficient specificity to define the appropriate themes of patient consent. Without defined patient consent models, implementation is difficult.

- Real-world testing and piloting: No standard without sufficient industry experience should be recommended for a federal mandate prior to being fully tested or piloted in a “real-world” environment. This testing approach will both ensure that a new standard will work in the current business environment and build support within the health care community for adoption.

- HIPAA waiver education: CMS has instituted a process that permits providers, payers, clearinghouses, and supporting vendors to voluntarily use new or revised standards prior to federal rulemaking. The agency also requires participating entities to submit a report outlining the results of the testing, including a cost-benefit analysis. We strongly support this waiver and report process and urge CMS to consider funding these testing efforts and expanding industry awareness of the waiver process.

  WEDI strongly opposes any stakeholder requiring, through contract, another stakeholder to use a standard other than what is adopted as a national standard. We recommend that any entity wishing to use a new or revised standard be required to include in their application a statement from all participating entities that they are willing and able to conduct transactions using the new or revised standards. This process will avoid a situation where participants are being coerced to participate.

- Creation of an effective implementation glidepath: For mandated standards, it is important to create a glidepath that serves to support the industry as it transitions to a new standard. A successful implementation glidepath will include several components, including gaining experience through trial implementations, production-level demonstrations, and identification of best practices.

- Establishment of appropriate compliance timelines: Compliance timelines should be established that meet industry needs and do not impose undue burden. We also recommend establishing an official testing and evaluation period where a covered entity (CE) would not face enforcement action. When establishing compliance timelines, the federal government should also take into account other mandates that a CE would be required to meet within similar timeframes.

- Enforcement: It is critical that the federal government more effectively enforce the longstanding HIPAA and Patient Protection and Affordable Care Act (ACA) administrative simplification requirements. Increased awareness of filed complaints and enforcement actions taken by the government will encourage others to come forward and report issues. If we as an industry are to take full advantage of the mandated transactions, operating rules, national identifiers, and code sets, it is imperative that providers, health plans, and clearinghouses fully comply with these standards.

- Stakeholder education: HHS should regularly publish and make available guidance regarding the appropriate and correct use of standards and operating rules. HHS should leverage its traditional outreach levers, including teleconference and webinar educational efforts, MLN Matters articles, and Remittance Advice comments. We also recommend that HHS engage with WEDI to ensure that a consistent message is conveyed to the industry.

- Need for trusted terminology standards: Terminology standards must be credible, comprehensive, and developed using rigorous and evidence-based processes in order to support today's needs for data interoperability. The Current Procedural Terminology (CPT®), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) are terminologies that are critical for describing medical services, procedures, and diagnoses. Equally important terminology standards are the Current Dental Terminology (CDT) for describing dental services and the National Drug Codes (NDC) for describing drugs and biologics. They are all evidence-based, flexible, reflect current clinical practice, universally used, and trusted by the health care system.

- Minimize variations in standards: The allowance of variations within standards results in administrative burdens. Variations of standards requirements are typically found in the differing interpretations of data content reporting rules. The result is the need for organizations to support multiple variations of a standard, causing a loss of efficiency and increased costs.

  One specific example is the failure to adopt Current Procedural Terminology (CPT®) Guidelines and Conventions (CPT Guidelines) under HIPAA. The CPT Guidelines are critical to the correct use of the CPT codes. Their omission from HIPAA has resulted in some organizations creating their own instructions for how to report the CPT codes, thus imposing a burden on the entire health care system.

Standards that promote data exchange between providers and payers

- Acknowledgement transactions: We support the X12 999 standard acknowledgement transaction for health care and the X12 277 Health care Status Notification transaction, used specifically to confirm the

receipt of an X12 276 Health Claim Status Request transaction.

- Prior authorization: WEDI strongly supports the automation of the prior authorization process. We note that meeting the goals stated by the federal government in the recently-withdrawn regulation will require that relevant stakeholders have ready access to several key capabilities and functions. Providers must know whether payers require prior authorization for a service along with the required information needed by the payer for the authorization. It is important to focus first on making these criteria as widely available and useful as possible, even if multiple approaches may be required.

- Health Level 7 (HL7) standards: WEDI supports the following Fast Health care Interoperability Resources (FHIR) standards in support of prior authorization automation:
    - HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0.
    - HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) Implementation Guide: Version STU 1.0.0.
    - HL7 FHIR Da Vinci - Prior Authorization Support (PAS) Implementation Guide: Version STU 1.0.0.
    - HL7 FHIR Da Vinci - Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0. 20 of 28
    - HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0.
    - HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0.
    - HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1.
    - HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0.

  WEDI strongly supports standards for automatable and scalable processes that eliminate burden and waste. WEDI supports FHIR and the work of Da Vinci and their resulting IGs.. We do have concerns with these IGs, as currently they are standards for trial use (STU) and have not been widely tested in real-time scenarios. WEDI believes the HL7 IG development process will finalize these IGs in a reasonable timeframe. It is our understanding that these IGs support both direct and clearinghouse connections, do not require “Direct Connect,” and are harmonized with the X12 278 transaction process.

- Documentation Requirement Lookup Service (DRLS) application programming interface (API): We support the implementation of a FHIR-based DRLS API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0 and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0 IG, populated with their list of covered items and services for which prior authorization is required, and with the organization’s documentation requirements for submitting a prior authorization request, including a description of the required documentation.

  The CAQH CORE Prior Authorization operating rules also support using the X12 278 transaction to provide documentation requirements. With much of the value of the DRLS process derived from its real-time capabilities, it is imperative that CMS delineate how DRLS will be deployed within provider workflows in a manner that will best take advantage of its automation opportunities. WEDI urges CMS to work with us on identifying the ROI with the DRLS technology and modeling how the current and new standards can work together. Additionally, testing and timing of availability for the new technology is necessary. While the new technology is needed today, the industry is looking for proven functionality.

- Attachments: WEDI strongly supports the adoption of an attachments standard and has repeatedly called for this requirement. An electronic attachment standard was mandated by Congress in HIPAA in 1996 and

re-mandated in section 1104 of the ACA in 2010. Yet, CMS has not issued a final regulation naming the standard. WEDI urges the expedited release of that regulation and ensure that it is harmonized with this proposed rule to align the requirements for the exchange of supporting documentation.

- National Council for Prescription Drug Programs (NCPDP) real-time pharmacy transactions: We believe the electronic, real-time formulary and benefit checks and prior authorizations for prescription drugs and covered outpatient drugs will significantly reduce administrative burden. Replacing time-consuming manual processes between providers and pharmacists will improve patient care by ensuring they obtain appropriate medications in a timely manner. When integrated into a pharmacy management system, electronic prior authorization streamlines the approval process and patients can start their medications sooner. The result is increased patient satisfaction, adherence to medication regimens, and fewer visits to the emergency room. Furthermore, automated processes are more efficient for payers.

- Innovation promotion:The industry would greatly benefit from a process that fosters innovation and accelerates the adoption of automation standards. HHS should financially support administrative automation "innovation laboratories," "sandboxes" and "connect-a-thons" all aimed at leveraging FHIR-based solutions to improve health care data exchange.

Data sharing with patients

- Sharing health information with patients: WEDI supports the work by CARIN, as it is directly related to the CMS Blue Button initiative already in use. The CARIN IG provides a method for all payers to make available submitted and processed claims data to patients and has sufficient maturity to ensure a successful implementation. However, WEDI has concerns about requiring more than one IG for specific types of care, such as proposing to permit payers to use the US Core and PDex IGs, and payment processes.

  WEDI is in strong support of clear and unambiguous standards to achieve true interoperability. As with operating rules that constrain more general standards mandated under HIPAA, the HL7 accelerator groups, such as the CARIN Alliance and the Da Vinci Project, have further refined the more general HL7 FHIR US Core IG to align more tightly with the specific patient data exchange processes associated with burden reduction.

- Provider Access API for individual patient information access: We support a Provider Access API that allows providers to have access to an individual patient's and multiple patients' information. The HL7 FHIR Bulk Data Access specification is designed to "periodically retrieve updated clinical data" and not for daily bulk claims and clinical transactions among changing cohorts or enrollees and provider relationships as discussed in the CMS interoperability rule. WEDI supports limiting the Provider Access API to individual enrollee data requests, and that CMS not require the FHIR Bulk Data Access specification be adopted for the Provider API at this time but consider it a later date when the specification has been more thoroughly tested by HL7.

  In addition, payers must be given sufficient time to administer out-of-network provider requests. In addition to the complexity associated with verification of a care relationship, technical logic to automate out-of-network provider access API would significantly escalate the cost of compliance, and manual administration would increase health plan administrative costs. There are no user identifiers and password credentialing security data for most non-participating providers. For these reasons, WEDI would support an iterative approach that starts with payer participating providers and adding out-of-network

providers at a later date.

- Electronic exchange of behavioral health information: WEDI understands the challenges of balancing the confidentiality of sensitive patient information with its accessibility for care delivery. We strongly believe that behavioral health and other confidential information should be separate and apart from the general medical record information. Behavioral health and other confidential information, such as family planning, HIV, social risk, and other similar types of data should only be released on a need-to-know basis and only to designated, authorized individuals or organizations. WEDI urges CMS to convene a cross-industry group of impacted stakeholders to analyze the issues associated with this workflow and issue guidelines or best practices the industry can implement.

Privacy and Security Issues

- Privacy and security concerns with APIs: WEDI fully supports moving to a health care system where data flow seamlessly among stakeholders to achieve improved health outcomes for all individuals. However, it is imperative that the privacy and security of that information is maintained. With this as the goal, WEDI has concerns related to Open APIs as information sharing tools that will be used by consumers to access their electronic health information via provider and payer systems.

  WEDI recognizes the ability of APIs to facilitate access to health data and as such the API can allow patients to take increased ownership of their health. Some CEs have already built patient access APIs and are actively promoting their use. However, we remain concerned regarding the lack of robust privacy standards applicable to third-party application (app) developers and no currently recognized certification for these apps. The potential exists for protected health information (PHI) gained via the APIs to be inappropriately disclosed to the detriment of patients and their families. CEs that have no experience or expertise with third-party apps should attest for their commitment to adhering to recognized privacy and security protocols. WEDI supports patient access to their PHI via APIs, but asserts a national privacy framework is required to ensure that health care data obtained by third-party apps is held to high privacy and security standards. WEDI strongly encourages HHS to engage with WEDI for ideas about how confidentiality of PHI can be maintained in a new app economy.

  WEDI also encourages the HHS to harmonize the Office for Civil Rights requirements with those finalized in the May 2020 Office of the National Coordinator for Health Information Technology (ONC) final rule. That rule requires developers of certified health IT to share electronic health information (EHI) with third-party apps of a patient's choice through APIs that utilize FHIR protocols. We note that these third-party app developers, who are entering the health care market at a rapid pace, are typically not required to abide by the provisions in HIPAA due to the fact they offer their apps directly to consumers and not on behalf of CEs, such as providers or health plans. It is imperative that HHS develop an approach for how CEs that are, for the most part, CEs or business associates under HIPAA, share EHI with these non-HIPAA entities, and ensure that such third-party apps are equipped to securely handle sensitive patient information.

  We continue to be concerned that patients will not have adequate information to be educated consumers and may not fully comprehend that they are assuming the risk of the security practices implemented by their chosen app. Consumers do not necessarily understand when their information is and is not protected by HIPAA. While we appreciate HHS's recently released guidance clarifying that health care providers are not responsible under the HIPAA Security Rule for verifying the security of a patient's chosen third-party app, this "safe harbor" does not address the potential vulnerability of patient information when sent to the app.

Under current regulation, CEs are not permitted to require formal verification checks on individual third-party apps before allowing the application to connect to its API. It is imperative that HHS provide further guidance on the types of "verification" that will be permitted and allow CEs to undertake some form of review of third-party apps themselves before permitting them to connect to their APIs.

Further, HHS should engage with the private sector in the development of a privacy and security trust or certification framework for third-party apps seeking to connect to APIs of certified health IT. Once established, ONC should permit practices to limit the use of their APIs to third-party applications that have agreed to abide by the framework. Such a program would not only foster innovation, but also establish improved assurance to patients of the security of their information.

NCVHS Question 1b: What are the barriers to these improvements?

WEDI has identified the following barriers:

- Cost of required technology upgrades: There are significant costs to all organizations when implementing an updated version of standards, including system changes, testing, training, purchasing implementation guides, and resolving issues found in production. This emphasizes the importance of balancing the costs of implementing updated standards and operating rules against the anticipated benefits.

- Challenges with establishing and communicating the ROI associated with a new standard: Traditionally, the industry has not been successful in establishing a clear ROI prior to moving to a new standard. This, in turn, results in a lack of stakeholder buy-in and a protracted implementation process. There needs to be a business need and cost analysis for updates to standards and operating rules. Implementing new standards or operating rules or making updates to existing implementations comes with associated costs to implementers. These costs must be weighed against the resulting benefit. Prior to implementation of any new standard or operating rule, the business need must be established and cost analysis completed for any updates to standards and operating rules.

- Stakeholder involvement of the standards development process: WEDI is concerned that not enough stakeholder representatives with business process experience are involved in the development of standards and IGs. Consequently, there may be gaps and missing components in the workflow processes supporting the business functions.

- Lack of CE status for vendors: Practice management system software and electronic health record software vendors were not designated as CEs under HIPAA and thus are not accountable for meeting federal requirements. Absent this designation, these vendors are not required to support providers, health plans, or clearinghouses as they seek to comply with federal mandates. CEs rely heavily on their vendor partners to implement, test, and deploy new standards, and without this support, entities can experience protracted implementations and compliance challenges.

- Protracted release of regulations: WEDI recommends that HHS expedite the publishing of regulations soon after a recommendation has been received and accepted by the Secretary for a new or revised standard or operating rule (in accordance with what is permitted).

- Lack of flexibility: There may be times when the industry may need to have the flexibility to make updates outside of the full regulatory process, yet this type of flexible approach does not currently

exist.

- Implementation challenges moving to new standards, including stakeholder workflow modifications: Moving to a new standard requires stakeholders to develop and implement new workflows, a process that can be challenging. WEDI is willing and able to convene all impacted stakeholders to identify best practices for mitigating barriers so that stakeholders can implement the effective use of the standards and operating rules. WEDI Workgroups and Subworkgroups actively identify best practices in an effort to determine current critical issues. This work is typically built upon prioritizing use cases, which is a component of best practice identification.

- There is insufficient "trust" between providers and health plans: Lack of transparency is a barrier to establishing trust between providers and health plans. Increased trust in processes and how best to meet requirements will decrease burden and cost for all stakeholders.

- National standards may not always apply to all health plans: As we saw with the recently-released CMS rule on prior authorization (subsequently withdrawn), rules can be limited in scope and not apply to all health plans. This forces providers to deploy multiple workflows that defeats the intent of standardization.

- Insufficient testing and piloting: Mandating a standard prior to performing adequate testing or piloting is a consistent challenge in the health care industry. When there is insuffient industry experience, testing and piloting not only identify potential implementation problems but can also establish best practices. Further, successful testing and piloting can serve to accelerate stakeholder support and adoption. Testing and piloting must occur within real-world workflows. It is also important to note that some of the existing standards do not work for every stakeholder group (i.e., dental providers). Thus, it is imperative that standards be tested in all appropriate clinical and administrative settings.

- Lack of a standards roadmap: Providing the industry with a clearly articulated roadmap and implementation timeline for new and revised standards is critical for impacted entities to allocate sufficient staff and other resources, avoid disruption of operations and ensure compliance.

- Lack of federal resources: WEDI recommends that the division(s) responsible within HHS for HIPAA have their resources increased to facilitate the timely review, maintenance and adoption of national standards, including education and enforcement.

NCVHS Question 2a: Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

There are several SDOs that are creating standards and use cases for the health care industry. These organizations include CAQH, HL7, NCPDP, and X12. Each of these organizations is continuously updating existing standards and operating rules and developing new standards and operating rules. WEDI urges the NCVHS to reach out directly to each SDO to understand each organization's roadmap and identify new and revised standards that the Committee should review.

WEDI urges the NCVHS to review and recommend the most current standard for use by the industry and not endorse standards that will be outdated by the time a final rule is promulgated. In addition, the

NCVHS should avoid overlapping standards, ensure broad industry input when considering new standards, and only recommend standards and operating rules that solve clearly articulated business problems. By focusing on filling existing "gaps" and not just replacing standards that are working (look to the latest iteration of the CAQH Index for guidance), the NCVHS will be promoting positive change for the industry.

As we have stated in the past, we recommend that SDOs avoid working in silos and share roadmaps and work products with the other SDOs to improve harmonization and minimize overlap of work. As well, through our Strategic National Implementation Process (SNIP), workgroups, education, and white papers, WEDI has assisted the industry implement Versions 004010 and 005010, the International Classification of Diseases, 10th Revision, and the Medicare Beneficiary Identifier. As the industry moves forward in adopted new standards, our multi-stakeholder organization is here to support the industry and support new standards and operating rules once identified by the respective SDO.

We also support the addition of the HL7 Gravity Project's SDoH data elements in the USCDI, Version 2 (v2). The inclusion of SDoH as a new data class in the United States Core Data for Interoperability supports the policy objectives of HHS that focus on improving the experience of care, improving the health of populations, and avoiding unnecessary costs in health care.

NCVHS Question 3: How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

The financial industry is a good example of an industry that has effectively standardized, incorporated consumer-friendly (worldwide) interoperability. Banks today leverage APIs to solve business issues and meet consumer demands for immediate data access. This despite the banking industry being even more audited and regulated than health care. We note, however, that customers may have more power in the banking environment. They can change financial institutions at will, where many consumers tethered to the place of employment have limited ability to switch to a different health plan product.

Banks have also successfully implemented operating rules for such services as direct deposit and Automated Teller Machines. Banks worked in unison to create and implement rules, include stringent security protocols. In health care, not every stakeholder is at the table. It is important to remember, however, that with banks, their primary business function is also the customer focus-transactions. In health care, business administration is secondary to delivering patient care.

NCVHS Question 4a: What short-, mid-, and long-term opportunities or solutions do you believe should be priorities for HHS?

WEDI believes there are a number of actions HHS can take in the short-term that would advance administrative simplification and industry automation. These include:

- Publish critical outstanding regulations: There are several regulations that should be released expeditiously. These include the advancement of the latest iteration of the X12 suite of health care transactions, including the electronic attachments and acknowledgement transactions, and re-release of the *Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation*

Specifications (RIN 0938-AT99) regulation.

- Support for the No Surprises Act legislation: The No Surprises Act includes transparency sections regarding provider directories; furnishing advance cost estimates and estimated out-of-pocket costs for specific services; health plan maintenance of a provider price comparison tool; and disclosure of cost sharing and certain provider information on health plan identification cards. Several of these provisions require the government to issue guidance on how CEs are to achieve compliance.

  Section 111 of the Act calls for predetermination of benefits for anticipated procedures. This will require providers to submit the anticipated procedures to the health plan who would then price them according to their fee schedule and return this information to the patient and provider. While WEDI supports the intent of this legislation, absent specific guidance and sufficient implementation time, we are concerned that multiple proprietary solutions with be developed, such as individual payer portals, that will disproportionately burden providers and delay patients receiving information in a timely manner.

  The method and format for exchanging predetermination requests and responses has not been defined by the government. It is unclear if any of the currently mandated X12 Version 5010 electronic transaction can be used to perform the functionality of a predetermination request, except for the dental X12 837 transaction. Establishing an appropriate process for conveying predetermination information will be a critical component of the regulations supporting the No Surprises Act.

  Section 107 of the No Surprises Act includes a requirement for covered health plans to include "in clear writing" on any physical or electronic identification card the following information: "(1) Any deductible applicable to such plan or coverage; (2) Any out-of-pocket maximum limitation applicable to such plan or coverage; and (3) A telephone number and Internet website address through which such individual may seek consumer assistance information, such as information related to hospitals and urgent care facilities that have in effect a contractual relationship with such plan or coverage for furnished items and services under such plan or coverage."

  Health plan deductibles may be different between in-network versus out-of-network providers and potentially even between medical and pharmacy services. This potential variability of deductibles adds significant challenges for health plans seeking to include the required information on the identification card—especially the physical card. We urge HHS to work with the industry to ensure that this statutory requirement can be met without undue burden to stakeholders.

- Explore modifications to the standards development and rollout process: HHS should seek to increase the coordination between SDOs, enhance the ability of stakeholders to participate in the standards development process (with emphasis on increasing the number of providers), ensure SDOs have sufficient technical expertise, and, recognizing the limitations of volunteer organizations, financially support the standards development process.

  These modifications could also include the option to move to a new individual X12 transaction standard. We also urge HHS to examine the potential of moving to a yearly update schedule. This could mirror the current approach adopted by HHS in its yearly update of the ICD-10 code sets. To avoid potential industry disruption, any standard adopted under this format must be backwards

compatible.

- Augment compliance: The first step toward increased compliance is enhanced industry education. HHS should significantly increase its outreach to a CE and, leveraging past corrective actions and industry survey results, target areas where stakeholders require additional guidance. As well, absent a robust and transparent enforcement environment, a CE may not prioritize compliance with the federal requirements. HHS should take the appropriate steps to identify and penalize entities unwilling to comply with federal requirements. We also urge HHS to identify opportunities to ensure that not only health plans and clearinghouses are compliant with federal requirements, but providers as well.

When exploring mid-term opportunities, WEDI believes HHS should focus on issues including SDoH data exchange and exploring the standard transactions through a health equity lens. For example, HHS could examine whether health equity plays a role in health care claim and prior authorization denials. In addition, HHS should focus on developing point-of-care solutions that transmit data to providers at the time of service. Since 2010 when CMS implemented the Meaningful Use program, the priority has been the collection of data. We recommend HHS prioritize feedback loops to ensure that providers are sent actionable data in a timely manner.

Longer-term priorities for HHS include reducing the chance of SDOs working in "silos" and engaging in overlapping work by ensuring each has a delineated set of focus areas and improving communication between SDOs. Project collaboration and the sharing of information should be strongly encouraged. As well, HHS should engage in further work leveraging clinical data for multiple administrative purposes. This convergence of clinical and administrative data will improve efficiency and reduce burden for all stakeholders.

Finally, we recommend CMS establish an administrative automation advisory body with representatives from each impacted stakeholder group. This advisory body could mirror the ONC Health Information Technology Advisory Committee that provides that agency valuable insight and recommendations on a wide variety of health IT issues.

WEDI appreciates the opportunity to submit these responses to your specific questions and we look forward to continued collaboration with NCVHS. We stand ready to assist in clarifying our responses to your questions as needed. Please contact me at nancy.spector@ama-assn.org or Charles Stellar, President and CEO of WEDI, at cstellar@wedi.org with any questions pertaining to WEDI's comments.

Sincerely,

/s/

Nancy Spector

Chair, WEDI

cc: WEDI Board of Directors

WPF Comments to the National Committee on Vital and Health Statistics regarding Request for Public Comment on Healthcare Standards Development, Adoption and Implementation

July 30, 2021

Thank you for the opportunity to provide comments regarding NCVHS's Request for Public Comment on Healthcare Standards Development, Adoption and Implementation, https://ncvhs.hhs.gov/wp-content/uploads/2021/06/NCVHS-SS-August-25-2021-Request-for-Public-Comment.pdf.

The World Privacy Forum (WPF) is a nonprofit, non-partisan 501(c)(3) public interest research group. WPF focuses on multiple aspects of privacy, with health privacy being among our key areas of work. We publish a large body of health privacy information, including guides to HIPAA; reports and FAQs for victims of medical identity theft; and materials on genetic privacy, precision medicine, electronic health records, and more.[1] We testify before Congress and federal agencies, and we regularly submit comments on HIPAA and related regulations. Executive Director Pam Dixon has held a board level position on the HL7 standards committee, and has contributed meaningfully to that standard. Additionally, WPF has completed work on Voluntary Consensus Standards and how the FDA model using VCS could be applied more broadly to privacy standards. WPF participates in the WHO and serves on its data governance workgroup. You can find out more about our work and see our reports, data visualizations, testimony, consumer guides, and comments at http://www.worldprivacyforum.org.

WPF views standards, and the democratic functioning of standards development organizations, as crucial to the health ecosystem and to patient privacy protections. However, we do have

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[1] See World Privacy Forum, A Patient's Guide to HIPAA, https://www.worldprivacyforum.org/2019/03/hipaa/; see also our Health Category page for additional materials https://www.worldprivacyforum.org/category/health-privacy/.

concerns about the scope, implementation, and particularly third party use of patient health data. We observe that the health sector is about to undergo a rapid transformation — more so than it already has - which will bring it more in line with other sectors that have bi-directional, real time or near real time data ecosystems. In such ecosystems, there are often a pattern of systemic challenges with protecting data subject to regulations in one setting, and not subject to regulations in another. In the health sector, a good example of this is patients "donating" their data through a simple click to export their health files to a third party entity not covered under HIPAA. While many such entities are good actors, not all are. Health data is still at a premium, and numerous unsavory uses of patient data exist. For example, marketing lists.

Standards at the level of the API structures, and particularly in the user-facing interfaces, would be extremely helpful in mitigating some of the challenges. For example:

1. There needs to be a standard for notifying patients about the regulatory protections that they will lose if they share their health data to a non- HIPAA-covered entity. This should be along the lines of an NPP for sharing to third parties.
2. The health data ecosystem has expanded greatly, and providers and public health authorities are interested in broader data sets beyond the medical record. This is fine, but there needs to be standards for these alternative data. Alternative data about patients or patient population groups that is derived from marketing data needs a great deal of thought by HHS. Marketing data is notoriously inaccurate, and introduces risk for unintended error as well as potential for bias in systems that also include AI/ML components.

Without these and other mitigations that provide transparency, accountability, and proper notification to patients, trust in the health data ecosystems could be one of the most significant obstacles that HHS faces in working to increase interoperability.

Case studies in the digital identity ecosystem (for example, FINRA in the financial sector, due to its real time accountability systems) as well as the FDA use of VCS (for example, in the medical devices context), exist that could be utilized as models. FINRA in particular is a good model to consider in the case of entangled data within ecosystems, something WPF is studying, which is also mentioned in the Request for Comment.

To provide further background on our thoughts, we are including below a portion of our comments this year to HHS regarding Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945– AA00. Mentions of the NPRM in the comments that follow refer back to RIN 0945–AA00, but we also would like these comments considered in the NCVHS context.

Part I. General Comments

1. Access

The NPRM proposes a series of changes to improve patient access to their records. We support those provisions that:

1. Allow greater in-person inspection;
2. shorten response time to requests;
3. clarify the form and format of responses;
4. reduce the identification verification requirement;
5. require health care providers to respond to requests from other providers;
6. all provisions relating to fees, fee schedules, and fee estimates.

We would also support a requirement that mandates that all electronic record disclosures to a patient be without any charge at all. The costs of providing a copy of an electronic record are trivial, and the costs of collecting fees and making decisions about those unable to pay will be greater than any allowable direct costs.

We recommend that the Department take fees off the table entirely for patient access.

2. Care Coordination and the Loss of the Minimum Necessary Exception

The proposed rule would amend the definition of *health care operations* to clarify the scope of permitted uses and disclosures for individual-level care coordination and case management that constitutes health care operations. In this section, we discuss the reasons why the proposed care coordination language is deleterious and needs to be removed from the NPRM.

A. WPF disagrees with the proposal to remove patient consent for care coordination and case management

The proposed change regarding care coordination and consent is troublesome for several important reasons. First, it is another step down the road of removing patient consent from all use and disclosure decisions. The existing rule already does that to a tremendous extent, although we agree that not all of those choices are necessarily bad ones. However, there is still a role for patient consent even if it is inconvenient for the health care system to obtain consent. As one moves further and further away from direct patient care, the justification for evading consent grows weaker. Poorly defined care coordination and case management activities are excellent examples of consent exceptions that are not justified. When one analyzes the Department's justification, it is based on administrative convenience, not patient or other necessity.

B. HHS has not defined care coordination or case management

Second, the Department itself cannot define either *care coordination* or *case management*, and it admitted that in the NPRM:

> Although neither care coordination nor case management has a precise, commonly agreed upon definition, both refer broadly to a set of activities aimed at promoting cooperation among members of an individual's health care delivery team, including family members, caregivers, and community based organizations. (page 6449)

If this language is incorporated into the rule, the result will be that anyone in a health care setting, professional or otherwise, can decide to disclose a patient's record – without the patient's consent and over the patient's express objection – to virtually anyone who claims they are conducting *care coordination*. Teacher? Landlord? Grocery store shopper? Auto mechanic? Uber or Lyft driver? With the right spin, any of these activities could be construed as care coordination. Asking for patient consent in these circumstances would be messy. But removing the patient consent in the name of *care coordination* is in the long run much messier, and will create a lot of fresh problems.

The proposed change in regards to the care coordination and consent language is deleterious enough that we have to wonder why HHS decided that it was appropriate, and how HHS could justify this change on a fully-researched, factual basis, inclusive of patient experiences and actual fact patterns.

We understand that certain parts of the health care sector maintains that it isn't worth the trouble to ask patients for consent. Patients believe otherwise, however, and for good reason. At a time when patients are already smarting from having to disclose personal health information more widely than is usual due to the pandemic, this proposed language will add fuel to the fire of patient mistrust in the health care sector at a challenging moment in time when more, not less, trust is needed.

No matter how strong the justification may look on paper, in reality and practice this particular language is associated with increased risks for the patient, and could lead to meaningful privacy problems for patients, particularly for victims of domestic violence and other crimes, where information in the wrong hands can pose meaningful safety risks. Safety risks we note that are all too real, and do not suffer from being just theoretical privacy risks. What the Department chooses to do with this language will have real consequences for patients, particularly the most vulnerable.

C. The proposed changes to care coordination language will in effect repeal § 164.510 (b) HIPAA privacy protections

Third, other existing provisions of HIPAA allow a patient to object to sharing with family members, but this new provision says that patient choices are not relevant here. The effect is to *undermine* one of the few places in the existing rule that recognizes patient choice during the routine provision of health care.

The proposed language says, in essence, that **a provider can ignore a patient's objection to sharing with a family member that § 164.510(b) protects**. If this provision proceeds as is, the Department needs to explain how these conflicting provisions should be reconciled. Otherwise, the effect will be to repeal § 164.510(b). This would be a terrible outcome for patient privacy, especially at a time when patients are more concerned than ever about expanded flows of their health information.

D. No requirement that care coordination disclosures be made by a health care professional

Fourth, there is no requirement here that the decision to make these disclosures be made by a health care professional. Any employee of a health care provider, from the treating physician to the orderly who cleans the room, has the same authority under this provision to make these undefined disclosures.

We urge the Department to drop these changes entirely. Alternatively, if the Department is unwilling to drop the changes entirely, we suggest that the Department add procedural protections for patient privacy. Procedures offer a standard way of dealing with the inability to write clear standards that define and direct actions. We offer three ideas:

1. Require a judgment of a **health care professional** that the disclosure is necessary (or appropriate) for patient care;
2. require a **professional judgment that the disclosure is in the interest of the patient and likely to result in better outcome for the patient**;
3. direct each health care provider to **designate by role all personnel authorized to make these disclosures** and also designate those who are not authorized.

The problem the proposed language creates is made even worse by excepting care coordination or case management disclosures from the minimum necessary rule. The effect is that anyone can disclose anything and *everything* under a vague standard. As proposed, there is no need for a physician or any professional judgment. Anyone can just hit the SHARE button and send an entire patient record to some other organization not directly involved in treating the patient whether that organization needs the entire record or not. An exception from the minimum necessary rule just compounds the problem created in the first place.

The Department worked hard to stop the casual sharing of entire patient records. This is no time to stop. We urge the Department to reject this minimum necessary exception.

3. "Good Faith Belief" is a significant weakening of the existing HIPAA standard; WPF strongly opposes the proposed change

The Department proposes to replace the privacy standard that permits covered entities to make certain uses and disclosures of PHI based on *professional judgment*. The proposed replacement is

a standard permitting such uses or disclosures based on a covered entity's "good faith belief" that the use or disclosure is in the best interests of the individual. The proposed standard is even more permissive than it appears upon first glance. This is because it would presume a covered entity's good faith, but this presumption could be overcome with evidence of bad faith.

The World Privacy Forum opposes this change. We recognize the appeals made by families of individuals with substance abuse disorders, which we have sympathy for. However, the change appears to be guilty of "*doing something-ism"* rather than solving a clearly defined problem with a clearly defined response. It is an unfortunate example how edge cases can make bad law.

The Department recognizes that patients and patient advocates are "almost universally opposed" to modifying the rule in this regard (page 6480). That opposition is telling. The Department also recognizes that the privacy rule already allows many of the disclosures at issue here are already allowed by the privacy rule. If covered entities are unwilling to make allowable disclosures, it may not matter what the standard is. They can refuse just the same under a weaker standard. Overly cautious lawyers are likely to be just as overly cautious whatever the standard.

For example, we are aware that some covered entities still refuse to disclose PHI to a treating physician of another institution without patient consent, even though those disclosures are *expressly* allowed by the rule without any standard at all. There are few practical remedies that will overcome narrow-minded lawyers. Mandates and sanctions will not work, and no rule could be specific enough to accomplish the purpose, overcome the definitional challenges, and address the ethical objections.

What is most troublesome here is that the Department proposes to change the rule covering a large class of allowable disclosures while those seeking adjustment here only represent a small fraction of the affected universe. In effect, the proposal proves too much. This proposal removes existing protections that appear to be working without objection in other circumstances.

The proposed change cannot assure those who seek the change that they will obtain the outcome they seek, but it will certainly undermine meaningful privacy interests of everyone else. In short, the proposal will make many patients worse off while not guaranteeing that any patients will benefit.

Further, for that large class of other patients affected by the proposed change, it would be nearly impossible to make a case that a provider disclosed a record improperly under the good faith standard. The burden of proving bad faith and the burden of going forward would fall entirely on the patient. The only source of information belongs to the health care provider, who would surely treat the information as prepared in anticipation of litigation. Most patients would have no chance of success because the rule does not require that a provider adequately document any disclosure made under the good faith standard.

WPF joins the overwhelming number of patients and patient advocates and we strongly oppose this change. WPF opposes the NPRM language because it may not help any patients at all, but it will surely harm the privacy interests of almost all others. If the Department is determined to proceed, despite strong public objections from patient advocates, patients, and more, we suggest that the change **apply only in substance abuse matters**. The right principle is *do not harm*. Do not undermine everyone's privacy interest to assist a narrow class. We recognize the seriousness of the substance abuse problem, but the proposal will not help, no matter how well intentioned it is.

4. Proposed changes to rules of disclosure of PHI to avert threats to health or safety is too permissive

The Department proposes to expand the ability of covered entities to disclose PHI to avert a threat to health or safety when a harm is "serious and reasonably foreseeable," instead of the current stricter standard which requires a "serious and imminent" threat to health or safety.

This is a troublesome issue, and we understand the Department's search for a good faith solution. Nevertheless, we think that the proposed standard is far too permissive. The new standard appears to allow disclosures by covered entities based on these types of judgments:

1. If the patient continues to eat junk food, the patient may have serious adverse health effects in five years;
2. if the patient does not get more exercise, the patient may experience a heart attack or stroke in the future;
3. if the patient does not lose weight, the patient may die prematurely at some time in the future.

We worry that if the constraints of the current policy are lifted, then medical bureaucrats of all stripes could feel justified to take steps to stop patients from living their lives as the patients see fit. We recognize the benefits of better diets, exercise, and weight loss. Patients – all of us – face hard choices here. However, "emergency" interventions by health plans or others on the basis of a *serious and reasonably foreseeable* harm standard could produce unexpected and unwelcome actions, as well as unintended consequences.

All manner of well-intended interventions could occur at grocery stores and other retailers, at the patient's place of work, in travel scenarios, and with the patient's friends and family members. Based on the proposed language, several scenarios would be possible.

- If a covered entity were to circulate a list of chronically ill patients to bars and restaurants on the grounds that serving alcohol to them would present a *serious and reasonably foreseeable threat* to their health, it would be allowable under the proposed rule.

- Providers and health plans (for example, Medicare) could use the new authority to seek to force patients to follow recommended health standards whether the patients want to or not. One can readily imagine just-in-time, geolocation-based notifications to patients' mobile devices noting that a patient should not be ordering certain menu items, purchasing certain items, or engaging in any manner of other activities.

It would all be in the interest of preventing "foreseeable harm" that would occur in five hours, five weeks, or could even encompass warnings that prevent harms that could occur in ten years' time. Even if everyone were truly motivated by what they see as the patient's best interests, patients are not likely to agree.

We recognize the need for flexibility in making disclosures to avert genuine and imminent health and safety threats. We are not convinced that the requirement of *imminence* is that serious of a barrier. In the end, what is needed for these types of disclosures is **reasoned judgment by a covered entity under all of the circumstances**. It is hard to write a few words to direct that judgment in myriad circumstances.

We suggest that the Department consider using the notion of *emergency circumstances* as an alternative to *imminence*. There is a need for some restraint so that the authority for health and safety disclosures is not used routinely to address longer-term health care issues affecting patients because the standard is too weak and the authority is unbounded. The class of disclosures allowed under the health and safety standard must not be allowed to be routine. It should be based on some type of unusual or extraordinary circumstances, and the proposed change lacks that constraint. A rule that is so unconstrained that it might allow a provider or plan to have overbroad reach to object in real time to patients' choices in eating, shopping, or more is just too broad.

5. Changes in Patient Acknowledgement for Notice of Privacy Practices (NPP)

The Department proposes to eliminate the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's Notice of Privacy Practices (NPP).

The World Privacy Forum supports this proposal. The requirement was a good idea, but in practice it has proven to be a "click-through" situation that often defeats the purpose of the exercise. In practice, the collection of a signature from a patient became an act wholly separated from distribution of an NPP. It did little to improve patient understanding about privacy.

A related proposal would improve patient understanding of useful information in the NPP. We support those changes as well, but with some qualifications.

First, the rule requires that the header on an NPP be in ALL CAPS. We observe that text in all caps is harder for many people to read and understand. The Department may want to ask reading experts for views here, but we think that text in ALL CAPS should not be required.

Second, we have significant concerns about how the Department is making it easy for patients to share information with third parties — for e.g., data brokers, social media sites, and others who fall outside the scope of HIPAA protections and outside the scope of any privacy law at all. We have lengthy comments on this subject that we include in part II below.

Part II. The Dilemma Posed by Third-Party Access to EHRs

In this NPRM and in others, the Department is moving step-by-step to support patient access to records in a way that also allows third parties (e.g., social media companies, health apps, fitness apps, even data brokers, among many others) to serve as hosts. These actions by the Department present a pressing dilemma. On the one hand, both the Department and the World Privacy Forum agree that patients should have a broad right of access to their health records. That access is required by law, and we support that law.[2] The right of an individual to see and have a copy of their records is a fundamental principle of privacy that dates back to the origins of modern privacy policy. The report of the (HEW) Secretary's Advisory Committee on Automated Personal Data Systems, one of the most important policy documents in the history of privacy policy, concluded that individual access to their records is a major element of fundamental Fair Information Practices (FIPs).[3] FIPs are at the core of nearly all privacy legislation all around the world, including the HIPAA health privacy rule.[4]

On the other hand, in today's environment, providing patients with "one click" complete electronic copies of their health records will have significant deleterious effects on patients, their privacy, the practice of medicine, the cost of health care, and other institutions and policy objectives. In one sentence, the problem is that EHRs made readily available to patients will end up in the hand of third parties, including banks, data brokers, marketers, merchants, foreign governments, and an untold number of websites. Sadly, patient records will also be prized fodder for fraudsters, and we expect to see pronounced efforts over time to acquire and utilize patient records by fraudsters. Even for good actors and companies or educational institutions who are working to access records for legitimate purposes, many of those who currently want to be users of patient records are entirely unregulated for patient privacy in the United States.

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[2] WPF supports even broader access by patient to their records than the HIPAA privacy rule allows. We would narrow or eliminate some of the provisions that allow a covered entity to withhold records from a patient. Since the rulemaking does not raise that issue, we will not comment further on it. This is just a marker.

[3]Records, Computers and the Rights of Citizens (1973), http://epic.org/privacy/hew1973report/default.html.

[4]For a history of Fair Information Practices, see Robert Gellman, FAIR INFORMATION PRACTICES: A Basic History (last version 2017), http://bobgellman.com/rg-docs/rg-FIPshistory.pdf.

We emphasize that notwithstanding these unwelcome effects, we still fully support patient access to records in whole and in useful electronic formats. These comments address more about the problems and offer some thoughts about how to proceed in light of the dilemma.

It appears to us that the Department is fully aware of the dilemma that set out here. The Department is implementing a variety of legislatively directed mandates that give rise to the problem. We acknowledge that the Department is proceeding in good faith to carry out those mandates. One cause of the problem may be a lack of congressional attention to privacy and a lack of awareness of the consequences of some of its directions. This is not the first time that congressional actions failed to see the broad ramifications of legislation. Indeed, the history of EHRs is filled with other examples.

We have some suggestions for addressing the problems, but we admit that we do not have a comprehensive solution.

1. The Modern Health Data Environment: Complex health data ecosystems and implications for the NPRM approach to third parties

Today's health data ecosystems are incredibly complex. The complexity is well-known to health practitioners. These ecosystems have porous edges in many important respects — covered entities under HIPAA no longer hold all health data that is generated. There is a lot of pressure from the inside of the HIPAA-covered ecosystem to share health data within the system, and also outside of the system, with boundaries and rules in place. But that is not the end of it - there is also increasing pressure for health providers to utilize broader data sets than just PHI held under HIPAA in order to gain a broader context for a patient's health, or for analyzing disease patterns in a community, city, state, or nation.

WPF has been researching and writing about health data and health privacy for two decades. During this time, we have found that health care providers take HIPAA seriously. We have not found health care providers knowingly selling lists of patient data, excepting the truly bad actors, such as medical identity thieves, which is a separate issue. However, the protections of HIPAA that have in the past prevented ecosystem leakage, stand to be weakened by the NPRM proposal. The World Privacy Forum is concerned about the extensive implications of opening up complete patient medical records to "one click" transmission to non-health related third parties outside of the health care system.

We understand the deep trendlines in health data ecosystems; that is, the ecosystems are becoming more porous and allowing for more and easier sharing. However, we also understand the deep trendlines of rules and policies that create unhealthy data ecosystems, and some of the proposals HHS has put forward will indeed result in problems for health data ecosystems and patients. We have written in some detail about the key problems relevant to this NPRM.

A. Patients and EHRs

What will happen when patients have ready access to their EHRs? We believe this access is critically important, and we support better access. We do not deny these benefits. We note in passing that over the past several decades, the broad benefits of EHRs have been widely predicted and touted. The reality, as the Department is already fully aware, has been far different.

The promised benefits of administrative simplification were not realized in large part. The spread of EHRs changed the way that physicians practice medicine, as physicians spend their seven-minute visits with patients mostly in front of computer screens rather than actually examining or even looking at patients. EHRs became tools for upcoding, and EHR systems became non-interoperable because of the proprietary interests of EHR vendors.[5]

The new prohibitions against information blocking and supporting interoperability are, like the push for EHRs, intended for good reasons. The consequence of these changes could potentially result in positive changes for patient access, but because of how the rule has been proposed, the changes also result in the expansion of patient records going to third parties. WPF supports patient access. We are troubled, though, by the HHS proposal facilitating patient records going to non-health third parties.

We predict that the 3rd party change may make things worse for patients and providers in unpredictable and systemically deleterious ways. We are not against improved information technology, and we recognize that the health sector, broadly speaking, has lagged behind here. We merely observe that predictions about the benefits, process, and consequences of adding technology to health care have been consistently off the mark.

We note that in 2005, there was a strong push to move patients to EHRs, along with a strong push to develop a National Health Information Network (NHIN).[6] The World Privacy Forum testified before the NCVHS regarding the proposed National Health Information Network and EHRs, focusing on the risks of such a network, and the risks of EHRs.[7] To illustrate the risks, for

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[5]See generally, Fred Schulte & Erika Fry, Kaiser Health News, Death By 1,000 Clicks: Where Electronic Health Records Went Wrong (Mar. 18, 2019), https://khn.org/news/death-by-a-thousand-clicks/; Fred Schulte & Erika Fry, Kaiser Health News, FDA Chief Calls For Stricter Scrutiny Of Electronic Health Records (Mar. 21, 2019), https://khn.org/news/fda-chief-calls-for-stricter-scrutiny-of-electronic-health-records/.

[6] National Health Information Network Timeline, World Privacy Forum. Available at: https://www.worldprivacyforum.org/2009/02/report-nhin-timeline-documenting-the-history-and-development-of-the-national-health-information-network/

[7] Pam Dixon, Testimony: *Electronic Health Records and the National Health Information Network: Patient Choice, Privacy, and Security in Digitized Environments,* NCVHS, August 16, 2005. Available at: https://www.worldprivacyforum.org/2005/08/public-comments-testimony-before-the-national-committee-on-vital-and-health-statistics-ncvhs-subcommittee-on-privacy-and-confidentiality/

the first time in a public hearing, we testified about the issue of **medical identity theft** as a risk factor in EHRs and the NHIN.[8]

WPF documented the facts of medical identity theft in 2006 when we published the first known report documenting medical identity theft modus operandi, harms, protocols, and multiple cases of the crime and impacts. Medical identity theft results from the fraudulent use of patient health records in ways that were - and still are — profoundly harmful to patients. WPF saw this problem because of the data flows that already exist in electronic health records systems and health data ecosystems. Some of those data flows can be exploited by bad actors. Now, in the same way, WPF sees serious systemic problems arising from this HHS proposal for patient sharing of full patient records with non-health related third parties.

We want to address some key ways that EHRs shared with patients will pour out into the hands of third parties.

- **Data Breach.** the Department knows about the volume of data breaches from HIPAA covered entities.[9] In most cases, these breaches occur despite security measures required by the HIPAA security rules. When patients download their EHRs on their cellphones, tablets, and home computers, those EHRs will be much more vulnerable to being breached because securing home and person devices is exceptionally challenging. Those who steal passwords, account numbers, and financial data will be just as happy to steal EHRs from patients. The market for health data is well-established already, and there is regrettably an underground market, too.[10] Patients with EHRs on their devices could find themselves with additional risks from thieves and from foreign governments that may seek to collect and exploit health data on Americans for purposes that are at odds with American interests.

- **Medical Identity Theft.** The epidemic of medical ID theft will mushroom with the greater circulation of EHRs outside of the health care system. Already, medical identity theft occurs in every state in the US.[11] Medical ID theft occurs today even with limited available of health information. A patient name, account number, and

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[8] Id.

[9] Interactive Medical Data Breach Map, World Privacy Forum. Available at: https://www.worldprivacyforum.org/2016/09/2016-breach-interactive/

[10] See, e.g., Chris Bing, Cyberscoop, Abundance of stolen health care records on dark web is causing a price collapse (Oct. 24, 2016), https://www.cyberscoop.com/dark-web-health-records-price-dropping/; Jennifer Schlesinger & Andrea Day, CNBC, Dark Web is fertile ground for stolen medical records (Mar. 11, 2016), https://www.cnbc.com/2016/03/10/dark-web-is-fertile-ground-for-stolen-medical-records.html.

[11] Pam Dixon, The Geography of Medical ID Theft, December 2017, World Privacy Forum. https://www.worldprivacyforum.org/2017/12/new-report-the-geography-of-medical-identity-theft/

Medicare or insurance number is more than enough to allow crooks to profit.[12] With full EHRs obtained legitimately or fraudulently from patients, medical ID theft will skyrocket. Data indicate that medical identity theft is already growing steadily each year in the US.[13] Based on the information available, it is highly likely that data brokers and others will be able to acquire, compile, analyze, and sell identifiable patient data with details of insurance coverage and other detailed information, such as insurance identification numbers. We are concerned that fake health clinics — such as those we documented in our Medical Identity Theft report and those that are well-known to CMS fraud investigation units — will be able to scour this new source of EHRs to find justification to bill for expensive tests and procedures fully justified by a patient's actual documented health condition. Patients affected by this crime will find it even harder to keep up with and correct erroneous additions to their EHRs, and the erroneous information will follow them around because HIPAA provides inadequate remedies for patients seeking to recover from medical ID theft.[14]

- Malpractice. Lawyers who bring malpractice suits on behalf of patients will find EHRs outside of HIPAA to be a vast new resource. They will be able to scan records electronically looking for possible causes of action against, physicians, hospitals, pharmaceutical and device manufacturers, and others. We can already hear the late-night television ads offering the hope that your health records will point the way to a multi-million-dollar malpractice judgment. Just sign the consent form and wait to see if money will come your way.

The uses of these records for highly targeted advertising are so obvious that we will not stop to dwell on them other than to observe that personally targeted health ads based on an actual diagnosis will become much more ubiquitous and much more focused than they are today.

2. Methods of access

It is likely that there will be several ways for a patient to use an EHR. Some may be able to access and use an EHR hosted by a HIPAA-covered entity on a website maintained by the covered entity. This may be the best of all possible worlds because patients will have access, the EHR will presumably be regularly updated by the covered entity, and the covered entity will be

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[12] Pam Dixon, Medical Identity Theft: The information crime that can kill you, World Privacy Forum, May 2006. https://www.worldprivacyforum.org/2006/05/report-medical-identity-theft-the-information-crime-that-can-kill-you/ .

[13] Pam Dixon, The Geography of Medical ID Theft, December 2017, World Privacy Forum. https://www.worldprivacyforum.org/2017/12/new-report-the-geography-of-medical-identity-theft/

[14] FAQ: Medical ID Theft: How to recover if you're a victim, and what to do if you are worried about becoming a victim, World Privacy Forum https://www.worldprivacyforum.org/2012/04/faq-victims-of-medical-id-theft/

responsible for the security of the entire system. In our minds, this is ideal. Patients will still face new risks because the usual cast of fraudsters will seek to steal passwords and to use the passwords to access and perhaps download the entire EHR. However, using an EHR system hosted by a HIPAA-covered entity affords the provider the opportunity to educate patients about providing third party access, and to create a protective layer of information and interfaces around that decision point.

A second way for a patient to use an EHR is to download the EHR onto a personal computer or to a mobile phone. A record stored in either location will be more vulnerable to access by others. We are concerned that at some point in time, third parties will request access to EHR data routinely, along with the patient's contacts, location, and other information on the mobile phone. Once an EHR passes into the hands of a patient, the EHR falls outside of HIPAA so that any downstream recipient (other than a covered entity) will be able to use the EHR without any HIPAA constraints.

A third way for a patient to use an EHR is to use a resource provided by a third party app or a website that offers to host the EHR. The data in EHRs will be so lucrative that sites and apps will line up to obtain access by hook or by crook.[15] EHRs stored in this fashion will also fall outside of the HIPAA protections.

In the Covid-19 era, there are now many third parties who might seek patient consent for EHR access. These now include travel-related companies such as airlines or cruise lines or hotels, seeking data for the spate of forthcoming "vaccine credentialing systems" such as the Digital Green Pass, which is but one of many initiatives in this area seeking to certify patient vaccination. Other entities that may want access to patient records include gyms, life insurers, schools, health practitioners not subject to HIPAA, state motor vehicle departments, immigration authorities in the United States and in other countries, countries that issue visa to travelers from the United States, and any institution with market power over individuals.

When and if EHRs become readily available to third parties, we predict that new start-ups will emerge to exploit the records, and most of these activities will not benefit patients or the health care system in any useful way. The average consumer will not stand a chance. Many of those who chose to download their EHRs will end up with their entire health records in the hands of multiple third parties. The records in the hands of these third parties will have little or – more likely no – legal privacy protections at all.

Most consumers will be unaware of these consequences. After a patient's health records end up in the hands of an unregulated party, that record will be used by marketers, junk mailers, quacks,

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[15] See, e.g., Ed Cara, Gizmodo, Researchers Create Fake Profiles on 24 Health Apps and Learn Most Are Sharing Your Data (Mar. 21, 2019), https://gizmodo.com/researchers-create-fake-profiles-on-24-health-apps-and-1833474535.

fake supplement sellers, and more. [16]There is no time limit. The record will haunt the patient for the rest of their life, and for their heirs as well. There is no way under current law to stop unregulated actors or to retrieve the records they obtain with patient consent. Records that find their way to the dark web will be irretrievable lost forever beyond all hope of control.

We would suggest the possibility that EHRs could be exported to third countries and to actors there who are beyond the reach of American law and institutions. However, most other countries around the world have general purpose data protection laws that provide meaningful privacy rights to data subjects. The export of EHRs to evade restrictions here is, at present, undesirable because there are more privacy protections for consumer records almost everywhere else in the world than in the United States.

3. Costs

The fiscal cost of health care is not an issue the World Privacy Forum studies. However, we observe in passing that many of the consequences of patient access and the spread of patient data across multiple data ecosystems (data brokering, advertising, and potentially many others) are likely to bring increased costs for the health care systems overall. We also note that the costs of fraud and misinformation could mount to surprising levels after patients' EHRs become widely available by patients' consent to third parties. After this point, there is no telling how the ingenuity of fraudsters — from fake supplement manufacturers to fraudulent health clinics, and assorted others will expand to soak up more money from the health care system and from patients unable to distinguish truth from fantasy. This is a serious risk, and the proposal from HHS has not offered any mitigation for concerns of fraudulent requests for patient health care data, or uses of that data after acquiring it.

Here is one possible scenario. A patient has a blood test on Friday. The results are posted to the patients EHR and online portal on Saturday. The patient's EHR host (or other third party the patient has granted access to) obtains the results immediately upon posting based on the patient's previous authorization. The test results are normal, and the patient won't hear that from the provider until Monday or later. However, we can take just one element of the test to illustrate the problem. The blood test finds that the calcium level is 8.7. The normal range for that result is between 8.6 and 10.3. The result is normal. But to a marketer of dubious supplements, that test result is low, in fact, well below the average. We leave it to your imagination how that marketer might contact the patient with multiple, urgent messages that the patient needs to take immediate action to raise that calcium level. A clever marketer might compare the result to the previous blood test that showed a result of 8.9, suggesting that the calcium level is dropping like a rock. The marketer can promise next day delivery of calcium supplements.

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[16] See, e.g., Natasha Singer & Katie Thomas, Drug Sites Upend Doctor-Patient Relations: 'It's Restaurant-Menu Medicine' (Apr. 2, 2019), https://www.nytimes.com/2019/04/02/technology/for-him-for-hers-get-roman.html.

We observe that greater accessibility to patient EHRs could create new opportunities to affect health care in other unwelcome ways. For example, a campaign against generic drugs might attract considerable funding (on a not-for-attribution basis, of course) from those with a vested interest in proprietary drugs. An advertising campaign targeting individuals using information from their EHRs has great potential to be successful enough, especially when the facts are not of any particular concern to true believers or to crooks. We note that anti-vaccination campaigns have met with success even though there is often no financial incentive to oppose vaccination. Those who can find a way to profit can inflict considerable harm on the health care system in general with actual patient information in their hands.

B. Ideas for Solving the Problems Created by Third Party Access to Patient Health Files

1. Federal Trade Commission involvement

The Federal Trade Commission has jurisdiction over many of the companies not covered by HIPAA that engage in the collection and sale of consumer health information. We urge HHS to hold a joint hearing or workshop with the FTC that examines the intersection between commercialization of patient health data, patient consent interfaces (including dark patterns that can trick patients into disclosing records), and the forthcoming free flow of patient records through multiple non-health data ecosystems.

The FTC does have limitations and cannot be expected to enforce away a bad regulation that allows unrestricted sharing. But working with the FTC to ensure there are state-of-the-art consent mechanisms, proper notice, and some form of FTC involvement could be helpful here.

2. HIPAA-covered entities should have a role in being able to refuse or restrict requests from non-health entities which could be harmful to patients

No matter how well-meaning the intent, HIPAA-covered entities will not be able to police how EHRs are accessed or used by third parties outside the domain of HIPAA. After patients click a tick box to release their records, the records will be in the hands of a third party. Covered entities are likely to view this as not their problem. If patients obtain their own EHRs and transfer the records to third parties, then covered entities will play no role at all in the activity. Even if a covered entity tries to limit release of an EHR to a third party in some circumstances, there will almost certainly be another covered entity willing to provide the records. When “Junk Mail America, Inc.” contacts a hospital with signed authorizations from 5000 patients, the hospital has no grounds to contest the demand for records.

The World Privacy Forum suggests that the Department revisit 45 CFR § 164.524(c)(3)(ii). No covered entity should be able to impede direct demands from patients, patient’s lawyers, or personal representatives, nor should there be barriers to the disclosure of health information to

other health care providers. But covered entities need to have a way to restrict or refuse demands from any entity which could be harmful to patients. This could fall into myriad categories, some of which will shift and change with time.

We note here that apparently no consideration was given to victims of crime, including crimes of domestic violence. There are significant safety issues relating to the release of health records to third parties who have attempted to harm the patient in a criminal act. This is particularly true in domestic violence incidences. We also note that during the Covid-19 emergency, we have seen a significant uptick in problematic health information releases to unsafe third parties who are family members. This and other safety issues need to be addressed by HHS in a way that aligns with the protections already afforded in the Violence Against Women Act.

3. Self-regulation: *No*. Voluntary Consensus Standards: *Yes*.

WPF does not believe that "self regulation" should be an option here. Self-regulation has proven to be highly ineffective.[17] However, Voluntary Consensus Standards (which OMB has outlined in OMB Circular A-199 https://obamawhitehouse.archives.gov/omb/circulars_a119_a119fr) are fit for purpose here. VCS are already in use by HHS. The FDA utilizes Voluntary Consensus Standards to allow industry and other stakeholders to create VCS standards for medical devices, this in lieu of lengthy ANSII processes for standards. It has worked extremely well; see for example the 1,400 - plus medical devices standards created under voluntary consensus standards: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/results.cfm. The approach of utilizing one-sided, industry-only self-regulation without any direct and meaningful participation by consumer representatives and other stakeholders has consistently failed to protect consumers in any meaningful way. With the availability of voluntary consensus standards under OMB Circular A-119, this should be the only consensus mechanism considered.

4. Consumer education

Educating consumers about anything is a hard task. We do not oppose consumer education, but we have no great expectation that it will be as effective as it needs to be to provide adequate consumer protection. In a nutshell, there is too much competition to educate consumers about issues like blood pressure, nutrition, computer security, financial matters of all stripes, auto safety, and dozens of other important topics. The health care system does a poor job of educating patients about HIPAA. The World Privacy Forum has some experience here. We offer *A Patient's Guide to HIPAA*, [18] and we observe that even after 12 years of publication, there are few, if any,

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[17] See generally World Privacy Forum, Many Failures – A Brief History of Privacy Self-Regulation (2011), https://www.worldprivacyforum.org/2011/10/report-many-failures-a-brief-history-of-privacy-self-regulation/.

[18]See World Privacy Forum, A Patient's Guide to HIPAA, https://www.worldprivacyforum.org/2019/03/hipaa/; see also our Health Category page for additional materials https://www.worldprivacyforum.org/category/health-privacy/.

comparable guides for patients available anywhere. The notion that someone, somewhere will effectively educate patients about the real-world and quite meaningful consequences of sharing their EHRs with non-health third parties is, unfortunately, unlikely. What we try to do is provide information to patients who want it. That is the best audience.

Those who seek to exploit EHRs — and there are many non-health related data acquirers who are interested in this — will have no trouble cajoling, tricking, deceiving, cheating, misleading, and generally inducing patients into giving up their EHRs for non-health purposes. Requirements for consent or authorization will not work either. Records obtained by patients will have no procedural prerequisites before the records can be shared with third parties. If there is money to be made by obtaining records from the health care system with patient approval, those who seek to profit will find a way to comply with any access requirements. Remember too that it only takes one slip for a patient's entire health history to end up in the hands of a data broker. Once that happens, the record and its information will be gone forever, scattered in the files and profiles of untold numbers of companies.

Again, we recognize the many parties that want to use this type of data responsibly. We have watched the data arena for a very long time, and have well-grounded reason to believe there will be some quite serious abuses unless there are procedural or other protections put in place. It is in this context that we want to mention briefly the ways we have documented that health care data is utilized outside of the HIPAA-covered entity ecosystem.

WPF has written extensively about our research into data brokers and their impact on people. See *The Scoring of America* for detailed research about data brokers.[19] This report contains a section on using a variety of marketplace data to score consumers in the health arena. We have also testified about sensitive health data and the ways that it tends to escape the protections of the HIPAA data ecosystem. The harms and problems we have already documented have not gotten better; they have worsened. The fact patterns indicate that if HHS goes through with its proposal to allows patients to simply deliver their EHRs into non-health hands without any notice, education, or intervention, that an ugly free-for-all will ensue, one that is focused on acquiring detailed patient data for purposes of monetization.

We have written extensively about data broker *lists* in the past. These lists still exist, and they are shocking for people who are unaware of them. We have found lists of sufferers of particular diseases like asthma, heart disease, and literally thousands of ailments. We have found lists of people on specific prescription medications - including medications that are especially sensitive. We have found lists of people inferred to have certain diseases or conditions. But today, those lists that used to be on paper, are now digitized. Those digitized records are seldom used alone. Most often now, datasets with identifiable patient information are hosted on one or more cloud

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[19] Pam Dixon and Bob Gellman, The Scoring of America, World Privacy Forum. April 2014. http://www.worldprivacyforum.org/wp-content/uploads/2014/04/WPF_Scoring_of_America_April2014_fs.pdf

services, and a menu of APIs for rich and rapid data access along with add-ons of analytics services can be utilized together as a service.

In short, the data broker model has evolved radically. It is now possible (and simple) for health datasets to be found, acquired, and modeled analytically with real-time inferences. This is a positive development for healthcare when used for health-related purposes and covered under either HIPAA or the Common Rule. Full patient health records belong in the HIPAA-covered ecosystem when they are identifiable. Fully identifiable patient health records should not be so readily clicked over to non-health third parties without some vetting and determination of purpose.

Utilizing and analyzing individuals' health data is a big business, and there is a lot of profit involved in acquiring accurate health data to feed this engine. A leading source of this data will in all likelihood be the patient EHR as shared with third parties, unless HHS ensures there are sufficient procedural and administrative controls in place.

C. Things that might help

We wish we could offer a simple, one-step solution to the dilemma we identify here. We do not believe that there is any single magic bullet here. We offer instead some ideas and some thoughts that have some potential to help when used in combination.

Commission a Study: The full consequences for patients of the availability of EHRs that the NPRMs propose will be enormous. We believe that health care costs for everyone will increase, that the practice of medicine will change for the worse, and that patient privacy will be devastated as lifetime patient records leak out into the world. We acknowledge here, as we said in the introduction, that there are benefits as well. Nevertheless, the negative consequences will be significant and, for patients who allow their EHRs to "escape" into the hands of data brokers, those consequences will last a lifetime and will affect their heirs. the Department should commission a study of all of the consequences before moving ahead. The National Committee on Vital and Health Statistics is one existing group that could be asked do a study without much effort or additional administrative steps. We would prefer to see the Department commission an advisory committee like the Secretary's Advisory Committee on Automated Personal Data Systems that first proposed FIPs in 1973.

Expand HIPAA: There are still health care providers and health plans not covered by HIPAA. This choice by the Department has already had many unfortunate consequences, and one is that EHRs covered by HIPAA end up in the hands of those not covered by HIPAA. A few of the problems raised by the NPRMs would be reduced or eliminated if the Department expanded HIPAA to cover all health care providers. The Department has the authority to accomplish this, and we think extending HIPAA to cover *all licensed health care providers* (regardless of their use of electronic transactions) would be most beneficial. This change will provide a measure of

help. We admit it will not address the core of the privacy problem we identify, however, it still improves the overall picture.

Wait for Congress. The big problem and the principal cause of the dilemma in waiting for Congress is the absence of any general-purpose privacy law that covers the vast universe of data aggregators, collectors, analysts, and others waiting to get full patient records. We suggest that the Department ask for improved privacy protections for EHRs that end up in third party hands as a result of increased interoperability. We fully understand the frustrations of waiting for congressional action, and we urge HHS to create a safety net of procedural protections for patients. See next point.

Set Procedural Barriers. First, we do not propose limiting direct patient access, access by a patient's personal representative, a patient's lawyer, or another health care provider. However, we also recognize that unfettered access by third parties to patients' health records can create systemic privacy problems. We already suggested modifying 45 CFR § 164.524(c)(3)(ii) to give covered entities a basis to resist transferring EHRs to most third parties outside the health care system. Other procedural barriers that focus on those who would exploit patient records for non-health purposes could help as well. When presented with a patient authorization from a data broker, marketer, or the equivalent, covered entities should be allowed to contact the patient, explain the type and potential consequences of the authorization, and give the patient the opportunity to change their mind. Also, regulations can make it easy for patients to limit an authorization that they have already signed, perhaps by the date of treatment, a restriction on what may be disclosed, require an additional authorization for genetic information, and a flat 30-day (or one-year) expiration date so that those seeking to exploit patient health records must obtain a new authorization. This will only help so much because the entire record will already have been obtained under the original authorization. But it could still be helpful. Allowing a 90-day waiting period could also be helpful. Used creatively, procedural barriers have potential to help.

Standards. We already said that industry self-regulation has no real hope of helping. We recognize that the authority of the Department to regulate third party users outside the health care system ranges somewhere between limited and non-existent. Nevertheless, inviting industry and consumers to work together to establish privacy standards and limits under the *OMB Circular A-119 - Voluntary Consensus Standards*, could prove beneficial. There are some better players in industry who might accept this approach. For the US definition of VCS, and the baseline procedures that must be in place, see *OMB Circular A-19* at: https://obamawhitehouse.archives.gov/omb/circulars_a119

We understand that the crooks, quacks, and charlatans waiting to exploit EHRs will ignore standards activities, but the Department may make some progress by appealing to the better nature of reasonable actors. There are so few options to ameliorate the situation that this has some appeal despite the inherent limitations. The Department's role can be limited to that of convener, with the real burden shifted to those willing to develop and accept the standards.

Specific steps to take in this NPRM. We recognize that there is only so much that the Department can do in this NPRM and in the context of the HIPAA privacy rule. However, there are steps that might help.

The improved NPP that the NRPM proposes could be adjusted to require that any place where an NPP mentions third party access, the notice must include a statement like this:

> **Any health record given to a third party outside the health care system will not be protected by the HIPAA health privacy rule in the hands of that third party. Your health information might be sold, shared, or otherwise utilized by that third party.**

A notice like this might make some patients think about before authorizing disclosure.

We wish it were possible to do more than just a notice, and we would certainly welcome other steps. What is most important is that the Department step up to the plate and take some action, any action, that will warn patients about the consequences of data sharing. To date, Departmental actions are solely facilitating use of patient data by any and all third parties without any steps to recognize the dilemma that we identify in these comments: not all third parties are trusted third parties.

We thank you for the opportunity to submit these comments.

Pam Dixon,
Executive Director
World Privacy Forum
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July 30, 2021

Denise E. Love, BSN, MBA
Richard W. Landen, MPH, MBA
Co-Chairs, Subcommittee on Standards
National Committee on Vital and Health Statistics
Email: NCVHSmail@cdc.gov

Re: Request for Public Comment on Healthcare Standards Development, Adoption, and Implementation

Dear Ms. Love and Mr. Landen,

I would like to thank the Subcommittee on Standards for the opportunity to provide input on healthcare standards development, adoption, and implementation.

X12 has operated as an ANSI-accredited standards development organization (SDO) for more than 40 years. As a consensus-based SDO, we focus on the development, implementation, and ongoing use of interoperable electronic data interchange standards that drive business processes globally. X12 is supported by a strong and diverse membership that includes business leaders, process experts, and technologists, encompassing health care, insurance, transportation, finance, government, supply chain, and other industries.

X12 standards are the workhorse of business-to-business exchanges proven by the billions of transactions based on X12 standards that are used daily in various industries including supply chain, transportation, government, finance, and health care. Millions of entities around the world have an established infrastructure that supports X12 transactions.

X12's annual development, maintenance, and publication processes support suggestions from the public related to any of the X12 products. These processes allow X12 to be responsive to the needs of the public while maintaining predictable publications schedules and controlled processes that ensure the integrity of the standards and related products.

As you are aware, the majority of the administrative transactions adopted under the Health Insurance Portability and Accountability Act (HIPAA) and other related legislation and regulations were developed and are maintained by X12. X12 has developed a robust set of transactions and code sets beyond those already adopted that are in use within the health care industry; these transaction sets are implemented voluntarily. X12 intends to propose some of these for adoption, some of these are highlighted in our written comments.

Please contact me at csheppard@x12.org for more information or any questions.

Sincerely,

Cathy Sheppard
X12 Executive Director

Question 1: How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

Standardized data content that adheres to a broadly used and extensively adopted metadata standard, regardless of the syntax a particular exchange is based on, can improve data sharing between the health care actors. Standardized syntax is not enough. In the complex heath care industry, implementers should be able to choose between their trusted and well-established syntax and an alternate syntax as necessary to achieve their business objectives. This ability to move data across the ecosystem in efficient and seamless exchanges provides the diverse health care stakeholders with the opportunity to meet their business needs and still support interoperable use of the data.

X12's metadata definitions, described in numerous implementation guides for specific business purposes, have been developed, refined, and use-tested for more than 40 years. Since the 1990's X12 metadata has been and continues to be exchanged in millions of health care transactions a day. This model supports the exchange of well-defined, appropriately constrained, and consistently represented data across health care stakeholders

One of the barriers to improved leveraging of standardized metadata is there are too many organizations trying to redefine metadata that has been used successfully throughout the industry for decades. Traditionally, X12's metadata was most focused on administrative transactions and HL7's metadata was most focused on clinical transactions. In today's world the lines blur between those segments of the industry more than they did in the past and the two SDOs should work cooperatively with all health care industry stakeholders to reduce inconsistencies and disconnects so that accurate data can move freely through the industry work flows as needed. This requires inclusive, neutral, and unbiased discussions and decisions as to which ANSI-accredited standards developer has the best metadata for specific uses and purposes and once agreement is reached, it requires that both SDOs commit to not duplicating or overlapping with the other SDOs metadata in a way that introduces ambiguity for health care implementers. Elimination of ambiguity is required under the HIPAA legislation so avoiding ambiguity by reducing overlap and duplication is at the core of the original HIPAA goals and should be brought back to the forefront to eliminate the conflicts implementers are trying to work through today. Having the right data available in the right syntax at the right time benefits every health care stakeholder.

Question 2: Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

X12 has a number of transactions that have not yet been considered for adoption but are available to be leveraged in ways that support interoperability, burden reduction, and administration simplification.

Examples of X12 transactions and implementation guides that could be, and in some cases already are being, leveraged to support interoperability and administration simplification include:

Acknowledgments:

X335 - 999 Implementation Acknowledgment for Health Care Insurance
X321 - 824 Application Reporting For Insurance
X330 - 277 Health Care Claim Acknowledgment
X331 - 277 Health Care Claim Pending Status Information

Health Care Claim Attachments:

X340 - 277 Health Care Claim Request for Additional Information
X341 - 275 Additional Information to Support a Health Care Claim or Encounter
X343 - 275 Additional Information to support a Health Care Services Review

Health Care Price Transparency:

X304 - 832 Health Care Fee Schedule
X109 - 274 Health Care Provider Directory
X253 - 274 Health Care Provider Information
In Process – Good Faith Estimate Exchange

Payer to Payer Transfers:

In Process X274 - 275 Electronic Health Record Data Transfer Between Trading Partners

All Payer Claim Databases:

X298 - 837 Post-adjudicated Claims Data Reporting: Professional
X299 - 837 Post-adjudicated Claims Data Reporting: Institutional
X300 - 837 Post-adjudicated Claims Data Reporting: Dental
X326 - 837 Health Care Service: Data Reporting

Question 3: How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

As a multi-industry SDO, X12 has experience with different implementation, testing, and certification models in other industries, including supply chain, transportation, aerospace, and finance. In some of these industries, there is only one strong industry group that tests and certifies implementers within their ecosystem and provides best practice implementation steps. In others, market forces encourage the largest implementer organizations to agree among themselves related to testing and certifying and then impose those principles on other industry stakeholders. Neither of these models matches up well with the health care industry model but there are takeaways that could help inform advancements in these areas in health care.

Question 4: What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

In the short-term, the highest priority should be for HHS to complete the rule-making process required in the original HIPAA legislation related to the adoption of the X12 implementation guides for claims attachments and the associated HL7 CDA standards.

Also in the short-term, HHS should publish an Interim Final Rule asserting that use of the X12 999, TA1, 277s, and 824 transactions are mandated by reference since instructions for those acknowledgements are included in already mandated implementation guides.

Based on the expectation that X12 will be advancing recommendations through required federal processes in the short-term, in the mid-term HHS should begin preparing for an NCVHS recommendation related to advancing the version on currently-mandated transactions, supporting additional syntaxes for some of the mandated transactions, and new mandates related to other X12 transactions and code sets.

Also in the mid-term, HHS should assess the various federal agencies, departments, and groups working toward or issuing health care industry-related mandates to eliminate or reduce overlap and conflicts in the federal edicts and eliminate confusion among health care stakeholders as to which instructions supersede other instructions in cases of overlap and conflict.

In the long-term, as has been repeatedly suggested, HHS should shorten and simplify the federal processes related to mandating messaging standards and advancing the version on already mandated standards so that the health care industry can implement transactions and versions that support the health care industry's business requirements in a much more timely fashion.