



## Fiscal Year 2020 Committee Report

### Background

The National Committee on Vital and Health Statistics (NCVHS) advises HHS on health data, statistics, privacy, national health information policy, and the Department's strategy to best address these issues. A key aspect of this work involves advising the Secretary on HHS's implementation of provisions established in health care-related legislation. For the Health Insurance Portability and Accountability Act (HIPAA), the Committee advises HHS regarding the implementation of the Administrative Simplification provisions of the law, specifically adoption and implementation of standards, identifiers, and code sets and the privacy and security rules.

In FY20, the Committee's focus was geared toward this work more so than usual as it conducted a review of new proposed rules and began work on its periodic Report to Congress. The primary goal of the report is to update the status of implementation of the Administrative Simplification provisions of HIPAA, informing decision-making on HHS data policy, states, local governments and the private sector. As stipulated in the Patient Protection and Affordable Care Act (ACA), the Committee provides advice and guidance regarding operating rules and is designated as the official Review Committee for health care transactions – consisting of

standards and operating rules – and advises HHS on opportunities to improve standardization and uniformity in a number of areas. With passage of the 21st Century Cures Act, the Committee coordinates with the Office of the National Coordinator of Health Information Technology (ONC) and the Health Information Technology Advisory Committee (HITAC) on policy development for clinical (electronic health record [EHR]) and administrative data standards.

### NCVHS FY20 Recommendation Letters to the HHS Secretary

- Letter to the Secretary: Recommendations for Adoption of New Pharmacy Standard Under HIPAA (April 22, 2020)
- Letter to the Secretary: Additional recommendations for HHS actions to improve the adoption of standards under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (December 9, 2019)
- Letter to the Secretary: Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard (November 29, 2019)

## **Fiscal Year 2020 Overview**

The Committee started FY20 with several vacancies, welcoming seven new members over the course of the fiscal year. Nominations for James Cimino, MD, Margaret Skurka, MS, RHIA, Denise Chrysler, JD and Melissa Goldstein, JD were approved early in the fiscal year, followed by approval of three additional members whose terms began in the latter part of the year – Tammy Feenstra Banks, MBA, Jamie Ferguson and Wu Xu, PhD. In addition, Valerie Watzlaf’s nomination was approved to begin in October 2020. The Committee said good-bye to Bob Phillips, MD, Co-chair of the Subcommittee on Population Health and Roland Thorpe, PhD, member of the Subcommittee on Population Health early on in the fiscal year.

With FY20 being the final year for NCVHS Chair Bill Stead, and Subcommittee on Standards co-chair Alix Goss, the Committee focused on completion of two major projects led by the Subcommittee on Standards. As was the case for all government agencies, five months into the fiscal year, the Committee turned its attention toward the impact of the COVID pandemic, with the focus on methods and approaches to collect, use, protect, and share data to deal with the pandemic through the Subcommittee on Privacy, Confidentiality and Security.

Highlights from the fiscal year:

- **Recommendations on Upcoming Transition from ICD-10 to ICD-11**

At its November 2019 meeting, the Committee approved a letter and recommendations to the Secretary on the upcoming transition to ICD-11 including that HHS conduct research to evaluate the impact of different approaches to the transition and implementation of ICD-11 in the United States for mortality and morbidity classification; and provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11. With insight gained from in-depth expert input, the Committee included a targeted research agenda and communication plan as part of its recommendations to emphasize the goal to avoid the delays encountered during the transition from ICD-9 to 10.

- **Additional Recommendations to further the Predictability Roadmap**

Also, at the November 2019 meeting, the Committee approved a letter with recommendations for HHS actions to improve the adoption of HIPAA standards in follow up to its February 2019 letter on the same topic. The Committee developed these recommendations in response to extensive input from healthcare industry stakeholders seeking relief, recommending that HHS: 1) Provide guidance on data needed to support adoption of standards; 2) Secure support for testing and evaluation of standards and operating rules prior to adoption; and 3) Facilitate a more nimble approach to standards development to better support federal policy objectives, industry business requirements and emerging technologies.

- **Launch of Project to Study Convergence of Clinical and Administrative Data using Prior Authorization as a Use-Case**

For the November 2019 meeting, the Subcommittee on Standards organized an expert panel on prior authorization as a use-case to inform their work on advancing convergence of clinical and administrative data. Representatives from CMS, AMA, AHIP, CAQH CORE, WEDI and the World Privacy Forum briefed the Committee followed by a significant discussion with Don Rucker, MD, National Coordinator for Health IT on the future of data convergence. That dialogue catalyzed proactive collaboration between NCVHS, the Office of the National Coordinator (ONC) and its federal advisory committee, Health Information Technology Advisory Committee (HITAC), to identify approaches to further the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of “record once and reuse.” As a result, HITAC convened a Task Force focused on the Intersection of Clinical and Administrative Data (ICAD) using the prior authorization transaction as a use-case. Four NCVHS members served on the ICAD Task Force, including both co-chairs of NCVHS’s Subcommittee on Standards, Alix Goss and Rich Landen. Alix Goss served as co-chair of the ICAD Task Force.

- **Recommendations for HHS Adoption of Updated NCPDP Standard**

In January 2020, NCVHS considered a Designated Standards Maintenance Organizations (DSMO) request to recommend the adoption of an updated version of the pharmacy standard. The Committee issued a request for public comment prior to the March Committee meeting, which provided constructive insight to inform development of the following recommendations to HHS: 1) Adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6 to replace version D.0; 2) Time the implementation of F6 in accordance with industry requests; and 3) Act on the two previous NCVHS recommendations to adopt the Batch Standard and the Medicaid Subrogation Standard put forth in the Committee’s May 2018 Letter.

- **Data Access, Privacy and Security During COVID-19**

At its June meeting, senior HHS leadership suggested that the Committee consider potential options for providing advice on data accessibility together with privacy and security protections related to current public health surveillance activities. As a result, the Subcommittee on Privacy, Confidentiality and Security convened a virtual roundtable meeting of experts in September 2020. Invited experts presented and engaged with members on data stewardship principles designed to guide the privacy and security of individually identifiable health information when new technologies are deployed for public health surveillance during an emergency, including new uses of medical data, social media, geolocation data, proximity or adjacency data, and contact tracing applications. The Committee will use this input to inform development and dissemination of a toolkit outlining

methods and approaches for safeguarding individually identifiable health data collected, used, and shared during a pandemic or long-term nationwide public health emergency.

- **Review of CAQH CORE's Three Proposed Operating Rules**

In response to a request received in February 2020, from CAQH CORE, the Subcommittee on Standards issued a request for public comment followed by a two-day hearing to consider three new operating rules for federal adoption: 1) CAQH CORE Prior Authorization Data Content Rule; 2) CAQH CORE Prior Authorization Infrastructure Rule; and 3) CAQH CORE Connectivity Rule. Invited industry stakeholders provided testimony to members on the anticipated benefits, costs and possible downsides of each rule. The full Committee will deliberate on recommendations at its November 2020 meeting.

### **Committee Impact and Influence**

The Committee developed three sets of recommendations this fiscal year, which were submitted in letters submitted to the HHS Secretary – all pertaining to HHS leadership in standards development and adoption. The Committee has been a steady influence in providing guidance and support for the administrative simplification processes. In many cases the impact or effect of NCVHS recommendations has come to fruition years beyond their issuance. Examples of the Committee's influence and impact this fiscal year include:

- **Final Rule to Rescind the Unique Health Plan Identifier**

In October 2019, HHS acted on the recommendation of NCVHS and issued a Final Rule to rescind the Unique Health Plan Identifier and Other Entity Identifier (OEID). NCVHS is referenced throughout the notice for its recommendations and input into the process. The Final Rule eliminates the regulatory requirement for health plans to obtain and use an HPID and eliminates the voluntary acquisition and use of the OEID. The Final Rule also simplifies the process for deactivating the existing identifiers to minimize operational costs for covered entities. NCVHS held a hearing in May 2017 on the issue and subsequently submitted recommendations to the Secretary in June 2017. See <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2017-Ltr-HPID-June-21-wws-w-sig.pdf>.

- **ONC, HITAC and NCVHS Collaboration on Data Convergence with Prior Authorization as a Use Case**

ONC's [HITAC advisory committee](#) launched a Task Force to study the Intersection of Clinical and Administrative Data (ICAD) using prior authorization as a use case in collaboration with NCVHS. The aim of the Task Force was to recommend solutions toward achieving convergence of clinical and administrative data, thereby improving data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of “record once and reuse.” The Co-chair of NCVHS's Subcommittee on Standards, Alix Goss, served as Co-chair of the ICAD Task Force together with three additional NCVHS members, together with members of HITAC and other experts. NCVHS anticipates leveraging the ICAD

recommendations as it moves forward to define the Committee's scope of work to continue this work into FY21. On June 2, 2020, The Journal of AHIMA cited NCVHS in an online article, "Bringing Together Administrative and Clinical Data," including kudos on the joint collaboration with NCVHS and ONC/HITAC on the work of the ICAD Task Force.

- **HHS/CMS Reports on HIPAA Transaction Compliance Statistics**

In January 2020, the Centers for Medicare & Medicaid Services (CMS) Division of National Standards released [revised statistical reports](#) regarding the [CMS HIPAA complaint enforcement program](#). The Complaint Enforcement Program handles allegations of violations of the HIPAA transactions and code sets rules and the operating rules by covered entities. The redevelopment of these reports was done in part based on NCVHS recommendations stemming from NCVHS's Predictability Roadmap initiative. The CMS Enforcement Program's goal was to refine the complaint enforcement statistical reports in an effort to meet the industry's expectations for enforcement visibility and to yield useful data for covered entities and for Standards Development Organizations and Operating Rules Authoring Entities. The [revised statistical reports](#) illustrate to external stakeholders the quantity and quality of complaints received by CMS. In addition, the revised statistical reports provide complaint types submitted by covered entities, violations based on type of transaction, and resolution time frames. CMS anticipated that revised reports would provide greater insight and foster greater collaboration with covered entities to achieve full compliance with [HIPAA Administrative Simplification](#).

- **Wider Distribution of NCVHS Beyond HIPAA Report**

The eHealth Initiative & Foundation (eHI) and the Center for Democracy and Technology (CDT) included the NCVHS *Beyond HIPAA* report as part of its development work for its *Consumer Privacy Framework for Health Data*. They shared the report with a diverse group of meeting participants, including representatives from tech firms including Facebook, Apple, and Google; major retailers such as Walmart and Amazon; consumer groups including the National Partnership for Women and Families and Consumer Reports Advocacy; privacy advocates including the Future of Privacy Forum and LGBT Tech; medical associations; academic leaders; and observers from the HHS Office for Civil Rights and the Federal Trade Commission. CDT and eHI issued their draft Framework on August 26, 2020; it included a description of the health data that warrant protection, as well as the standards and rules that should govern them. Much of this work aligns with NCVHS's prior recommendations on this topic. The Framework also includes a self-regulatory model that would hold companies accountable to these standards and rules. The work is the first output of a collaborative effort addressing gaps in legal protections for consumer health data outside of the Health Insurance Portability and Accountability Act's (HIPAA) coverage. The collaboration was funded through a grant by the Robert Wood Johnson Foundation.

- **In response to NCVHS's recommendations on the transition from ICD-10 to 11**, the [WEDI Board of Directors](#) and Jay Eisenstock, Chair, sent a letter to the HHS Secretary in February 2020 applauding the Committee's work. In the letter, WEDI also offered its

continued support of NCVHS, and more specifically, offered WEDI's assistance on several recommendations and next steps on ICD-11. Specifically, they wrote:

"We support the overall request by NCVHS to begin analyzing the International Classification of Diseases, version 11 (ICD-11) to prepare for its potential adoption. We are offering our assistance to a few specific recommendations made by NCVHS. At this point in the evaluation process of ICD-11 for morbidity reporting, WEDI may be able to provide support for the following activities.

- ♦ Identify use cases for ICD-11 and evaluate how well ICD-11 will meet these needs.
  - ♦ Evaluate the impact of the ICD-11 code structure changes in different environments and on other health information standards adopted under HIPAA.
  - ♦ Identify the potential of ICD-11 to support greater convergence of clinical and administrative standards.
- In addition, NCVHS received correspondence from ANS, the French governmental Agency for e-Health regarding NCVHS's report and recommendations on the upcoming transition to ICD-11. As the French Health Terminology Management Center (HTMC) aims to organize the terminologies ecosystem used in France, they remarked on the usefulness of the Committee's work and interest in collaborating with U.S. government counterparts.
  - The Milbank Quarterly published [Well-Being in the Nation: A Living Library of Measures to Drive Multi-Sector Population Health Improvement and Address Social Determinants](#), a synthesis of NCVHS' recommendations to HHS, including a measurement framework for community health and well-being grounded in the social determinants of health. Two NCVHS members contributed to the subsequent Well-being in the Nation (WIN) work led by the Institute for Healthcare Improvement's 100 Million Healthier Lives project to publish a framework of measures for use by states and communities as recommended by NCVHS.
  - Additionally, the design of *Healthy People 2030*, the nation's program for tracking public health goals, priorities and challenges, was influenced by NCVHS' measurement framework presented in the above Milbank Quarterly article, notably with additions of two topics – "Social Determinants of Health" and "Settings and Systems" that mirror the measurement domains envisioned by the Committee.

## **Other Noteworthy Updates**

- The National Institute for Standards and Technology and HHS Office for Civil Rights invited NCVHS Chair Bill Stead and Linda Kloss, former Chair of the Subcommittee on Privacy, Confidentiality and Security to present at the October 2019 OCR/NIST Safeguarding Health Information conference. In their presentation, they highlighted NCVHS' Framework for the Use and Protection of Health Information Beyond HIPAA, and related work of the Committee. This session garnered additional interest in the Committee's work on de-identification and other issues.
  - ♦ As a result of the NIST presentation, AMIA contacted NCVHS for input on the Committee's privacy work as part of their work with Senate staff regarding consumer protections for privacy outside the current HIPAA boundaries. Alongside a host of other groups, AMIA has been communicating with ONC and the Hill on the

deficiencies of HIPAA given the evolving health data landscape through various public and private channels.

- ♦ In a blog post covering the OCR/NIST conference, Marcy Wilder wrote: “The National Committee on Vital and Health Statistics has developed a framework for protecting health data outside the HIPAA context. Its recommendations include the establishment of federal standards for health information security and privacy for health data registries, mobile device manufacturers, and mobile app creators. The Committee’s report on the framework also urges the development of consumer guidance concerning direct-to-consumer genetic testing that is not protected by HIPAA.” ([LexBlog, 10/21/2019](#))
- In January 2020, NCVHS Chair Bill Stead presented at the ONC Annual Meeting framing up a discussion on convergence of clinical and administrative data during the session “Merging Clinical and Financial Standards: The Shift to Value and Transparency.”
- Several Committee members presented NCVHS recommendations to stakeholder organizations, for example Alix Goss presented an update during the March 2020 HIPAA Summit and Rich Landen presented a similar update in April 2020 to the National Uniform Claim Committee.

## **NCVHS Meeting Highlights**

The full Committee convened three times during the 2020 fiscal year, in-person for the fall meeting and virtually for the remainder due to the pandemic. To follow is a high-level summary:

### November 13-14, 2019 Full Meeting – Cohen Building, Washington DC

- The full Committee met to deliberate and approve two letters to the HHS Secretary with recommendations on: 1) How to prepare for the national conversation on adoption of ICD-11 as a mandated U.S. health data standard including a suggested research plan and a suggested communications plan, and 2) Additional actions that HHS could take to improve the adoption of standards under HIPAA in follow up to the Committee’s February 2019 letter with recommendations. These recommendations were based on significant input to the Committee by health care industry stakeholders. The Committee found that the current pathway for HIPAA-related rulemaking is not meeting the needs of HIPAA-covered entities, nor is it serving federal policy objectives around efficiency, effectiveness, and reductions of burden.
- As part of the Committee’s ongoing collaboration with ONC regarding challenges with prior authorization, the Committee convened a panel with representatives from AMA, AHIP, WEDI, CAQH/CORE, the World Privacy Forum, and CMS. Panelists provided an update on present-day burden facing patients and providers directly as a result of problems with the prior authorization transaction. Following the panel, NCVHS members and the HHS National Coordinator for HIT discussed next steps for a possible federal effort to develop an approach to ameliorate present day challenges – then focused on harnessing greater use of

technology and interoperability combined with changes in approach in the implementation of prior authorization.

- An official with the Office for Civil Rights updated the Committee on OCR's HIPAA policy work and enforcement activities. OMB staff discussed current work underway to implement the Federal Data Strategy, suggesting approaches for working directly with federal agencies to increase availability of data at the sub-county level.

#### March 24-25, 2020 – Held virtually

- At its spring meeting, the Committee welcomed four new members to NCVHS. The Committee unanimously approved a motion to recommend that the HHS Secretary adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6. The standard applies to retail pharmacy and medical transactions. The Committee requested input and comments from the public in advance of this meeting to inform its deliberations about the benefits and/or costs of changing to this new version.
- The Subcommittee on Standards introduced a new project scoping statement for its work on convergence of administrative and clinical data standards using the prior authorization transaction as a use-case. The Subcommittee also updated the Committee on its activities in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and the Health Information Technology Advisory Committee (HITAC) regarding the opportunity for burden reduction through this work.
- Together, CMS and ONC updated the Committee on their respective agencies' recently released Interoperability Rules to facilitate a new data exchange landscape. ONC also briefed the Committee on the FHIR at Scale Task Force (FAST).
- NIST presented the agency's Privacy Framework, a voluntary tool that the agency released in January 2020 designed to support health providers with managing privacy risks, to optimize the beneficial uses of data and to minimize adverse consequences. It will also help organizations fulfill their compliance obligations and encourages privacy risk assessment – offering privacy management practices and resources.
- The Subcommittee on Privacy, Confidentiality and Security led a discussion to assess priority areas for focus.

#### June 17-18, 2020 – Held virtually

- The Committee focused on the work of the Subcommittee on Privacy, Confidentiality and Security (PCS). In light of the pandemic, ASPE suggested that the Subcommittee focus a portion of its workplan on data accessibility and privacy. The PCS chair led a discussion with the full Committee regarding potential options for providing advice on data privacy and security protections related to current public health surveillance activities. Two invited data privacy experts briefed the Committee on the topic to inform the discussion. CDC's Deputy Director for Public Health Science and Surveillance (DDPHSS), the Director of the National Center for Health Statistics (NCHS), and Deputy of NCHS's Division of Vital Statistics each



briefed the Committee on CDC activities, including on public health data modernization, to inform discussions on the data landscape transformed by the pandemic.

- The Subcommittee on Standards updated the full Committee regarding plans for the upcoming August 2020 hearing that solicited information about the costs, concerns and benefits of a new operating rule for connectivity and operating rules for the prior authorization transaction proposed by CAQH CORE. The Subcommittee also provided an update on progress of the Office of the National Coordinator (ONC) HITAC Task Force on Intersection of Clinical and Administrative Data (ICAD), on which four NCVHS members participated. CMS's Division of National Standards (DNS) provided an update including activities to provide education on and revitalize interest in using an exception to the process included in the HIPAA regulations, which allows covered entities to request an exception to test or pilot new standards and new approaches to HIPAA transactions. DNS recently released a memo with information on the process and how to extend the exception, which is time-bounded.
- The Committee initiated discussions on the NCVHS 14th Report to Congress, including a proposed approach, major themes and timeline for its development and completion over the coming months.

## **Subcommittee Convenings**

NCVHS Subcommittees convened the following two meetings in FY20:

### August 25-26, 2020: Subcommittee on Standards Hearing - Held virtually

The Subcommittee on Standards met to address a request received February 24, 2020, from CAQH CORE to consider three new operating rules for federal adoption: 1) CAQH CORE Prior Authorization Data Content Rule; 2) CAQH CORE Prior Authorization Infrastructure Rule; and 3) CAQH CORE Connectivity Rule. Invited industry stakeholders provided testimony to Committee members on the anticipated benefits, costs and possible downsides of each rule. The Data Content and Infrastructure Rules pertain specifically to the prior authorization (278) transaction. The Connectivity Rule is to be more broadly applied to four HIPAA transactions and is designed to facilitate interoperability. CAQH CORE developed these rules for the purpose of improving utilization of administrative transactions, enhancing efficiency and lowering the cost of information exchange in healthcare. The Committee requested and received comments from the public to inform the Committee's deliberations about the benefits of adopting these rules in advance of this meeting and considered them along with the oral input of subject matter experts at the hearing – over 35 interested individuals and organizations submitted.

### September 14, 2020: Privacy, Confidentiality & Security Hearing – Held virtually

The Subcommittee on Privacy, Confidentiality, and Security explored the privacy, confidentiality and security considerations for data collection and use during a public health emergency in light of the nationwide COVID-19 pandemic. The Subcommittee heard from invited industry

stakeholders and reviewed written testimony received in advance from interested individuals, organizations and stakeholders. Public health experts presented and engaged with members regarding data stewardship principles designed to guide the privacy and security of individually identifiable health information when new technologies are deployed for public health surveillance during an emergency, including new uses of medical data, social media, geolocation data, proximity or adjacency data, and contact tracing applications. Privacy, civil rights, and public interest advocates have raised concerns over the potential discrimination and harm based on the use of information intended to protect the public if repurposed for unrelated uses, such as law enforcement, immigration, or unrelated research or commercial enterprise. The Committee will use this input to inform development and dissemination of best practices for safeguarding individually identifiable health data collected, used, and shared during a pandemic or long-term nationwide public health emergency. Comments from the public were requested to inform the Committee's deliberations in advance of the meeting and were considered together with the oral input of subject matter experts at the hearing.