National Committee on Vital and Health Statistics

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February 21, 2018

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February 14, 2018

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, DC 20201

CHARTER

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

Authority

The National Committee on Vital and Health Statistics is authorized under Section 306(k) of the Public Health Service Act, as amended, and codified at 42 U.S. Code§ 242k(k). The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Objective and Scope of Activities

The Committee shall assist and advise the Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. The Committee also shall assist and advise the Department in the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act, and shall inform decision making about data policy by HHS, states, local governments and the private sector.

Description of Duties

As the Department's statutory public advisory body on health data, statistics and national health information policy, the Committee shall assist and advise the Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues.

A. Specifically, the Committee shall assist and advise the Secretary:

1) To delineate statistical problems bearing on health and health services which are of national or international interest;
2) To stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;
3) To review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;
4) To cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;
5) In complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

B. Shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

C. Shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

D. Shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act.; and

E. Assist and advise the Secretary in complying with the requirements imposed under Part C of Title XI of the Social Security Act;

F. Study the issues related to the adoption of uniform data standards for patient medical record information and the electronic interchange of such information, and report to the Secretary recommendations and legislative proposals for such standards and electronic exchange;

G. Advise the Secretary and the Congress on the status of the implementation of Part C of Title XI of the Social Security Act;

H. Submit to the Congress and make public not later than one year after the enactment of the Health Insurance Portability and Accountability Act, and annually thereafter, a report regarding the implementation of Part C of Title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

- The extent to which persons required to comply with Part C of the Act are cooperating in implementing the standards adopted under such part;

- The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards;

- Whether the federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part;

- Any problems that exist with respect to implementation of such part;

- The extent to which timetables under such part are being met.

I. Assist and advise the Secretary in the development of such reports as the Secretary or Congress may require.

J. Monitor the nation's health data needs and current approaches to meeting those needs; identify emerging health data issues, including methodologies and technologies of information systems, databases, and networking that could improve the ability to meet those needs.

K. Identify strategies and opportunities to achieve long-term consensus on common health data standards that will promote (i) the availability of valid, credible, and timely health information and (ii) multiple uses of data collected once; recommend actions the federal government can take to promote such a consensus.

L. Study and identify privacy, security, and access measures to protect individually identifiable health information in an environment of electronic networking and multiple uses of data.

M. Identify strategies and opportunities for evolution from single-purpose, narrowly focused, categorical health data collection strategies to more multi-purpose, integrated, shared data collection strategies.

N. Identify statistical, information system and network design issues bearing on health and health services data which are of national or international interest; identify strategies and opportunities to facilitate interoperability and networking.

O. Advise the Department on health data collection needs and strategies; review and monitor the Department's data and information systems to identify needs, opportunities, and problems; consider the likely effects of emerging health information technologies on the Department's data and systems, and impact of the Department's information policies and systems on the development of emerging technologies.

P. Stimulate the study of health data and information systems issues by other organizations and agencies, whenever possible.

Q. Review and comment on findings and proposals developed by other organizations and agencies with respect to health data and information systems and make recommendations for their adoption or implementation.

Agency or Official to Whom the Committee Reports

The Committee shall provide advice and recommendations regarding health data and statistics, privacy, Administrative Simplification, data standards and health information policy to the Secretary of Health and Human Services.

Support

The National Center for Health Statistics, CDC shall provide executive secretariat and logistical support services to the Committee. The Assistant Secretary for Planning and Evaluation shall oversee and coordinate the overall management and staffing of the Committee.

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $583,738. Estimated annual person-years of staff support required is 4.8, at an estimated annual cost of $726,325.

Designated Federal Officer

ASPE and CDC will select a fulltime or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call the Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Committee reports. The DFO or his/her designee shall be present at all Committee and subcommittee meetings.

Estimated Number and Frequency of Meetings

Meetings shall be held not less than annually at the call of the Designated Federal Officer, who shall also approve the agenda. The Designated Federal Officer shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary, HHS or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and Section 10(d) of the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by the applicable laws and departmental regulations. In the event a portion of a meeting is closed to the public as determined by the Secretary, HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and Section 10(d) of the Federal Advisory Committee Act, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of Committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Duration

Continuing.

Termination Date

Unless renewed by appropriate action prior to its expiration, the charter for the National Committee on Vital and Health Statistics will expire two years from the date this charter is filed.

Membership and Designation

The Committee shall consist of 18 members, including the Chair. The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of up to four years. The Secretary shall appoint one of the members to serve a two year, renewable term as the Chair. Members shall be deemed Special Government Employees (SGEs).

Of the members of the Committee, one shall be appointed by the Speaker of the House of Representatives after consultation with the minority leader of the House of Representatives; one shall be appointed by the President pro tempore of the Senate after consultation with the minority leader of the Senate, and 16 shall be appointed by the Secretary.

Members will be appointed for four year terms by the Secretary. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which his or her predecessor was appointed shall be appointed only for the remainder of such term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Members who are not full-time Federal employees shall be paid at a rate not to exceed the daily equivalent of the rate in effect for an Executive Level IV of the Executive Schedule for each day they are engaged in the performance of their duties as members of the Committee. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by Section 5703, Title 5, U.S. Code, for employees serving intermittently.

Subcommittees

Standing and ad hoc subcommittees and working groups consisting of members may be established with the approval of the Secretary, HHS or designee to address specific issues and to provide the Committee with background study and proposals for consideration and action. The Chair shall appoint members to the subcommittees and designate a Chair for each subcommittee from the full Committee. The subcommittees shall make their recommendations to the parent Committee for deliberation. Timely notification of the subcommittees, including charges and membership, shall be made in writing to the Department Committee Management Officer by the Executive Secretary.

Recordkeeping

The records of the Committee, established subcommittees, or other subgroups of the Committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Infom1ation Act, 5 U.S.C. 552.

Filing Date

January 16, 2018

APPROVED:

1/16/2018
Date

Eric D. Hargan
Acting Secretary

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NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
January 3, 2018

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National Committee on Vital and Health Statistics

Predictability Roadmap
Fall 2017

Background

The Secretary has the authority to adopt new or updated administrative standards annually. The federal government's health information technology strategic plan and interoperability road map calls for the use of electronic health records by all providers, and the electronic exchange of patient information between all users of the data.

The Secretary last adopted a new version of both administrative and pharmacy standards for the exchange of administrative and financial information in 2009 (mandated for use in 2012). A new version of the administrative standard was developed several years ago – X12 version 6020, but was not brought forward to NCVHS for a recommendation to be adopted. Another new version of the X12 standard, 7030, has been under development for several years, though there have been delays in its development and review by industry. It was anticipated in 2016, but may not be brought to NCVHS until 2018. This is a ten year window; under current industry and regulatory processes, industry's ability to implementation could be four to six years away.

Pharmacy standards are updated on a regular schedule, but these new versions have not been proposed to NCVHS, or recommended to the Secretary since 2012. The pharmacy industry is using outdated telecommunications standards as a result. The latest version of the eprescribing standard was adopted in November 2012 with a November 2013 effective date. NCPDP is working with the Center of Medicare and the HHS Division of Health Information Technology to name a new version of the ePrescribing standards this year (2017). In addition, an NCPDP task group is investigating and gathering industry feedback on establishing a predictable cycle for bringing forward new versions of the ePrescribing standards for adoption.

The challenge facing the health care industry, vis a vis administrative/financial (non-pharmacy) transaction standards and operating rules is this: the schedule on which most standards and operating rules are updated and adopted is not predictable. It is not knowable, routine, or reliable. This makes it impossible for covered entities to plan for their business and their finances, and to have confidence in the processes or procedures.

The purpose of conducting a comprehensive information gathering initiative with the (administrative) standards development organizations, operating rule authoring entity and HHS is to identify the barriers to the update and adoption processes. These (barriers) result in the inability of covered entities to reliably know when they will, can or should upgrade their systems and operations to take advantage of efficiencies and cost saving opportunities – particularly those that would be available through standards related technology. The same group that creates and experiences the barriers, can help identify mitigation options and strategies, their feasibility, pros and cons.

Proposed Activity

NCVHS will convene a conference call and one or more workshops with the Standards Development Organizations (SDOs) and Operating Rule Authoring Entity[1] to:

a) validate the current timeline and procedures for updating the adopted standards and operating rules;

b) identify barriers to updating the standards and operating rules on a predictable timeline;

c) identify opportunities for mitigating the barriers to updating the standards;

d) identify opportunities for recommendations to the Secretary of Health and Human Services.

Outcomes

Participants will collaborate to identify opportunities for improvement in their own and each other's processes. The expected outcomes of the workshop will be:

a) Implementable ideas for process improvements for each standards development organization and operating rule authoring entity (ORAE) short term (within 12 months[2]) and longer term;

b) Analysis of alternative opportunities to adopt standards and operating rules for Health and Human Services (HHS) under current administration and future;

c) A summary report of the conference call and workshop to be publicly available and used to solicit feedback from other stakeholders;

d) Actionable recommendations for the Secretary of HHS.

The Subcommittee on Standards "Summary Report of the Appreciative Inquiry Workshop for the Predictability Roadmap," held August 2017 is available on the NCVHS website.

[1] The current operating rule authoring entity is not ANSI Accredited and has a different method of updating its operating rules than the SDOs. NACHA is also not ANSI Accredited, but governed by another authority, to be identified. All should be included in the project to identify and/or create synergies in the overall process.
[2] While this timeline may not be the end goal, we want to use SMART goals that are measurable and actionable in a reasonable time frame to be meaningful to industry and HHS.

National Committee on Vital and Health Statistics

CIO Forum 2018

Project Team: Nick Coussoule, Alix Goss

Description

a) **Purpose:** To solicit input about the business value of and challenges with the HIPAA standards and operating rules from senior level implementers, to inform the predictability roadmap.
b) **Objectives:**
   i) Obtain input to inform the predictability roadmap from the perspective of the end users of standards and operating rules.
   ii) Identify issues related to the update process of standards as it impacts the ability of implementers to conduct long term strategic planning activities.
   iii) Identify opportunities for improved governance of the update and approval process of standards and operating rules.
   iv) Identify opportunities for improvements to the regulatory processes for updating standards and operating rules.
   v) Learn about technology trends that are driving health care leaders and what they would like the next wave of standards to provide in support of these trends.
c) **Program:**
   i) Format options: half day roundtable and half day post mortem with committee or one full day of several discussion topics.
   ii) Topics:
      (1) Business value of standards and operating rules
      (2) Governance of standards and operating rules
      (3) Regulatory process
      (4) Trends in health care technology driving business change
         (a) Transport
         (b) Data Content
         (c) Collaboration tools
         (d) Interoperability
         (e) Patient engagement to improve care
      (5) Trends in health care system driving technology change
         (a) Clinical and administrative data integration and dependencies
         (b) Payment model changes
         (c) Integrated care model changes
      (6) Presentations by CIOs who are implementing systems to use data to meet new business needs for their organizations?
         (a) E.g. EPIC announcement about the creation of a new division to add billing and claims to its EHR system; the goal is to simplify the payment and revenue cycle management for small providers.

d) **Out of scope**: The forum will not be a detailed review of the specific standards and operating rules and related implementation challenges.

Outline of Major Components/elements of Work:

a) Confirm Date: May 17, 2018
b) Confirm topics
    i) Value of standards
    ii) Value of operating rules
    iii) Governance of standards and operating rules
        (1) Current state, DSMO process, inclusion of other valued entities to assist in process
    iv) Technology
    v) Roadmap recommendations
    vi) Visioning – What are CIO issues on 3 to 5 year horizon that depend on or could be significantly influenced by the standards and operating rules and associated processes?
c) Identify speakers for each topic
    i) Types of organizations to be represented
        (1) Technology –
        (2) EHR vendors - (e.g. EPIC, McKesson, Cerner and others to be named)
        (3) Associations (HATA, WEDI, CHIME, AMA, AHA, MGMA, AHIP, BCBSA, HBMA)
        (4) SDOs, ORAE
        (5) Health Plans – Kaiser (also provider)
        (6) Providers –
        (7) Federal Agencies
        (8) State Agencies
d) Venue: HHS
e) Invitation letter via email with question set
f) One page summary of program
g) Notify CMS leadership; include HHS and CMS IT staff
h) Write and publish Federal Register Notice
i) Write meeting summary
j) Publish meeting summary
k) Other meeting logistics (from set up to wrap up)

Key inputs (these are examples of the types of initiatives that may be informing the work of SDOs, and CIOs as they consider how standards will be used in their systems in the future):

a) USCDI
b) DSMO Requests, e.g. the most recent updates to the NCPDP standards for pharmacy
c) CMS initiative on patients before paper
d) Opioid Crisis initiatives
e) FHIR
f) BlockChain
g) Cybersecurity
h) Privacy modifications

Timeframe

a) November 2017. Solidify scope at the November meeting to enable planning for a 2nd quarter 2018 forum.
b) First Quarter 2018 task(s) to be considered in preparing for the forum in early second quarter.
    i) Plan CIO Forum
        (1) Committee member assistance in development of the questions for participants.
        (2) Committee member assistance in identifying panelists.
        (3) One page write up for the participants to have in advance
    ii) Hold CIO Forum (2nd quarter)
    iii) 2nd quarter (April - June)
        (1) Summarize feedback at the CIO forum and tie it to the predictability roadmap to address their needs or insights.
        (2) Tie feedback to the NCVHS Visioning work. Synthesize the feedback and draft recommendations in mid to late-2018. Recommendations could be incorporated in the roadmap and NCVHS's visioning work to include privacy work on Beyond HIPAA and population health's next generation eVital standards.

Questions (preliminary):

1. Does the current strategy of development, updates, adoption and availability accommodate the way health care is changing? What improvements might be proposed? What other changes in health care necessitate different standards, operating rules or models.

2. What business needs lack technology or standards that meet current or pending needs?

3. What modifications are needed to current standards and operating rules to better enable developing health care trends?

4. How are data content requirements impacting the use of standards, or needs for standard functionality?

5. Discuss the current standards update and review process. What works well and how can it be modified to make it more nimble?

6. Discuss the current regulatory process.

7. What constitutes a return on investment for updated standards and operating rules?

Potential Speakers (preliminary)

- Craig Knier, Director, Product Management Innovation and Technology, Change Healthcare. http://www.healthcareitnews.com/news/intelligent-278-creating-standard-shared-decision-support Healthcare IT News "The Intelligent" 278: Creating standards for prior authorization decision support
- David Krause, VP Business Improvement, Anthem http://www.healthcarefinancenews.com/news/anthem-vp-healthcare-billing-system-broken#.WoGFCkLT5IE.email
- Other innovative health plan CIOs
- George Hoffmann, CIO CMS
- VA and/or DoD CIOs
- Recommendations from CHIME, HATA, HBMA, US Digital Service, and others

CIO Forum Project Summary

*use of the term standards is inclusive of operating rules after its first use in the narrative below

The purpose of the CIO forum is to obtain perspective about the future of health care technology from end users of standards* and operating rules, to understand how these individuals perceive the topics of updates to the standards, improvements to the process for updating the standards, the use of the standards themselves, and where standards fit into changes in health care technology overall. Most health care CIOs would agree that their role involves volatility, uncertainty, complexity and ambiguity. They would also agree that the CIO's role within all health care organizations has taken on significantly more importance in strategic planning in the past five to ten years than it ever had before because of the changing nature of the delivery and payment mechanisms, from Telehealth, digital health, wearable technology, accountable care organizations, new payment models, patient engagement, constant security issues, changes in reimbursement methods, new rules, and the ever present standards. All of these things are contained in the mantra: volatility, uncertainty, complexity and ambiguity. CIOs deal with these four issues in real time, and must plan for them in the future.

How do CIOs keep up with emerging technologies? In today's disrupt-or-be-disrupted world, it's a necessity to survive. CIOs and IT leaders must prioritize their quest for knowledge and their day to day role of keeping the computers running and transactions processed. NCVHS wishes to ask IT leaders from different sectors to share their perspective on how the pace of updating standards and operating rules for administrative transactions pace impacts their organizations today, and how it could affect their plans for the future.

CIOs are the "what if" thinkers in their organizations. Therefore, CIOs are critical to our next phase of understanding how to proceed with the predictability road map. How can we best interpret and act on some of the ideas we heard in the predictability workshop from their perspective?

National Committee on Vital and Health Statistics

Health Terminologies and Vocabularies

Background

The NCVHS Charter calls for the Committee to "Study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information and report to the Secretary of Health and Human Services (HHS) recommendations and legislative proposals for such standards and electronic exchange." Further, the Committee is to "Advise the Department on health data collection needs and strategies; review and monitor the Department's data and information systems to identify needs, opportunities, and problems." NCVHS has offered recommendations supporting the adoption of ICD-10-CM and ICD-10-PCS but last examined health terminology and vocabulary "needs, opportunities, and problems" more broadly in 2003 when it offered recommendations to the Secretary on PRMI (Patient Medical Record Information) Terminology Standards.

Use of the terminologies and vocabularies are included in Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA), related regulations and adopted transaction standards. Generally, the term "code sets" is used to reference terminology and vocabulary.

The National Center for Health Statistics (NCHS) (within HHS' Centers for Disease Control) serves as the World Health Organization (WHO) Collaborating Center for the Family of International Classifications for North America and is responsible for coordination of all official disease classification activities in the United States relating to the ICD and its use, interpretation, and periodic revision. ICD-10, effective October 1, 2015, is the current version used for cause of death and morbidity classification. U.S. developed the Clinical Modification (ICD-10-CM) for morbidity classification based on WHO's ICD-10. The Collaborating Center is also responsible for the WHO Family of International Classifications, which includes the International Classification of Functioning, Disability and Health (ICF).

HHS' Center for Medicare and Medicaid Services (CMS) is responsible for development and maintenance of Procedure Coding System (PCS) used for acute care procedures in the United States (US). Outpatient and physician office procedures are coded using the Current Procedural Terminology (CPT) developed and maintained by the American Medical Association (AMA). The ICD-10 Procedure Coding System (ICD-10-PCS) is a newly designed system and is not based on an international coding system. Representatives from NCHS and CMS co-chair the ICD-10 Coordination and Maintenance Committee meetings. Responsibility for maintenance of the ICD-10 is shared between these two agencies, with NCHS having lead responsibility for ICD-10-CM for diagnoses and CMS having lead responsibility for ICD-10-PCS for inpatient acute care procedures.

The National Library of Medicine (NLM) is the central coordinating body for clinical terminology standards within the Department of Health and Human Services (HHS), so designated by the Secretary of HHS in 2004 in response to a recommendation from the NCVHS. NLM has long supported the maintenance, dissemination, and free US-wide use of SNOMED CT (2003-), Logical Observation Identifiers Names and Codes (LOINC) (1999-), and RxNorm (2001-), the primary clinical terminology standards required for electronic exchange of clinical health information under Stage 2 Meaningful Use.

NLM also develops and provides tools to facilitate their adoption and use, including subsets, mappings, APIs, and the Value Set Authority Center.

SNOMED CT, required for problem lists, procedures and some clinical findings, is now owned and maintained by SNOMED International (the International Health Terminology Standards Development Organization (IHTSDO)), a not-for-profit organization. NLM is the US IHTSDO member and the National Release Center for SNOMED CT, paying the US membership fee and providing SNOMED CT data and resources under the SNOMED CT Affiliate License (incorporated as part of the Unified Medical Language System (UMLS) Metathesaurus license). RxNorm, a standardized nomenclature for clinical drugs required for medication data, is produced by NLM in cooperation with the FDA and is linked to NDCs and many of the drug vocabularies commonly used in pharmacy management and drug interaction software. LOINC, a nomenclature and coding system for tests and measurements, is produced and disseminated free of charge by the Regenstrief Institute, with financial support from NLM. LOINC is required for reporting laboratory tests and clinical documents; it also covers clinical measurements, including questionnaires and assessment instruments. NLM also actively promotes the use of UCUM (Uniform Code for Units of Measure). In addition to being available separately, SNOMED CT, RxNorm, and LOINC are all included in the UMLS Metathesaurus, where they are linked to many other classifications and vocabularies, including the HIPAA code sets, MeSH, the Gene Ontology, etc.

In addition to the systems developed, maintained, and supported by HHS agencies, US healthcare uses proprietary terminologies and classifications such as CPT, DSM and others.

Project Description and Goals

This project is designed to take a contemporary look at the health terminology and vocabulary landscape in order that NCVHS is able to advise the Secretary regarding

1. The changing environment and implications for timing and approach to terminology and vocabulary standards adoption,
2. Needs, opportunities, and problems with development, dissemination, maintenance, and adoption of terminology and vocabulary standards,
3. Actions that HHS might take to improve development, dissemination, maintenance, and adoption of standards.

Plan

This project will be carried out in two phases:

Phase I – Briefings on adopted terminology and vocabulary standards. Rather than starting at a subcommittee, these briefings will be before the full Committee. This will be done in two parts:

- June 2017 – Briefings from NCHS, CMS and NLM
- September 2017 – Briefings from non-governmental developers and other stakeholders in a position to contribute to the committee's understanding about development, dissemination, maintenance, and adoption opportunities and barriers.
- January 2018 – Report summarizing the current state

Phase II - Analyze what was learned from briefings and formulate areas of opportunity for improvement in at least the following areas:

- Standards adoption
- Maintenance and dissemination
- Governance and coordination

Approach: The Executive Committee will need to consider how to transition from Phase I to Phase II. Depending on what we learn in Phase I, we may want to consider drafting a coordinated framework to allow development, maintenance and dissemination to shift toward continuous enhancement. In that case, phase 2 would include drafting the framework; holding a hearing to get input on the draft; issuing a report; and preparing letter with recommendation for the Secretary to optimize the value of terminologies and vocabularies for health reform going forward. Potential recommendations might include:

- Criteria for adoption of named code sets
- Governance and coordination of code set standards
- Strategies for adoption that align with the NCVHS' Standards Predictability Road Map and ONC's health IT Strategic Plan

It may be appropriate to appoint an ad hoc committee (home-based in one of the subcommittees) to ensure the framework takes into account standards, public health, administrative simplification and other perspectives.

Timetable

Phase I: June 2017 – January 2018 Committee meetings
Phase II: Ad hoc committee frames issues and opportunities for discussion by Committee in May 2018; hearing summer 2018; Report and Letter to Secretary in Fall 2018 or January 2019

References

1. Report on Uniform Data Standards for Patient Medical Record Information (2000), https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf .
2. Information for Health: A Strategy for Building the National Health Information Infrastructure. Report and Recommendations from NCVHS (2001), https://aspe.hhs.gov/report/information-health-strategy-building-national-health-information-infrastructure.

National Committee on Vital and Health Statistics

Health Information Privacy and Security Beyond HIPAA

Background

NCVHS is charged with studying and identifying "privacy and security and access measures to protect individually identifiable health information in an environment of electronic networking and multiple uses of data." The Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishes a regulatory framework for managing and using personally identifiable health information by covered entities and business associates. For the past two decades the Committee has advised the Secretary of Health and Human Services on HIPAA privacy and security implementation. The Committee also reports to Congress on the status of HIPAA privacy and security as part of its legislatively mandated Reports to Congress on HIPAA.

The challenges of safeguarding privacy and security of health information using even de-identified information are far greater today than when HIPAA privacy and security rules went into effect. Uses for increasingly complex health data are expanding as powerful new tools allow combining data sets to extract information. Expanded uses for health information and innovative tools offer great promise for improving health and wellness. At the same time, they may carry risk to individuals through inadvertent disclosure of confidential information, unauthorized reuse and misuse.

NCVHS Looks at Privacy and Security Frameworks 'Beyond HIPAA'

Because HIPAA addresses individually identifiable health information created, received and maintained by covered entities and business associates, privacy and security issues may arise from uses of patient data beyond HIPAA's relatively narrow jurisdiction. NCVHS has recommended privacy and security stewardship frameworks and guidance for entities using health data beyond HIPAA covered entities and business associates for over a decade. For example, the 2008 report for policy makers, *Enhancing Protections for Uses of Health Data: A Stewardship Primer* [1]calls on any person or entity that "collects, views, stores, exchanges, aggregates, analyzes, and/or uses electronic health data to practice sound data stewardship."[2] In 2012, NCVHS recommended *A Stewardship Framework for the Use of Community Health Data.* Recently, NCVHS addressed current issues in de-identification of health information for a growing range of uses.[3] The Office of the National Coordinator for Health IT and the Office for Civil Rights have contributed to policy and guidance for those who access or use health information but are not covered entities or business associates.

[1] Health Data Stewardship: An NCVHS Primer

[2] A Stewardship Framework for the Use of Community Health Data

[3] Recommendations on De-identification of Protected Health Information under HIPAA

This 'Beyond HIPAA' initiative builds on NCVHS's past work and the work of other government and private initiatives to consider a health data privacy and security framework for 21st century health information challenges. Specific goals are to:

1. Identify and describe the changing environment and the risks to privacy and security of confidential health information; highlight promising policies, practices and technology;
2. Lay out integrative models for how best to protect individuals' privacy and secure health data uses outside of HIPAA protections while enabling useful uses, services and research;
3. Formulate recommendations for the Secretary on actions that HHS and other federal Departments might take; and
4. Prepare a report for health data stewards.

Understanding the Evolving Health Information Environment

Through a series of briefings and review of authoritative reports, NCVHS will first explore key health information privacy and security challenges beyond the scope of HIPAA. The environmental scan will explore existing and emerging policy frameworks, practices and technologies to better frame key issues, and drivers of change in the following areas:

1. Big data and expanding uses and users
2. Cyber-security threats and approaches
3. Personal devices and internet of things
4. Laws in other domains (e.g. Fair Credit Reporting restricting uses of consumer data)
5. Evolving technologies for privacy and security
6. Evolving consumer attitudes

September 2017 Briefing

This first briefing focused broadly on the "Beyond HIPAA" drivers and specifically focus areas # 1-4. In briefing the Committee, experts considered the following questions.

1. The Committee is interested in real or potential impacts on privacy and security of the expanding uses of health data outside the protections of HIPAA. What are you seeing in your work that might help the Committee understand the range of issues?

2. How are these issues changing with new technologies, applications, markets, and attitudes?

3. What ideas have you come across for advancing individual health, public policy goals, and private enterprise in a privacy appropriate environment?

4. What legal, ethical, practical or operational problems does the current environment not address?

5. What recommendations might you have for the Committee as it continues its study of the issues "Beyond HIPAA"?

Fall 2017

Through a contract, the Committee commissioned the report, "Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges." It is publicly available on the NCVHS website.

Spring 2018

With the Beyond HIPAA Environmental Scan report completed as background, the Committee will focus on how to improve the protection of data that are outside HIPAA's jurisdiction. Initial focus will be on selected applications that involve protected health information (PHI) but are not maintained by covered entities or business associates. Hearings on Beyond HIPAA identified two potential applications for initial focus: Clinical data registries and consumer devices that capture data shared with clinicians. These applications share the following characteristics:

1. They are widely deployed and their use is growing.
2. They demonstrate challenges of data linkage between covered entities and non-covered entities:
    - Registries rely on PHI obtained from a variety of sources, e.g., EHR linkage
    - Consumer devices may be a source of new clinical data to be accessed by covered entities through EHRs or other apps
3. Their study may reveal principles and best practices that could inform other Beyond HIPAA Use Cases.

Project Plan

For each of the selected use cases:

1. Review relevant research and develop annotated description of each use case.
2. Define what is and is not in scope for this inquiry – for example, the types of registries or consumer devices to be included or excluded.
3. Describe the issues regarding data protection, privacy and security. These might include issues regarding sensitive information, data accuracy, technology, evolving applications, uses, market forces, and attitudes.
4. Promising practices and models for handling PHI that may be generalizable.
5. Areas requiring further investigation or research.
6. Any short term recommendations that could advance the Beyond HIPAA inquiry.