NCVHS Update
National Plan Automation Group 2019
The Lodge at Gulf State Park
Gulf Shores, AL
August 27, 2019

Rich Landen
Member, National Committee on Vital and Health Statistics
Co-chair, Standards Subcommittee

The National Committee on Vital and Health Statistics

NCVHS is the US Department of Health and Human Services’ (HHS) statutory public advisory body on health data, statistics and national health information policy
NCVHS Domains

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<th>Areas</th>
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<td>Standards</td>
<td>Public health informatics and data standards; standards, code sets, and operating rules for administrative transactions as required under HIPAA and other legislation.</td>
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<tr>
<td>Population Health</td>
<td>Monitoring the nation’s health data needs and current approaches to meeting those needs. Recent focus on making small area data more available and on the vital registration and statistics data systems.</td>
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<td>Privacy, Confidentiality and Security</td>
<td>Emerging issues related to health information privacy, confidentiality, security and data stewardship.</td>
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NCVHS Membership

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Roland J. Thorpe, Jr., PhD, Johns Hopkins University, Baltimore, MD
Recap of 2016 - 2018 NPAG Updates

• September 2016 (Charleston, SC)
  • Transaction Standards, Operating Rules, Code Sets & Identifiers
    • Covered Entities; education; implementation consistency; enforcement; acknowledgment; predictability
  • Phase IV Operating Rules and on Claims Attachment
  • Where are we in the EDI life cycle?

• May 2017 (Monterey, CA)
  • Need for Health Plan Identifier (HPID)
  • Predictability of HIPAA transaction set version updates
  • EDI life cycle

Recap of 2016 - 2018 NPAG Updates

• August 2018 (Lake Placid, NY)
  • NCPDP Versions Telecom F2, Batch 15 & Medicaid Subrogation 10
  • Next Generation Vital Statistics System
  • Comments on ONC US Core Data for Interoperability (USCDI) Expansion
  • Environmental Scan: Health Information Privacy Beyond HIPAA
  • Measuring Health at the Community (sub-county) Level
    • Work subsumed into Population Health: current challenges in sub-county population health, including small area data, resources and data access
NCVHS Work Products since NPAG 2018

- June 18, 2019 – Report-Framework for Health Information Privacy
- June 18, 2019 - Letter to the Secretary-Improving Privacy Protection for Health Information not Subject to HIPAA
- February 21, 2019 - Recommendation Letter-Regulatory Simplification of ICD
- February 13, 2019 - Recommendation Letter-New Approaches to Improve the Adoption of National Standards for the Health Care Industry [Predictability Roadmap]
- February 13, 2019 - Recommendation Letter-Criteria and Guidelines for Health T-V Standards
- September 30, 2018 – Draft Report-Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules: Paving the Way to a Predictability Roadmap
- September 14, 2018 - Report-Terminologies and Vocabularies Expert Roundtable Report
- September 14, 2018 - Report-Terminologies and Vocabularies Environmental Scan

Current NCVHS Activities and Today’s Agenda

- Follow-on to Predictability Roadmap recommendations
  - HIPAA rulemaking options
  - SDO agility
  - DSMO/industry coordination evolution
- Terminologies and Vocabularies
  - Recommendations on adoption & implementation; curation & dissemination
  - ICD-11
- Coordination between NCVHS/NCHS, CMS/DNS and HITAC/ONC
  - Prior Authorization
  - Convergence of clinical and administrative data
- Privacy Beyond HIPAA
• Themes we heard from industry:
  • HIPAA (and ACA) was successful at moving industry away from paper claims and payments; achieved large efficiencies
  • Industry implementation of required new updates extremely burdensome
    • Updates are too large; need smaller iterations, “digestible bites”
  • Frequency of updates is too slow
    • Not keeping pace with evolving business needs
  • Update cadence is too irregular: impossible to do proper dollar and staff budgeting
  • Small end-users cannot afford to send staff to the SDO meetings
    • How can small organizations get their ‘pain points’ into SDO deliberations?
  • Rigidity stifles innovation

Predictability Roadmap: Recommendations, February 2019

1. Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.
2. Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.
3. Improve the visibility and impact of the administrative simplification enforcement program.
4. Provide policy-related guidance from HHS regarding administrative standards adoption and enforcement.
5. Re-evaluate the function and purpose of the Designated Standards Maintenance Organizations.
1. No major changes to rule promulgation process
2. Continue to use the existing “exceptions” mechanism for voluntary use
3. Gradual evolutionary expansion of enforcement
4. The 2018 tools for Guidance
5. Willing to discuss DSMO

Predictability Roadmap, continued

- Next Steps
  - NCVHS Standards Subcommittee dialogue with CMS Division of National Standards
  - Evolving the DSMO
    - Takeaways from July 2019 Visioning Session
      - See next slide
  - Continuing dialogue with SDOs and industry
    - X12 tentatively scheduled to present at NCVHS fall meeting
    - NCVHS presentations at WEDI conferences
**Predictability Roadmap: DSMO Visioning Session, July 2019**

- Common Themes Emerging from the July 2019 Visioning Session
  - Piloting/testing – then evaluation, refinement
  - Stakeholder inclusion and involvement and engagement
  - Leveling the playing field, a clear reason to play
  - Availability of funding for sustainability of processes
  - Mandatory vs. available for use – agile, flexible, easy voluntary use of new standards
  - Enabling innovation – Innovation moves faster than regulation
  - Understand timing/pace of different moving parts. Speed to market.
  - Federal leadership (or authority?) to solve some of regulatory process logjams – can HHS be more supportive of voluntary use of newer standards?
  - Predictable process
  - Oversight, accountability: Authority to coordinate
  - Identify elements of process that are constant – and those that can be changed

**Terminologies and Vocabularies**

- Take a contemporary look at the health terminology and vocabulary landscape in order to advise the Secretary regarding:
  - What is the universe of health care codes sets, terminologies and vocabularies and who maintains them?
  - The changing environment and implications for timing and approach to health terminology and vocabulary standards adoption
  - Needs, opportunities, and problems with development, dissemination, maintenance, and adoption of health terminology and vocabulary standards
  - Actions that HHS might take to improve development, dissemination, maintenance, and adoption of standards

- **Milestones**
  - Environmental Scan Report, September 2018
  - Expert Roundtable, July 2018
Terminologies & Vocabularies: Recommended Criteria for Adoption and Curation, February 2019

1. The Secretary of HHS should approve the Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards
   • as delineated in Attachment A of the 2/13/2019 letter

2. The Secretary of HHS should approve the Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards recommended.
   • as delineated in Attachment B of the 2/13/2019 letter

Terminologies & Vocabularies: Recommendations ICD Adoption, February 2019

1. HHS should use **sub-regulatory processes** to make version updates to the International Classification for Diseases (ICD) in the same way it handles updates to all the other named HIPAA code set standards.

2. HHS should invest now in a project to evaluate ICD-11 and develop a plan that will enable a smooth and transparent transition from ICD-10 to ICD-11 at the optimal time.

3. HHS should clarify that ICD-10-PCS is completely separate from ICD-10 and will not be updated with the transition of ICD-10 to ICD-11.
Terminologies and Vocabularies: ICD-11

- World Health Organization approval May 25, 2019
- Earliest MORTALITY US implementation date 2023 - 2025
  - NCHS codes cause of death from state vital statistics text reports
  - No rulemaking; can it be accelerated?
- Morbidity implementation timeframe much longer
- Opportunities and challenges
  - X12, NCPDP, HL7
  - Dx/Rx implications for underwriting, coverage, payments
  - Clinical Modification for US?
  - Mappings
  - Computerization and computability
  - State databases, HIE
  - Rulemaking

Comparative Timeline: ICD-10

- 1990 - World Health Organization approval
- 1999 - US implementation date for Mortality
- 2003 - NCVHS recommendation on adoption for Morbidity
- 2008 - First NPRM
- 2012 - First mandatory go-live date
  - Then twice postponed
- 2015 - Final go-live date October

- Total elapsed time: 25 years!
Major Differences between ICD-10 and ICD-11

• Codes look different
  • Alzheimer’s disease
    • ICD-10 – G30
    • ICD-11 – 8A20

• ICD-11 Simplified code structure
  • Alpha numeric (1A00.00 to ZZ9Z.ZZ)
  • Clustering Stem code
  • Extension codes
    • Codes starting with ‘X’ are extension codes
    • More than 7200 4-character categories
    • Pre-coordination and post-coordination

Major Differences between ICD-10 and ICD-11, continued

• Clustering of codes
  • Combining 2 or more codes in an explicit post-coordinated way to describe a diagnostic entity
  • E.g.: Duodenal ulcer w/acute gastrointestinal bleeding
    • Stem Code: DA63 Duodenal ulcer, unspecified
    • Additional Stem Code: ME24.90 Acute gastrointestinal bleeding, not elsewhere classified
    • Cluster: DA63/ME24.90

• Example of post-coordination and clustering, with extension codes
  • Left inguinal hernia with acute obstruction expressed as DD51&XK8G/ME24.2&XT5R
Major Differences between ICD-10 and ICD-11, continued

• One of the main ICD-11 Revision Goals:
  • Ensure that ICD-11 will function in an electronic environment
    – Digital product
    – Link with terminologies (e.g., SNOMED) and other classifications
    – Support electronic health records and information systems

• Computerization and computability. If it works as designed:
  • AI, machine learning and big data
  • What opportunities does this open up?

Environmental Differences ICD-10 and ICD-11

• The Plan environment has changed
  • HITECH (Meaningful Use incentives) happened
    • Hospitals and physicians gone from 10% EHR penetration to 90%+
  • Value-based purchasing and precision medicine happening
    • ACOs, etc., mean different business models; providers taking on risk and needing to act more like payers
    • Heavier reliance on HIT; real-time clinical and administrative data
  • Health Plans starting to take on aspects of care providers
    • Capitation/outcomes management
    • It’s not just about paying claims any more
  • ONC continues to drive APIs and interoperability
  • Technology is evolving rapidly
  • Where will your proverbial puck be in 5 – 10 years?
ICD-11: NCVHS Expert Roundtable, August 2019

• Meeting Objectives:
  1. Develop a shared understanding of lessons from the ICD-10 planning process/transition and the differences between ICD-10 and ICD-11.
  2. Reach consensus on the research questions to be answered to inform evaluation of cost and benefit of transition from ICD-10 to ICD-11 for mortality and morbidity – and to identify impacts of not moving to ICD-11 for morbidity.
     • Cost/benefit is not just dollars and cents
  3. Identify key topics/messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

ICD-11: Your Homework

• Plan your planning
  • Assemble your team; dust off your ICD-10 transition plans
  • Start engaging now
• What resources and budgeting will you need in-house?
• What can you expect from your vendors/developers, e.g., timing, interfacing, magnitude of cost?
• What are your threats? What are your opportunities?
  • Is this regulatory compliance, operations maintenance or innovation/ROI generator?
• What are the positions you want to take vis-à-vis ICD-11 and:
  • Your C-suite and Board?
  • Your trade association/professional society?
  • Federal advisory and regulatory requests for input/testimony/comment?
  • You Standards Development Organizations?
Coordination Among NCVHS/NCHS, CMS/DNS and HITAC/ONC

- Prior Authorization
  - Identify high volume but non-complex use cases
  - Non-pharmacy
  - Leverage work, studies, pilots being done elsewhere
- Convergence of clinical and administrative data
  - Ongoing conversations over time and across initiatives
  - CMS/DNS’ HIPAA Admin Simp regulations in perspective with ONC’s Promoting Interoperability regulations and initiatives

Health Information Privacy Beyond HIPAA

- Goals:
  - Identify and describe the changing environment and the risks to privacy and security of confidential health information; highlight promising policies, practices and technology
  - 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
  - Formulate recommendations for the Secretary on actions that HHS and other federal Departments might take
  - Prepare a report for health data stewards
Health Information Privacy Beyond HIPAA: Recommendations to the Secretary, June 2019

1. Establish **federal** health information security and privacy **standards** for health data registry sponsors.
2. Establish federal health information security and privacy standards for medical device and mobile application manufacturers.
3. Develop **consumer guidance** concerning use and protection of direct to consumer testing, such as genetic analysis, when it is not protected by HIPAA.
4. Support a federal **research** agenda on **de-identification** methods including the risks of reidentification related to various methods for de-identification.
5. Support a federal study of how **consumers** might exercise their rights of action to seek **redress** in the case of unauthorized access, misuse, or harm attributable to how their identifiable health information was used. This study should include tiers or categories of risks and harms.
6. Establish **federal baseline standards** for privacy and security protection of individually identifiable and de-identified health information held by commercial organizations **outside** of the scope of HIPAA.

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NCVHS Update

Questions?
Thank You!

Rich Landen  
Member, National Committee on Vital and Health Statistics  
Co-chair, Standards Subcommittee  
RichLanden@aol.com