Draft Background for NCVHS Ad Hoc Work Group on Secondary Uses of Health Data

June 13, 2007

Work Group Members and Participants

- Simon Cohn, MD, MPH Chair
- Justine Carr, MD, Co-Chair
- Harry Reynolds, Co-Chair
- Members:
  - J. Marc Overhage, MD, PhD
  - Mark Rothstein, JD
  - Bill Scanlon, PhD
  - Paul Tang, MD
  - Kevin Vigilante, MD, MPH
- Reviewers:
  - Jeff Blair, MBA
  - Larry Green, MD
  - Leslie Francis, JD, PhD
  - Judith Warren, PhD, RN
- Liaison Representatives
  - Kelly Cronin
  - Marybeth Farquhar
  - J. Michael Fitzmaurice, PhD
  - Steven Steindel, PhD
  - Karen Trudel
  - P. Jon White, MD
- Staff and Consulting Support
  - Jim Scanlon
  - Marjorie Greenberg
  - Debbie Jackson
  - Katherine Jones
  - Marietta Squire
  - Margret Amatayakul, Contractor to NCVHS
  - Kristine Anderson, Erin Grant, & Fatima Riaz, Booz-Allen Contractors to ONC/AHIC QWG

Excerpts from ONC Request for Assistance

- "Synthesize background information on policies and practices related to aggregation and use of electronic clinical [NCVHS: and administrative] data for non-clinical (or secondary) use of data for various population health purposes"
- "While quality measurement and reporting is a priority for HHS, there are other secondary uses of clinical data that could be potential sources of revenues to Health Information Exchanges (HIEs). These uses generally fall into two categories: research and population health. Identifying requirements and articulating roles various entities play for data sharing, aggregation is needed along with how they address role-based access, control data release, and data stewardship"
- "Develop initial set of recommendations to clarify allowable and appropriate approaches for use of data for quality measurement and reporting as specified by AHIC quality work group and ONC Quality Use Case (one of three top priority areas for HITSP, CCHIT, and some of NHIN contracts)"
- "Consideration also needs to be given on requirements for identified, anonymized, and de-identified data for various secondary uses and how HIEs would verify identity and authority of data users"
- "Clear policies and appropriate practices in this area will enable the emerging HIT infrastructure, including the NHIN, needed to realize the value driven health care system envisioned by the Secretary"
- "AMIA and others have documented the lack of clarity under current law with respect to allowable secondary uses of electronic clinical data which needs to be analyzed and addressed with an understanding of new and emerging approaches to data capture, exchange and aggregation in support of quality measurement and reporting. AQA and others have been exploring the need and potential scope of a data stewardship entity to ensure data is captured, aggregated, and analyzed according to rules and guidelines that ensure the precision and reliability of quality measures"
- There also needs to be a better understanding of how HIEs and other entities of end users of the data relate to each other and obtain appropriate disclosures and consents as needed to be compliant with current law and protect privacy and confidentiality

NCVHS Scope of Work

- **Premises:**
  - HIT should serve quality well because it enables more complete and accurate data capture and analysis.
  - For HIT to serve quality, however, there must be adherence to standards and appropriate privacy and confidentiality protections.
- **NCVHS Tasks**
  1. Develop a framework that addresses uses of electronically transmissible health data and elaborates upon the types of uses of data, including health-related (from individual to population), payer-related, research-related, and other.
  2. Include in the framework a taxonomy that defines terminology, e.g., anonymization, de-identification, aggregation, to the understanding of all stakeholders.
  3. Develop recommendations for HHS where there is a need for policy, guidance, regulation, and/or public education on expanded uses of health data and data linkage, with emphasis on how data for quality measurement, reporting, and improvement is authorized for use, (temporarily and permanently) stored, transmitted, and processed for use (in various forms).

Related Work and Collateral Documents

(To be added to as Project Proceeds)

- AHIC QWG and ONC supported by Booz Allen
  - AHIC is focused on flow of data for quality measurement
    - AHIC QWG Vision Summary
    - AHIC Quality Use Cases
  - ONC especially interested in how this relates to data across HIE & NHIN
  - Testimony from June 22, 2007 AHIC QWG; questions published in *Federal Register* May 31
- AHRQ National Health Data Stewardship RFI
  - Grew out of AQA Guidelines and Key Questions for Physician Performance Data Aggregation and Measurement Projects
- NCVHS
  - Recommendations to the Secretary Regarding Privacy and Confidentiality in the NHIN, June 22, 2006
  - Recommendations on the Initial Functional Requirements for a NHIN, October 30, 2006
  - Report on Measuring Health Care Quality, May 2004
  - Annual Reports to Congress on the Implementation of the Administrative Simplification Provisions of HIPAA
- Health Information Privacy and Security Collaboration (HISPC) reports from 34 states
- AMIA – Toward a National Framework for the Secondary Use of Health Data

Axes of Interest

(Serves as Basis for Questions to Ask All Testifiers)

Sources of Data

(Organizations that capture and use health data)

- Providers (hospitals, IPAs, etc.)
  - Claims +
  - Registries (often extracted from paper records)
  - Labs and other dx studies
  - EHRs
  - Enterprise-wide systems
- Individuals (PHRs excluded for now)

Uses of Data

- Primary (?) – Treatment, Payment, Operations
- Secondary (?)
  - Population health, public health
  - Other, e.g., statewide planning, research, commercial

Data Standards

Privacy and Security

("Clarity of Current Law")

- Consent – when needed?
- Identification level (e.g., anonymized, de-identified, aggregated)
- Data accuracy, integrity, availability
- Data stewardship/ownership
- HIE/NHIN vendor capability

Quality Use of Data

(Organizations Directing QI Activities)

- Patient-centric/Provider Encounters
  - Point of Care
  - Near Term
  - Long Term (longitudinal)
- Case Mgt/Disease Mgt
- Provider Performance
- Transparency/AHIC Quality Use Case

Hearing/Meeting Dates (All in DC Area)

- June 12, 11:00 – Noon Eastern Call
- June 21, 22 (at Noon) – immediately following NCVHS meeting
- July 17, 18, 19 (around Noon)
- August 1, 2, 3 (around Noon)
- August 23, 24 (around Noon)
- September 6 or 7 (will poll time availability for 3 hour call)
- September 25 – 26 NCVHS meeting
- October 4, 5 (around Noon)

Additional calls to be determined

Testimony

- Thought Leaders:
  - Clem McDonald
  - Don Detmer and/or Charlie Safran, AMIA
- NCVHS Roundtable during Discussion:
  - Justine Carr, Quality WG insights
  - Marc Overhage, HIE and NHIN Prototypes
  - Mark Rothstein, Privacy (paper presented at HIMSS?)
  - Paul Tang, Google, Intuit info
- **Other Initiatives**
  - Jon White, AHRQ Data Stewardship (June 21)
  - Floyd Eisenberg, HITSP
- ***"Clarity of Current Law"* Group**:
  - Drafters of HIPAA Privacy Rule Re: TPO and OHCA
  - Sue McAndrew, Deputy Director for Health Information Privacy, OCR Analysis of Complaints Re: Secondary Uses of Data
  - HISPC
  - Vickie Horner, Fox Systems
  - AHIMA (real world authorization/consent use)
  - American Health Lawyers Association (advice to PHOs) or GWU/RWJ
  - Other applicable laws (e.g., IRB regs/Common Rule)
  - Esther Dyson (per Carol McCall via Justine Carr)
- Taxonomy
  - Lori Reed-Fourquet/AHRQ paper

- ***Organizations that Capture and Use Data***
  - Provider Suppliers of Data
    - Quality initiatives, e.g., VHA Upper Midwest Quality Performance Improvement Alliance, Jennifer Lundblad
    - Representative RHIOs, e.g., Delaware Health Info Network
    - American College of Cardiology or Representative from practice with exemplary EHR, e.g., Cardiology of Tulsa
    - Representative integrated delivery network with owned and affiliated physicians with exemplary EHR, e.g., Peggy King, Evanston Northwestern Hospital; Marcelene Harris, Mayo
  - Health Plans
    - AHIP
    - BCBSA (e.g., MI)
    - Employer Group (e.g., Pepsi, Dell, IBM, Leapfrog)
  - Other Users of Secondary Data
    - Commercial (e.g., Thomson/Solucient/Medstat)
    - Statewide health planning (e.g., California)
    - Minnesota Community Measures
    - Public health department (e.g., NY, PA, NC)
- ***Organizations Directing Quality Improvement Activities***
  - CMS: Common data elements, Quality of Service
  - Joint Commission/ORYX
  - Oncology Data Alliance, DM registries (PECS) and Bureau of Primary Care, Cystic Fibrosis --, National Surgical Quality Improvement (VA and ACS) – June 19
  - IHI, AQA-HQA, NQF, NCQA
  - Managed Care Health Research Network
  - IOM
  - RWJ
- HIE/NHIN Vendors and Others – What's feasible?
  - CalRHIO (HIE vendor selection experience)
  - HIE Vendors: e.g., dbMotion
  - EHR Vendors: e.g., GE, Allscripts, Impac
  - Health record banking: Bill Yasnoff, IBM rep

Proposed Schedule for July Testimony

Names in italics are not confirmed but contact Initiated

Names in bold are not yet contacted

Tuesday, July 17	**Day 1: Context Setting, Background on Seminal Work**
9:00 – 9:30 9:30 – 10:15 10:15 – 10:45	Overview of Work Group Task (Simon Cohn) *Clem McDonald* Discussion
10:45 – 11:00	Break
11:00 – 12:45	Taxonomy: *Lori Reed-Fourquet, _____?*
12:45 – 2:30	Lunch (Margret has audio conference)
2:30 – 3:45	*OCR/HIPAA: Sue McAndrew*
3:45 – 5:00	*HISPC: Jodi Daniel, Linda Dimitropoulos, or other TBD*
Wednesday, July 18	**Day 2: Continue Background; Perspectives of Suppliers of Data and Users of Data**
9:00 – 10:30	AMIA: Charlie Safran, Steve Labkoff
10:30 – 10:45	Break
10:45 – 12:15	HITSP: *Floyd Eisenberg;* Glen Marshal*; Bill Braithwaite*
12:15 – 1:15	Lunch
1:15 – 2:45	*AHIMA;* **AHLA***;* **Vicki Horner, Fox Systems**
2:45 – 3:00	Break
3:00 – 4:30	Provider Suppliers of Data Panel: _____*
4:30 – 5:00	Working Session
Thursday, July 19	**Day 3 Perspectives of Suppliers of Data and Users of Data, Con't.**
8:30 – 10:00	Users of Data Panel: e.g., **AQA, Joint Commission, Oncology group***
10:00 – 10:45	Break
10:45 – 12:00	Working Session

* Both of these are just starts at these two perspectives. The August testimony would drill down in context.

Proposed Schedule for August Testimony

Wednesday, Aug 1	**Day 1: Drill down on Provider Suppliers**
9:00 – 10:30	
10:30 – 10:45	Break
10:45 – 12:15	
12:15 – 1:15	Lunch
1:15 – 2:45	
2:45 – 3:00	Break
3:00 – 4:30	
4:30 – 5:00	Working Session
Thursday, Aug 2	**Day 2 Drill down on Users of Data**
9:00 – 10:30	
10:30 – 10:45	Break
10:45 – 12:15	
12:15 – 1:15	Lunch
1:15 – 2:45	
2:45 – 3:00	Break
3:00 – 4:30	
4:30 – 5:00	Working Session
Friday, Aug 3	**Day 3**
8:00 – 9:30	Vendor Perspective: What's Feasible, What are the Traps?
9:30 – 9:45	Break
9:45 – 11:15	Uses of Health Data other than Quality
11:15 – 12:00	Working Session

Draft Questions From Axes of Interest

1. What sources of data do you use for quality measurement, reporting, and improvement?
   a. What are the primary sources of data you use today for quality purposes (paper abstraction, electronic registries, internal repositories, external warehouses)
   b. How do you assure the data's accuracy, integrity, and availability? What standard data sets do you use? Are there multiples of these?
   c. How would you define "use of data for quality" – what are all the various ways data may be used for quality?
   d. Do you obtain consent or authorization from the patient to use data for any or all quality purposes? Do your requirements for consent or authorization vary by type of use, and if so, how?
   e. Do you envision using additional sources of data in the future? If so, which; and would you expect to change your policies with respect to consent or authorization with respect to use of data from these additional sources?
   f. If you participate in any form of health information exchange (HIE), is your use of data for quality purposes altered in any way?
      - Are data from an HIE individually identifiable? If so, how are data protected during any temporary storage within the HIE and as they are transmitted through the HIE? If data are aggregated by the HIE, how is patient identity protected?
2. How do you use data for quality measurement, reporting, and improvement – In direct treatment? Relating to payment? And for healthcare operations?
   a. Does your use of consent or authorization vary by type of use?
   b. How do you inform your patients of these uses?
   c. How have patients responded when you have sought permission to use data for quality purposes or have published aggregate results from quality measurement, reporting, and improvement?
3. Do you collect, use, or supply health data for any purposes other than treatment, payment, or healthcare operations? If so,
   a. How do you obtain consent or authorization from the patient for these uses?
   b. If you use such data in aggregate form only, how do you protect its identification (identify which method for which data and describe process in depth):
      - De-identification process consistent with HIPAA
      - Limited data set consistent with HIPAA
      - Anonymization
      - Pseudo-anonymization

- Do you believe current laws provide sufficient protection for identifiable health data to be used in quality measurement, reporting, and improvement? If so, which laws are you referencing? If not, what gaps exist?
  – Do you believe current laws are sufficiently understood by covered entities, business associations, consumers, and others?
  – If not, what would help assure stakeholder understanding?
  – Are there other uses of health data for which you believe there are insufficient protection? Which and what would you recommend to assure protection?