Visioning Session to Re-evaluate the Designated Standards Maintenance Organization (DSMO)

Preliminary Meeting Summary

Held July 10-11, 2019

Subcommittee on Standards

National Committee on Vital and Health Statistics

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This report was written by NCVHS staff support Geanelle Herring, CMS, in collaboration with NCVHS Standards Subcommittee members.

To obtain a copy of the meeting transcript visit: ncvhs.hhs.gov

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Rich Landen, MPH, MBA, Subcommittee Co-chair *
Nicholas L. Coussoule *
Debra Strickland, MS *
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Meeting Facilitators
Margeaux Akazawa, MPH, Director, Ignite Accelerator Program, HHS, CTO
Maia Laing, MBA, Senior Business Consultant HHS, CTO

See Appendix B for a complete list of meeting attendees.

The National Committee on Vital and Health Statistics (NCVHS) serves as the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. 242k[k]). The Committee also serves as a forum for interaction with interested private-sector and industry groups on topical health data issues. Its membership includes experts in health policy, health statistics, electronic data interchange (EDI) of health care information, electronic health records (EHRs), privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing health care services, health care delivery systems, integrated computerized health information systems, health services research, quality measurement, patient safety, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the 18 members are appointed by the HHS Secretary to terms of 4 years each. Two additional members are selected by Congress. The NCVHS website provides additional information: ncvhs.hhs.gov

Introduction and Overview of the Visioning Session

The National Committee on Vital and Health Statistics (NCVHS) has two charges related to data standards, which are to: (1) 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 the Department of Health and Human Services (HHS) recommendations and legislative proposals for such standards and electronic exchange; and (2) advise HHS on health data collection needs and strategies, and review and monitor HHS's data and information systems to identify needs, opportunities, and problems. In partial fulfillment of these charges, over the past two years the Subcommittee on Standards has been working on a Predictability Roadmap to identify approaches designed to improve the update and adoption of standards and operating rules.

In early 2017, NCVHS initiated work to understand the barriers to the timely adoption and implementation of updated standards and operating rules to achieve the intended objectives of administrative simplification. The Subcommittee on Standards reviewed historical documents, held an Appreciative Inquiry workshop and conducted interviews with the standards development organizations (SDOs) and operating rule authoring entities (ORAEs). In 2018, the Subcommittee held a CIO Forum focused on end-user perspectives and published a report on the Predictability Roadmap findings. The Committee also published 23 draft recommendations for public comment and held an industry hearing in December 2018 to obtain feedback to support the Committee in its finalization of recommendations to HHS.

In February 2019, the Committee delivered five synthesized recommendations to HHS supporting the industry's need for a trusted cadence to improve the updates, adoption and implementation of transaction standards and operating rules to keep pace with innovative business needs and technology changes.

The five recommendations represented actionable steps for adopting, implementing, and enforcing the administrative simplification provisions of HIPAA and Affordable Care Act (ACA). Included in these recommendations, the Committee urged HHS "to re-evaluate the function and purpose of the Designated Standards Maintenance Organizations (DSMO)." In an effort to support HHS with this recommendation, the Subcommittee held a visioning session to obtain industry input with the intent of creating additional recommendations and insights for the Secretary's consideration.

Visioning is an approach to constructing problem statements in ways that invite broad exploration. The purpose of the visioning session was to develop ideas for improving the processes for both updating and adopting standards and operating rules. Improving both of these processes would enhance the predictability of implementation, enable innovation and support using advancements in technology.

This report is a summary of the Visioning Session held July 10-11, 2019 with members of the NCVHS Standards Subcommittee, representatives from each of the standards development organizations (SDOs), operating rule authoring entity (ORAE), and members of the health care industry that utilize HIPAA standards and operating rules.

Meeting participants spent one and a half days going through a series of exercises in phases to craft a new set of ideas related to "How Might We…." pertaining to the re-evaluation of the DSMO, and the impact that might have on a trusted cadence for standards updates and their ultimate adoption by the government.

Predictable and effective coordination between Division of National Standards in CMS/HHS, NCVHS, the DSMO, the SDOs, and ORAEs is vital to provide the industry with a known, repeatable process capable of providing a consistent and timely process for updates to the HIPAA mandated transaction standards and the accompanying operating rules. Following the meeting, the Subcommittee on Standards will draft additional recommendations for the full Committee to consider prior to submission to the HHS Secretary. These recommendations will take into account the input received during this facilitated visioning session.

Margeaux Akazawa and Maia Laing of the HHS IDEA Lab within the Office of the Chief Technology Officer at HHS served as the meeting facilitators.

Background

In August 2000, the Designated Standards Maintenance Organization (DSMO), was adopted in Transaction and Code Sets final rule (65 FR 50312) and codified at (45 CFR § 162.910) for the purpose of maintaining the *Health Insurance Portability and Accountability Act* (HIPAA) standards adopted by the HHS Secretary. The Secretary named the six DSMOs organizations in the regulation. These six organizations entered into a Memorandum of Understanding (MOU) establishing a steering committee and formalizing the processes for reviewing updated or new standards in advance of a recommendation to the NCVHS.

The DSMO established a framework for the review and maintenance of HIPAA mandated standards. Initially the focus was to incorporate modifications to the original HIPAA mandated transaction standards, beginning with a fast-track effort resulting in the adoption of Accredited Standards Committee X12 Version 004010A1 and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Version 5.1 and Batch 1.2 in 2001.Once the fast-track review was completed, the DSMO turned its attention to other changes that have been, or will be, incorporated into future versions of the transaction standards. This included the adoption of X12 5010 and NCPDP D.0 specifications in 2009. Each year the DSMO presents a report to the NCVHS on changes adjudicated by the DSMO review process. Between 2001 and 2004, the DSMO steering committee received more than 150 change requests. Today, the

DSMO receives fewer than 10 change requests per year. The DSMO appears to have accomplished the purposes for which it was established.

DAY ONE

Visioning Session: Members of the Standards Subcommittee and invited participants engaged in a series of exercises in order to "vision" new approaches and re-evaluate the function and purpose of the Designated Standards Maintenance Organizations (DSMO).

Meeting Proceedings

The Subcommittee co-chairs welcomed the invited participants to the meeting, indicating that their input would help guide the Subcommittee in framing the next set of recommendations to the Secretary. The Subcommittee co-chairs also indicated that follow up recommendations are needed to support the initial recommendations submitted in the February 2019 letter, which was to remove the regulatory mandate for modifications to adopted standards and to move towards industry-driven upgrades. The co-chairs reiterated their interest in working with the industry representatives to identify some "blue-sky" approaches.. This session was designed differently than typical NCVHS workshops to take advantage of creative approaches to identifying opportunities. The intent is to establish a predictable and reliable approach to meeting evolving business needs of industry trading partners and their business associates. One of the co-chairs reiterated that the original HIPAA adoption process simply doesn't meet today's needs for timely updates, digestible bites, predictability, reliability, and testing of solutions for rapidly evolving business needs.

Ice Breaker

The meeting facilitators began with an 'ice-breaker' exercise to create an environment

conducive to generating dialogue and new ideas. The facilitators asked participants to use

Post-it notes to introduce themselves. In a second Post-it note, participants were asked to share their "Super Power." These super powers included curiosity, problem solving, connecting people, not being afraid of change, seeing things differently, flexibility, being detail oriented and federal register reviews. The strength and diversity in the group promised great depth in the discussion.

Celebrating the DSMO: 20 years of Success

Lorraine Doo, Senior Policy Advisor with CMS's Division of National Standards provided a history of the DSMO as context for the visioning session (slides from the presentation are available by request from NCVHSmail@cdc.gov.) Lorraine provided an overview of the DSMOs and explained how its work had evolved over the past 18 years. Based on the scope of the Memorandum of Understanding between the six DSMOs and HHS, there is general consensus that the DSMO has done its job in accepting and reviewing early change requests from the SDOs (designated DSMOs) and referring those to the standards organizations for processing. The DSMO also submitted completed standards to NCVHS for consideration. While change requests for standards were initially anticipated to flow through the DSMO, these are now being sent directly to each SDO. When coordination is needed between the standards bodies, communication does take place for data content questions and there are additional methods of collaboration among the DSMO entities during the implementation guide and operating rule development. Participants celebrated the DSMO with a congratulatory toast.
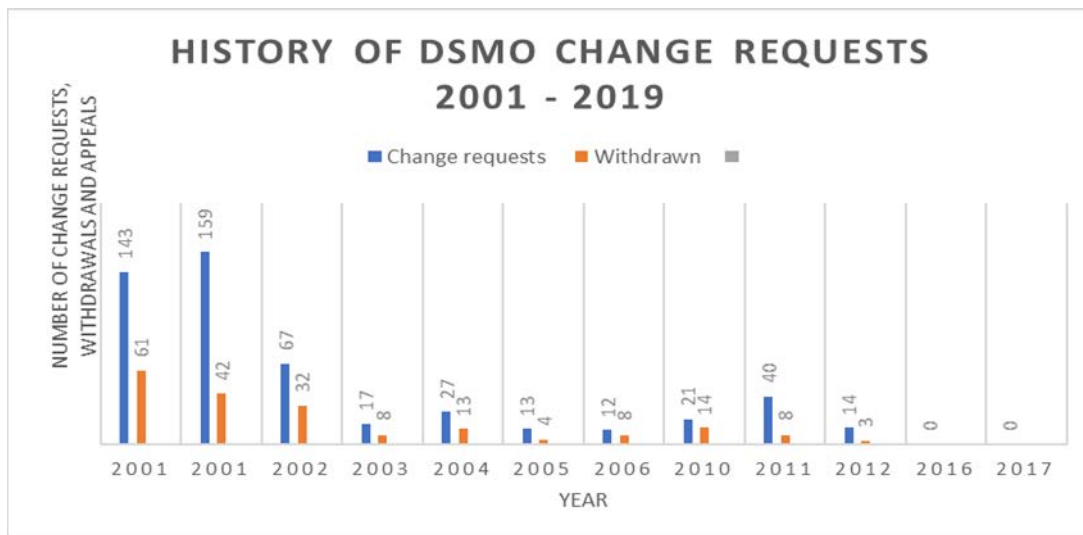
Exercise 1: Cause and Effect on Stakeholders

Prior to the visioning session, members of the Standards Subcommittee had worked with the facilitators to draft an initial problem statement related to the DSMO process. This statement was presented to the session participants for their reaction and discussion. The problem statement reflected the broad scope of issues impacting the update and adoption of standards – not just those pertaining to the DSMO process and its role in the overall challenges of enabling innovation.

> **Problem Statement:** Barriers exist for the industry to adopt and implement updated versions of standards, implementation guides, or operating rules on a predictable, reliable, and timely basis, sufficient to meet the evolving business needs of industry, trading partners, and their business associates.

Participants, who were seated in groups of five to six, were given an opportunity to identify causes and effects connected to the problem statement and review the ideas for persistent themes. While the exercise generated a wide volume of ideas, the top themes included administration, financial and regulatory in both areas.

Participants also identified the stakeholders who might be impacted by the issue—listed belowin alphabetical order. Based on the resulting list, a broad spectrum of organizations and entities could be affected by the updating, adopting and implementing standards and operating rules. The challenge for the group was to identify what part of the problem statement, and what barriers could be addressed in the visioning session, what could be actionable, and what benefits would result from change.

STAKEHOLDERS

- Analysts
- Clearinghouses
- Code List Maintainers
- Conformance Testers
- Consultants
- Data Brokers
- Educators
- Employers

- Health & Human Services (HHS)
- Insurance Commissioners
- IT Service Providers
- Lawyers
- Medical Device Manufactures
- Operating Rules Authors
- Patients
- Payers

- Privacy Advocates
- Public Health
- Regulators
- Researchers
- SDOs
- Security Specialists
- State Health Data
- State Medicaid

- Health Information Exchange
- Pharmacy
- Policy Makers
- Trade Associations
- Vendors
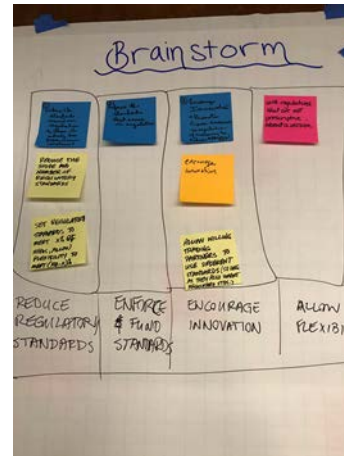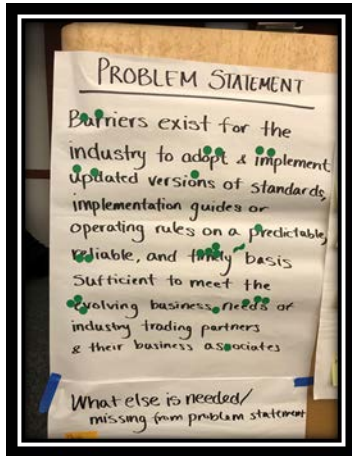
Exercise 2: Statement Starters

In the next exercise, participants were asked to think about the problem statement from a different perspective, exploring the issues with a "How might we" question. This exercise was an approach to framing a problem statement in a way that invites broader exploration. The facilitator gave the group some tips and examples for how to come up with useful "how might we" questions, thinking about the desired results impact (how might we help this person remember to take her prescriptions on time?), or emotional, or action oriented (how can we eliminate the need for a particular drug), or metaphors (how can we make reminders more like a Disney event). The facilitator specifically advised the group to avoid words that end in "er" such as how might we make taking a prescription drug "better," or accessing some service "faster," because those "er" words do not invite open-endedness and curiosity.

This activity then required brainstorming to generate fresh alternatives to the status quo and to develop a large number of ideas in a short period of time.

"How might we" statements developed during this exercise included:

- How might we produce updates that maximizes industry engagement in both development and implementation of standards to achieve value and ensures a regulatory process that is consistent, timely, and predictable?

- How might we transform the current data exchange to mirror real-time retail transactions?

- How might we write the regulations to update standards like we update code sets annually?

- How might we implement new standards and technologies without regulatory interference while addressing appropriate priorities to better serve patients?

- How might we create systems that can be updated to new invisible standards as easily as my antivirus files are done now?

Exercise 3: Problem Tree Analysis or Importance/Difficulty Matrix

This exercise required participants to quickly prioritize the themes they had been considering

during the previous exercise. The use of an importance-difficulty matrix helps groups prioritize items quickly and can help with deliberations on certain topics. The vertical axis represents the difficulty of an action and the horizontal axis represents the importance or impact of that action. Each group organized their proposed ideas for action by relative importance along the horizontal axis.
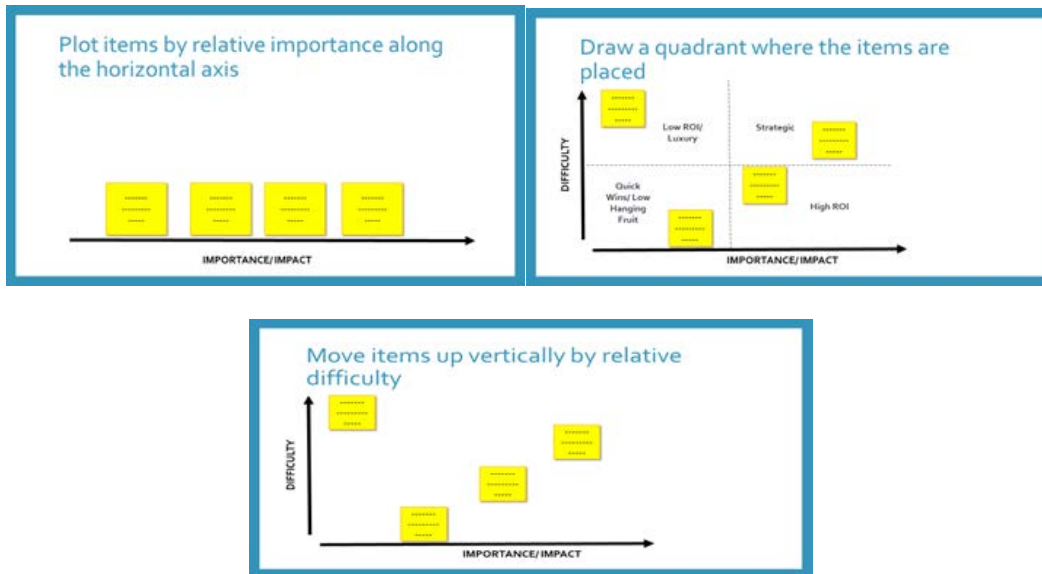
Exercise 4: Concept Diagrams

In the fourth exercise, each group of participants was asked to design a concept diagram using an idea from the priority matrix and to fine-tune that idea. Each group created a diagram of their concept and made a presentation to the larger group explaining the design, its features, how it could work, and the stakeholders. Images of these concept diagrams are in Appendix C of this report.

Group 1 Concept: The right standard for the right purpose at the right time (R3). This concept included incentives for testing and voluntary adoption of new and updated standards. It would require funding for the testing component.

Group 2 Concept: This concept tackled stakeholder engagement and participation in the standards development process. It addressed industry business needs through outreach and education and sped the adoption of standards through such engagement. The concept acknowledged the regulatory process as important for compliance but gave more significance to the need for education and awareness.

Group 3 Concept: QARA. This concept, called the Quick Administrative Regulatory Approval Process (QARA) addressed the goal of decreasing the time to market for new administrative transactions. This concept seeks to address the long timelines that are sequential and serial. It embeds the regulatory process with the standards development process to improve synergies and collaboration.

Group 4 Concept: The Innovation Regulation Ecosystem attempted to solve the problem of predictability, timeliness, and consistency. This concept solves predictability, timeliness and consistency with the big ideas for the life cycle of innovation with appropriate regulation. New technology, standards or methods get demonstrated, then evaluated, then either approved or adopted, or sunset if they do not work. This concept pre-supposes some regulatory flexibility and transparency that does not exist today.

Group 5 Concept: Industry Steering Wheel. Through this concept the industry would be tasked as the driver or mover of the products that are delivered out of the SDO to NCVHS for final recommendation into whatever regulatory process exists. There are a number of items that must be assessed, overseen and vetted. The group acknowledged that a better, more level playing field is required.

PUBLIC COMMENT FROM DAY ONE

Statement from CMS Health Informatics Office

CMS agrees with many of the themes that have emerged from the NCVHS forums and Predictability Roadmap discussions in the past several years, including:

- The current lengthy rulemaking process for the HIPAA/ACA administrative transactions is not functioning adequately to meet industry's business needs. It stifles innovation, cannot keep up with changing business requirements or changing technology, and is not aligned with standards development on the clinical side of the business.

- Because of the mismatches between business needs and the pace of technology development, on the one hand, and the slow standards development, and lack of provider uptake, on the other, the health care industry's strategic needs are not being met.

The CMS Health Informatics Office (HIO) believes that more iterative and agile models are needed to get Standards Development Organizations (SDOs) to create standards faster and to get vendors and providers to adopt them more quickly. The CMS HIO feels that the CMS HIPAA standards adoption process might work more effectively if providers were not limited to adopting standards and accepting certain transactions only after they have gone through the full adoption process and officially finalized in regulation. Perhaps a more agile approach is possible where industry development, testing, and initial use is permitted prior to any necessary official documentation.

CMS HIO and the Office of the National Coordinator (ONC) are working closely with industry to move interoperability forward. The HL7 FHIR standards provide a significant opportunity to do this. However, the current X12 standards necessary for HIPAA compliant transactions are not currently aligned creating tension as we try to provide industry the tools to innovate and operate most effectively and efficiently. For example, the CMS HIPAA regulations for prior authorization requires that every prior-authorization transaction between covered entities must use the ASX X12 278 standard. The Medicare Fee-For-Service (FFS) program expended considerable resources to comply with this regulation. It made modifications to its Electronic Submission of Medical Documentation (eSMD) system to be able to accept 278s from providers. In the 4 years since the eSMD system has been capable of receiving a 278 transaction, not a single one has been submitted by a provider.

The CMS Medicare FFS program has been participating in the HL7 Da Vinci project since its inception in 2018. CMS sees great promise in the FHIR-based "Prior Authorization Support" standard that is emerging from the Da Vinci process. The Da Vinci process is creating a Prior Authorization Support Implementation Guide which is slated to go to ballot in the HL7 September ballot cycle. The Office of the National Coordinator (ONC) for Health IT has tasked

MITRE with developing a Reference Implementation for the Prior Authorization Support standard.

Because vendors, providers and payers may not realize that they would be in compliance with the HIPAA regulation by converting a FHIR transaction to an X12 transaction, the CMS HIO is concerned that the HIPAA regulation requiring payers to accept 278 transactions have caused:

1. Vendors and providers may perceive that they are prohibited from adopting the new FHIR-based transaction for submitting a PA request, and
2. Payers to perceive that they are not permitted to receive or respond to the new FHIR-based PA request transactions.

The CMS HIO encourages the NCVHS Visioning Meeting to discuss ways to overcome these impediments and allow vendors, providers and payers more agility and opportunity to use the standards that will help move the health care industry forward. #end statement#

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DAY TWO

Day 2 – **Subcommittee Synthesis**. The members of the Standards Subcommittee engaged in exercises that aided deliberation of the information gleaned from day one. The invited participants from day one were welcome to attend as observers and for participation in certain discussions.

Facilitator Margeaux Akazawa began the morning session revisiting the concept diagrams. She asked Subcommittee members to think about whether and how the ideas could be actionable, and what could be harvested from the concepts to assist with development of recommendations for a new vision for the DSMO.

Margeaux suggested that the Subcommittee consider elements they liked, did not like, what was missing, and what questions they needed to ask each group to complete their understanding of the concepts.

In making connections between the concepts, the Subcommittee identified common themes:

1. The need for evaluation, pilot and testing of standards and operating rules.

   a. Or, if such activities are taking place, public information about the quantitative and qualitative results

2. Greater stakeholder inclusion and involvement in the development and balloting of standards and operating rules; greater ability to participate (cost to participate is both time, money and ease).

3. Leveling the playing field for participation in standards development – providing a clear reason to participate in relevant standards and operating rule development.

4. Availability of funding for sustainability of evaluation or review.

5. Ability to legally make use of standards available for use before they are mandated – and improving the communicating and process for such use. Parts of HHS are viewed as being more supportive of the voluntary use of standards, or may be able to be more supportive because of differing regulatory authorities.

6. Enabling innovation is important because innovation enables industry to use new data, technology, information, standards or operating rules faster than the regulatory process can update regulations; how can this be legally and logistically leveraged.

7. Timing/pace of different parts of industry (SDOs, developers, industry sectors) complexity. There is a difference in the "speed to market of different standards," e.g. NCPDP vs. HL7 vs. X12

8. Federal leadership may be needed to address and solve some of regulatory process logjams – supportive of voluntary use of newer standards. Need to determine if this is a Federal Leadership vs. Legal Limitation/Authority issue.

9. Need for predictably in the process to enable industry to plan effectively. Can standards development organizations provide specific timetable and truly meet them? Can HHS meet certain schedules? What factors are controllable and which not?

10. Balancing the accountability of the SDOs for meeting their ANSI required processes while finding innovative approaches to predictability.

11. Authority to coordinate ("the glass box") the cross collaboration across industry by providing more transparency into the regulatory processes and timing issues

Based on these themes, the Subcommittee discussed several scenarios that could be included in future recommendations. These were for preliminary idea generation purposes and are not necessarily those that will go forward to the Secretary in the future:

1. DSMO remains "as is." Work flow would be/could be as follows:
    a. Continue to receive updated versions of transaction standards from SDOs on unpredictable schedule; no role in conducting any substantive technical, business analysis or cost-benefit evaluation of the updated transactions.
    b. Continue to receive minimal change requests for the transactions;
    c. NCVHS will continue to rely on stakeholder testimony for input on the "readiness" of an updated transaction or version of a standard for adoption.

Under this scenario, there would be no impact on the ability for the industry to use an updated transaction when the SDO says it is complete and ready for use and/or adoption, there would be no value add to predictability of standards maintenance or valuation of upgrades.

2. DSMO makes changes to its MOU. Potential changes could include:

a. Addition of members, including, but not limited to, operating rule authoring entities, research bodies with capability of conducting analytical tasks, WEDI to increase industry implementation aspects
b. Addition of tasks
c. Addition of operating rule authoring entity
d. Change in process
e. Development of evaluation program
f. Development of pilot program
g. Development of cost-benefit analysis (value) program
h. Application for grant funding

Under this scenario, no specific action would be required of NCVHS because NCVHS is not party to the MOU. Rather, HHS would need to orchestrate change and address any needed regulatory aspects by writing anew proposed rule updating the DSMO process and entities, e.g. adding or changing designated standards maintenance organizations, changing responsibilities and requirements for the review process to include certain evaluation elements.

3. NCVHS sends HHS a letter with recommendations regarding improvements to SDO evaluation process within a certain timeframe
4. NCVHS considers conducting hearing (in person or virtual) to address recommendations that will successfully meet evaluation requirements
   a. NCVHS notifies SDOs of testimony requirements for future standard updates (demonstration of improvements, cost benefits)

The Subcommittee created a list of questions to consider subsequent discussions:

1. Do the themes address the "how might we" statement?

2. Do the themes address the problem statement?

3. How will the themes and/or the new problem statement be communicated to the participants in a timely manner?

4. What is our time-frame for the next steps?

5. How will we communicate with the participants going forward?

Closing

Next Steps

The Standards Subcommittee chairs framed up the next steps of the process, by advising the audience that within the next few weeks, the Subcommittee will get a synthesized report on content from this day and half visioning session from our expert facilitators. The facilitators will also give us some of their suggestions on a path forward, which may include first working on

honing the vision. And for the Subcommittee that would include marrying up with the effort of creating a new visual, along with the corresponding mappings of roles, responsibilities, authorities that we have talked about.

The chairs acknowledged the tremendous amount of consensus building, the discussion around the alignment of where we need to go next in order to try to clearly articulate our vision, define the roles, the triggers and to come up with some short, medium and long term, and to do so in very close orchestration with our industry partners.
So that is a long way of saying stay tuned. We will be back. We will give you more information. The chairs stated that they imagine there will be plenty of opportunity to comment and influence as we move forward.

The Subcommittee thanked meeting participants for taking part in the 2019 visioning session and all of the support staff that went into making the visioning session take place.

For additional information about the program, please contact:

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Comments or feedback on the contents of this summary meeting report can be sent to NCVHS at NCVHSmail@hhs.gov. Please include "2019 Visioning Session" in the subject line.

Appendix A: Meeting Participant List

Meeting Facilitators

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NCVHS Members

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Invited Guests

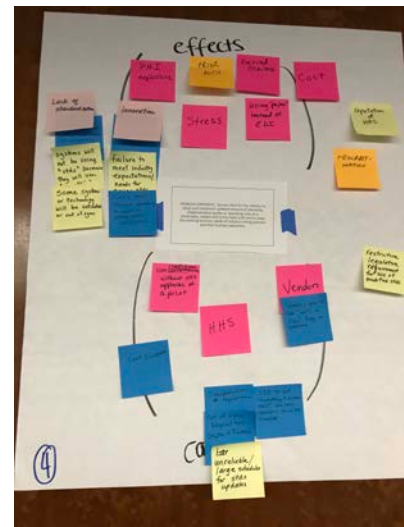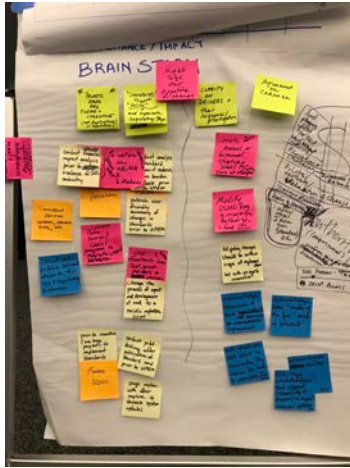|	
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Chris Bruns Immediate Past President Healthcare Administrative Technology Assoc (HATA)	**Laurie Burckhardt** Chairperson Designated Standards Maintenance Organization (DSMO)
Jay Eisenstock Board Chair	**Jamie Ferguson** Vice President, Health IT Strategy & Policy Kaiser Permanente

Workgroup for Electronic Data Interchange (WEDI)	
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Participants
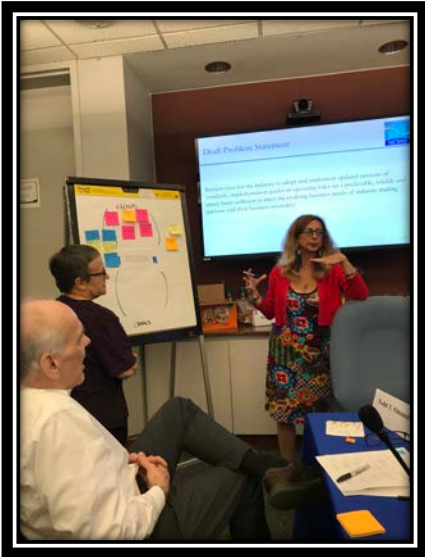
Rapid Brainstorming

Concept Diagrams