Subcommittee on Standards Report Out

September 19, 2024

Tammy Banks, Co-chair
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Topics for Discussion

I. Subcommittee on Standards Workplan

II. April 11, 12 NCVHS Full Committee Education Session Review

III. DRAFT – Request for Information (RFI) Exceptions from Standards to Permit Testing of Proposed Modifications (45 CFR 162.940) Overview and Proposed Questions

IV. DRAFT - RFI for the Harmonization of Standards and Data for Healthcare Interoperability Overview and Proposed Questions

V. Next Steps

Subcommittee on Standards Workplan

Modernizing the Standards Driven Healthcare Information Infrastructure & Ensuring the Privacy and Security of Data Exchange

(Data Modernization 1.0)

Data Modernization 1.0

The **regulatory process** established under HIPAA needs to evolve to meet the current and emerging business and clinical needs.

Broad industry requirement to **modernize the HIPAA transaction standards adoption framework**, **enhance privacy and security requirements, and harmonize clinical, public health, administrative, financial, and other standards.**

Data Modernization 1.0

Need for Comprehensive, well integrated set of standards across all health data including:

- public health,
- population health,
- state/territorial/tribal/local government,
- research,
- administrative and clinical systems
- as well as remote monitoring, patient wearables and other systems/devices/software programs that support the health data ecosystem.

Data Modernization 1.0

that:

- fully supports health information interoperability](including semantic, syntactical, and structural interoperability),
- data privacy, and
- security.

Data Modernization 1.0

Vision: To standardize data capture and improve availability of data across the healthcare data ecosystem that supports individual healthcare and wellness, health policy, privacy and security, and healthcare quality and safety. See examples below.

Examples: Individual health care and wellness, health equity/SDOH, public health, health policy, price transparency, coordination of care, improved patient outcomes, healthcare quality and safety, burden reduction, privacy and security, usability of personal health information, real-world data (RWD), including patient generated data, will become increasingly important over time.)

Subcommittee on Standards Workplan

1. **Ensure HHS** (OBRHI, NSG & ASTP/ONC) **and other Department Alignment**
2. **Examine mature and emerging standards** - how they can co-exist to support current and future business needs and their workflows.
    1. DRAFT - RFI on the Existing Regulatory Language and HHS Guidance on Requests for Exceptions from Standards to Permit Testing of Proposed Modifications (45 CFR 162.940)
3. **Review relevance of HIPAA in the current healthcare ecosystem**
4. **Harmonization of Standards and Data Requests**
    1. DRAFT - RFI for the Harmonization of Standards and Data for Healthcare Interoperability

Education Session Review

Full Committee Meeting, April 11-12, 2024

- **Meetings – National Committee on Vital and Health Statistics (hhs.gov)**

➢Standards for SDOH Data Elements: Successful SDoH approaches and challenges to promote health equity

➢Value Based Care Models vs Fee-For-Service: Implications for HIPAA Transaction Standards

➢Trusted Exchange Framework and Common Agreement (TEFCA) Update

Standards for SDOH Data Elements: Successful SDoH approaches & challenges to promote health equity

Moderators: Jamie Ferguson & Lenel James

- **Somava Saha, MD, MS**
  Executive Lead, Wellbeing in the Nation (WIN) Network
- **Meagan Khau, MHA**
  Director, Data Analytics & Research Group (DARG), Office of Minority Health (OMH), Centers for Medicare & Medicaid Services (CMS)
- **Vanessa Candelora**
  Senior Consultant, Gravity Project Program Manager, Point-of-Care Partners (POCP)
- **Prerana Laddha, MS**
  Director of Social Care and Behavioral Health, Epic Systems Corporation
- **Rachel Harrington, PhD**
  Senior Research Scientist, Health Equity, National Committee for Quality Assurance (NCQA)
- **Julia Skapik, MD, MPH, FAMIA**
  Chief Medical Information Officer, National Association of Community Health Centers (NACHC)
- **Dr. Gniesha Dinwiddie, PhD**
  Health Scientist Administrator, National Institute on Minority Health and Health Disparities (NIMD), National Institutes of Health (NIH)

Value Based Care Models vs Fee-For-Service: Implications for HIPAA Standards

Moderator: Deb Strickland

- **Farzad Mostashari, MD, ScM**
  Co-Founder and Chief Executive Officer, Aledade
- **Todd Couts, MS**
  Deputy Director, Business Services Group, CMMI, CMS
- **Aneesh Chopra, MPP**
  Co-Founder & President, CareJourney, Author, Innovative State
- **Erin Weber, MS**
  Chief Policy and Research Officer, CAQH

Trusted Exchange Framework and Common Agreement (TEFCA) Update

Moderator: Michael Hodgkins

- **JaWanna Henry, MPH, MCHES**
  Interoperability Systems Branch Chief, Office of the National Coordinator for Health Information Technology (ASTP/ONC)
- **Marianne Yeager, MBA**
  CEO, The Sequoia Project (the TEFCA Recognized Coordinating Entity)
- **Chantal Worzala, PhD**
  Principal at Alazro Consulting, LLC
- **Steve Gravely, JD, MHA**
  Founder, Gravely Group
  Principal author of the Data Use and Reciprocal Support Agreement (DURSA)

Request for Information on Guidance on Requests for Exceptions from Standards to Permit Testing of Proposed Modifications (45 CFR 162.940)

Overview and Proposed Questions

Requests for Exceptions from Standards to Permit Testing of Proposed Modifications

(45 CFR 162.940)

Background

28 years ago, in 1996, Congress established the requirements for the exception and application processes to request and conduct an exception to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transaction and code set standards.

The August 17, 2000 Transactions and Code Sets Final Rule (65 FR 50369) codified the process that an organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard.

HHS guidance on the exception process - https://www.cms.gov/files/document/guidance-letter-exception-process.pdf

Purpose of Exceptions from Standards

An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard.

The purpose is to test whether that modified standard is an improvement to the current standard, and increases the efficiency and effectiveness of data exchange for electronic administrative transactions

Five Stages of the Exception Process

1. Request for the exception;
2. Basis for granting an exception;
3. The Secretary's decision on exception;
4. Organization's report on test results; and
5. Requests to extend the exception.

Request for Exception

A request for an exception to compliance with an adopted standard, and permission to test a modification to that standard, should include the following elements:

a. A comparison of the proposed standard to the current adopted standard with **explanation of how the proposed modification would be a significant improvement to the current adopted standard**.

b. Specifications of the proposed modification, including any additional system requirements.

c. An explanation of **how the organization intends to test the standard**, including the number and types of health plans and health care providers expected to be involved in the test, the geographic areas affected, and the beginning and ending dates of the testing.

d. Written concurrences from trading partners who agree to participate in the test.

Basis for Granting the Exception

Assessment

- Whether the proposed modification **represents a significant improvement** to the current standard;
- The **extent and length of time of the exception testing**;

Granting Exception

- **Consultations with Designated Standards Maintenance Organizations** (DSMOs)
- The Transactions and Code Sets final rule specifies the DSMO organizations designated by the Secretary of HHS.

Secretary's Decision on the Exception under 162.940(c)

Exceptions Process | CMS

The notification will include

- The length of time for which the exception applies;
- The trading partners and geographical areas that have been approved for testing; and
- Any other conditions for approving the exception.

Within 90 days of completing the test, the organization must submit a report of its results including a cost-benefit analysis to the Secretary.

Exception Testing Completed

An extension of time for operating under an exception does not:

- alter any other conditions of the exception, nor
- **mean that the new standard will be adopted.**

It is expected that a successful test conducted through the exception authority and resulting in comprehensive and compelling data would facilitate the movement of a modification through the DSMO, NCVHS and rulemaking processes.
Change in HIPAA standard can only take place if a DSMO submits through the established process.

The Exceptions Process – 10 Principles 45 CFR §162.940

- **Improve the efficiency and effectiveness of the health care system** by leading to cost reductions for, or improvements in benefits from, electronic health care transactions
- **Meet the needs of the health data standards user community**, particularly health care providers, health plans, and health care clearinghouses
- Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards
- Have **low additional development and implementation costs relative to the benefits** of using the standard
- Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time

The Exceptions Process – 10 Principles 45 CFR §162.940

- Have **timely development, testing, implementation, and updating procedures** to achieve administrative simplification benefits faster
- Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard
- Be precise, unambiguous, and as simple as possible
- Result in **minimum data collection and paperwork burdens on users**
- **Incorporate flexibility to adapt more easily to changes in the health care infrastructure** (such as new services, organizations, and provider types) **and information technology**

The Exceptions Process

To date, HHS has received and approved three applications under the exception at 162.940.

- an alternative code set;
- use of the UDI in claims (one state), and
- use of an API for prior authorizations.

NCVHS Request for Information (RFI)

HHS has requested that NCVHS consider publishing an RFI to obtain industry input on the Exception Process. HHS and NCVHS are in the process of developing a question set to obtain input which can be compiled as a summary, as well as enable NCVHS to consider in providing recommendations to HHS on updates to the process.

Request for Information Rationale
To obtain information from stakeholders to inform recommendations to HHS on opportunities for improvement to the exception process.

Participants:
HIPAA-covered entities and other interested parties

Timing:
Submit FRI to Federal Register this calendar year.

RFI Question Categories

- Exception Process Instruction/Guidance
- Exception Process Application
- Exception Process Implementation
- Exception Process – Overall
- Approved Exceptions – Next Steps
- Testing of Standards Outside of Exception Process

Exception Process

Instruction/Guidance

1. Are you familiar with the exception process under HIPAA 45 CFR 162.940(a)(4), which permits an organization to request an exception from using a standard to test a proposed modification to that standard?

2. If yes, is the information clear and understandable or is there additional information from HHS needed regarding the process for applying for and executing an exception from a standard to permit testing of a modification? If yes, what information would be helpful?

Exception Process Application

Application

3. If you have experience with the HIPAA exception process, what worked well in your experience, and what did not? Please provide details with your response.
4. For those who have considered filing for an exception, but chose not to what are the reasons they are not filing?
5. If there was funding available for completing an exception process, would that increase participation.

Implementation

6. At 45 CFR 162.940(4), the applicant is to provide written concurrences from trading partners who would agree to participate in the test. Do you think the current requirement promotes participation in the exception process? Why or why not? If you believe the current HHS requirement is a barrier, what change would you recommend to this requirement?

Exception Process - Impact

7. Is the exception process at 45 CFR 162.940 to test a modification to a standard an effective policy tool to update HIPAA standards? If so, in what way? If not, what other policy tools might HHS use when evaluating different standards?

8. As designed, does the current exception process support testing and analysis of use cases for new standards?

9. For what other purposes might the exception process be used to support the adoption of updated standards under HIPAA?

Exception Testing Completed – Next Steps

10. NCVHS understands that approval of an exception report or permission to extend an exception by the Secretary does not mean that a standard tested during an exception process will be adopted. Furthermore, 45 CFR 162.940 does not require the organization to submit the standard for consideration to be adopted. In your view, should an organization be required to submit a request to HHS for adoption within a certain period of time after the test results have been evaluated and approved? Why or why not?
11. If an exception study has been completed, should such modifications be permitted voluntarily by other covered entities that may include updating their trading agreement?
12. Do you consider an exception from a standard to permit testing of a modification to be the same as testing a new standard?

Exception Testing Completed – Next Steps

13. Do you believe that the results from an exception project are sufficient to demonstrate that the tested standard should be considered for adoption to replace an existing standard? Why or why not?

14. What other changes to HIPAA statute or regulation to allow for updates to approved standards that may be different than those typically adopted under HIPAA process to promote innovation? For example, ASTP/ONC regulations support routine updates, tie with USCDI updates, etc.

Testing of Standards Outside of the Exception Process

In earlier Subcommittee work,

NCVHS asked each of the standards development organizations to discuss how development and testing is conducted before a new version of a standard or implementation guide is considered ready for federal adoption.

HHS is also interested in learning more about other testing tools used by industry as they conduct their implementation activities.

Testing of Standards Outside of the Exception Process

15. How does or should the industry define use case testing for this purpose?
16. What is your definition of backward compatibility, cross compatibility of standards? How should the industry define backward compatibility, cross compatibility of standards?
17. When should HHS realistically expect the industry to begin to assess the costs and benefits of a new or modified standard?
18. What type of standard, transaction, code set, operating rule testing occurs today that could be replicated for proposed HIPAA transactions. What entities provide these testing types?

Testing of Standards Outside of the Exception Process

19. Does or could your organization provide open-source synthetic data to test new or updated standards against?
20. Should new or updated standards be required to go through the exception process before submitting for consideration as a HIPAA standard, transaction or code set? If yes, would there be any reason a standard would not have to go through the exception process?
21. What potential funding sources are available for testing of standards outside of the exception process besides HHS?

Innovation Opportunities

22. What are the potential uses of Artificial Intelligence (AI) or other anticipated innovations to support and reduce the resources needed to build and test new or updated standards to ensure they meet current and emerging business use cases?

Next Steps

- Incorporation of comments from this meeting
- National Standard Group input
- RFI submission this calendar year

Draft Harmonization Request for Information (RFI)

Overview

- Introduction
  - Background
  - Purpose and Goal
  - Project Scope
  - Harmonization Approach
- Harmonization RFI
- Next Steps

Background

NCVHS has determined that there is a broad industry requirement to modernize the standards adoption framework, including enhancing privacy and security and harmonizing clinical, public health, administrative, financial and other standards.

Background

- Previous committee information gathering sessions have identified harmonization and collaboration issues between standards organizations

- Current US harmonization efforts appear to be ad hoc and inconsistent

Background

- These efforts lack a permanent support structure for harmonization of standards and data across all SDO's

- Such a structure could support and promote timely and efficient harmonization activities which in turn could reduce the burden placed on health organizations that are required to implement the standards

Purpose and Goal

Purpose: Identify existing and emerging harmonization efforts related to healthcare standards and data to support interoperable data exchange and diverse business needs

Goal: Identify strategies to modernize the standards-driven information infrastructure across the healthcare data ecosystem in partnership with key federal and industry stakeholder

Project Scope

The healthcare industry needs a comprehensive, well integrated set of standards that fully support health information interoperability that includes:

- Semantic, syntactical, and structural interoperability
- Data privacy and security across
  - public health, population health, state/territorial/tribal/local government;
  - research, administrative and clinical systems;
  - remote monitoring, patient wearables and other systems/devices/software programs that support the health data ecosystem

Harmonization of standards across Standards Development Organizations (SDO), users and state and federal regulatory agencies will be necessary to achieve the objective

Harmonization Approach

Harmonization efforts can be categorized into seven strategic areas:

- Regulatory framework
- Information/data elements
- Terminologies/code sets
- Security/trust framework
- Data privacy
- An information exchange framework; and
- A common standards development and implementation methodology

Harmonization RFI: Rationale and Target Groups

Rationale for RFI:

- Gain information to assist NCVHS in making thoughtful recommendations to HHS on the current and future process for Harmonization of Standards and Data.

Target Groups:

- Standards organizations and standards specifying private and public agencies
  - about their efforts to coordinate and collaborate with other standards organizations to harmonize standards and data
- Implementers
  - about the challenges or potential opportunities when implementing new or updated standards

Harmonization RFI: Areas of Interest

The committee is interested in any harmonization efforts related to the following areas:

- Information/data elements
- Terminologies/code sets
- Security and data privacy
- Information exchange formats
- Methodologies used to support harmonization efforts

Harmonization RFI: Areas of Interest

The committee is also interested in hearing from standards organizations and implementers about:

- Coordination and collaboration efforts: temporary/ad-hoc or continuous
- Advantages and disadvantages of having a group or organization that could support continuous coordination and harmonization efforts
- Recommendations concerning an existing group or organization (government or non-government) that could support continuous coordination, collaboration and harmonization efforts across standards organizations

Harmonization RFI: Areas of Interest

- Subject matter expert (SME) member composition to support successful harmonization efforts
- Current or innovative tools or technologies that could help reduce the level of effort to harmonize, map or convert standards/data or identify where harmonization, mappings or conversions should occur
- What NCVHS can do to help with efforts to coordinate, collaborate and harmonize standards and data

Three Target Responder Categories

- Implementers (e.g., AMA, AHA, BC/BS, EHRA, AHIP and others)
- Standards Development Organizations (e.g., HL7, X12, NCPDP, IHE, DICOM, IEEE and others)
- Terminology Organizations (e.g., NCHS, NLM, CMS, WHO, AMA and others)

Proposed Questions for Implementers

- Are there challenges or potential opportunities when implementing new or updated standards?
- What are you currently doing to address the challenges you encounter (i.e., harmonization, testing, mapping or other challenges)?
- Are you pursuing specific opportunities?
- What are your highest priorities that would positively improve efficiency and/or reduce costs?
- What should the role of federal agencies be in regards to harmonization of standards and data efforts?

Proposed Questions for All Others

- What are the incentives and challenges for organizations to work together?
- What are the existing points of coordination/current activities?
- What mechanisms might increase efficiency/reduce work across standards organizations?
- What do you hear from the end users about compliance challenges when implementing your standards?
- What should the role of federal agencies be in regards to harmonization of standards and data efforts?

Next Steps

- Submit RFI to Federal Register this calendar year
- Compile RFI responses and consider them together with input from subject matter experts
- After compiling responses, hold education sessions to gather additional feedback as needed

For more information

- Meeting summaries
- Educational Presentations
- Work products
- Reports
- Recommendation and Response Letters

Visit https://ncvhs.hhs.gov/