National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

NCVHS Standards Subcommittee CIO Forum

To Inform the Predictability Roadmap for Updating and Adopting Administrative Standards and Operating Rules

May 17, 2018

Bureau of Labor Statistics

Agenda

- Welcome
- Agenda and Logistics Review
- Predictability Roadmap Overview
- Participant Introductions
- Interactive Panel Discussions
- Public Comment
- Wrap Up and Next Steps
- Adjourn

Goals for the Day

1. Learn about participant experience and expertise with the adopted standards and operating rules;
2. Share innovative accomplishments, perspectives and challenges on the use of standards to enable evolving business models;
3. Solicit and compile ideas to improve the process and predictability of advancing administrative standards and operating rules.

History of the Predictability Roadmap

- HIPAA Legislation was enacted more than 21 years ago to promote administrative simplification efficiencies and effectiveness of the health care system through the use of standards for electronic transactions between health plans, clearinghouses and certain health care providers.

- The Patient Protection and Affordable Care Act included provisions to support HIPAA, both reinforcing certain requirements (adopt attachment standard), and adding new ones (adopt operating rules), increase enforcement.

- Industry feedback to NCVHS indicated the need for predictability in how standards are developed, adopted and implemented.

- We undertook a project engaging the industry in developing a predictability roadmap. We met with the following: Standard Development Organizations, Operating Rules Authoring Entity, Federal regulators, and industry stakeholders.

History of the Predictability Roadmap

Pre-2012

NCVHS submitted letters to the Secretary identifying concerns for the development, maintenance, and update process for standards and operating rules relating to administrative transactions.

2016

In its annual Report to Congress, NCVHS identified the development of a predictability roadmap as one of its priorities based on on-going industry feedback about the update and adoption process for standards.

2017-2018

NCVHS has been working to identify and understand the strengths and weaknesses in the current SDO/ORAE processes. The recommendations for actionable improvements will be compiled into the predictability roadmap.

What We've Accomplished

1. Met with standards organizations to understand current practices
   - **Outcome: Published a comprehensive overview of development procedures, organizational compositions and workgroup structures**.
2. Conducted a daylong visioning workshop with standards organizations, federal partners and interested stakeholders to identify specific opportunities for action
   - **Outcome: Summary report of the workshop, and consolidation of ideas into 5 agreed upon themes**
3. Interviewed HHS to understand the opportunities and limits of the regulatory process
4. Scheduled this CIO Forum to understand end-user perspectives

What Happens After Today?

1. Consolidate findings from all activities, including the CIO Forum, into a draft set of recommendations and actions
2. Hold a hearing to review the draft recommendations and obtain additional feedback
3. Finalize recommendations
4. Send final set of recommendations to the Secretary

What Has HHS Adopted to Date?

Adopted Standards

Standards or Operating Rules	Version	Dates Adopted & Mandated for Use
Claims – Professional, Institutional, Dental (837 P, I, D)	Version 5010	January 2009/January 2012
Remittance Advice (ERA)	Version 5010	January 2009/January 2012
Eligibility Inquiry & Response	Version 5010	January 2009/January 2012
Claim Status Request & Response	Version 5010	January 2009/January 2012
Health Plan Enrollment/Disenrollment	Version 5010	January 2009/January 2012
Health Plan Premium Payment	Version 5010	January 2009/January 2012
Referral Certification & authorization	Version 5010	January 2009/January 2012
NCPDP Pharmacy transaction: Telecommunication Standard & Batch Standard for Retail Pharmacy claims & supplies and professional services	NCPDP D.0 & Batch Standard Version 1.2	January 2009/January 2012
Medicaid Pharmacy Subrogation	Version 3.0	January 2009/January 2012
Electronic Funds Transfer (EFT)	NACHA	January 2012/January 2014

Adopted Operating Rules

Operating Rules	Version	Date Adopted/Mandated for Use
Operating Rules for eligibility and claim Status transactions	Phase I and II	December 2011/January 2013
Operating Rules for EFT and ERA	Phase III	August 2012/January 2014
Proposed for remaining Tx (excluding Attachments)	Phase IV	Not recommended by NCVHS

Operating Rules must still be developed and adopted for these transactions:

1. Claims (all)
2. Enrollment and Disenrollment
2. Premium Payment
3. Referrals and Prior Authorization
4. Coordination of Benefits
5. Attachments

Participant Introductions

CIO Forum

BREAK

Participant Introductions

Before we begin...Logistics

- Subcommittee members will provide a brief background on each of the five themes;
- One or two priming questions will be offered to launch the discussion, but these are not the only questions to be answered – all commentary is welcome;
- We want to hear from you as end-users and experts in your field;
- Raise your tent cards to signal interest in speaking;
- Public comments will be taken at the end of the day;
- For those listening on the phone, please send comments through the live WebEx broadcast dashboard, or send comments to NCVHSmail@cdc.gov.

Discussion of the Roadmap Themes

1. Governance

2. Standards Adoption

3. Regulatory Process

4. Data Harmonization

5. Third Party Entities

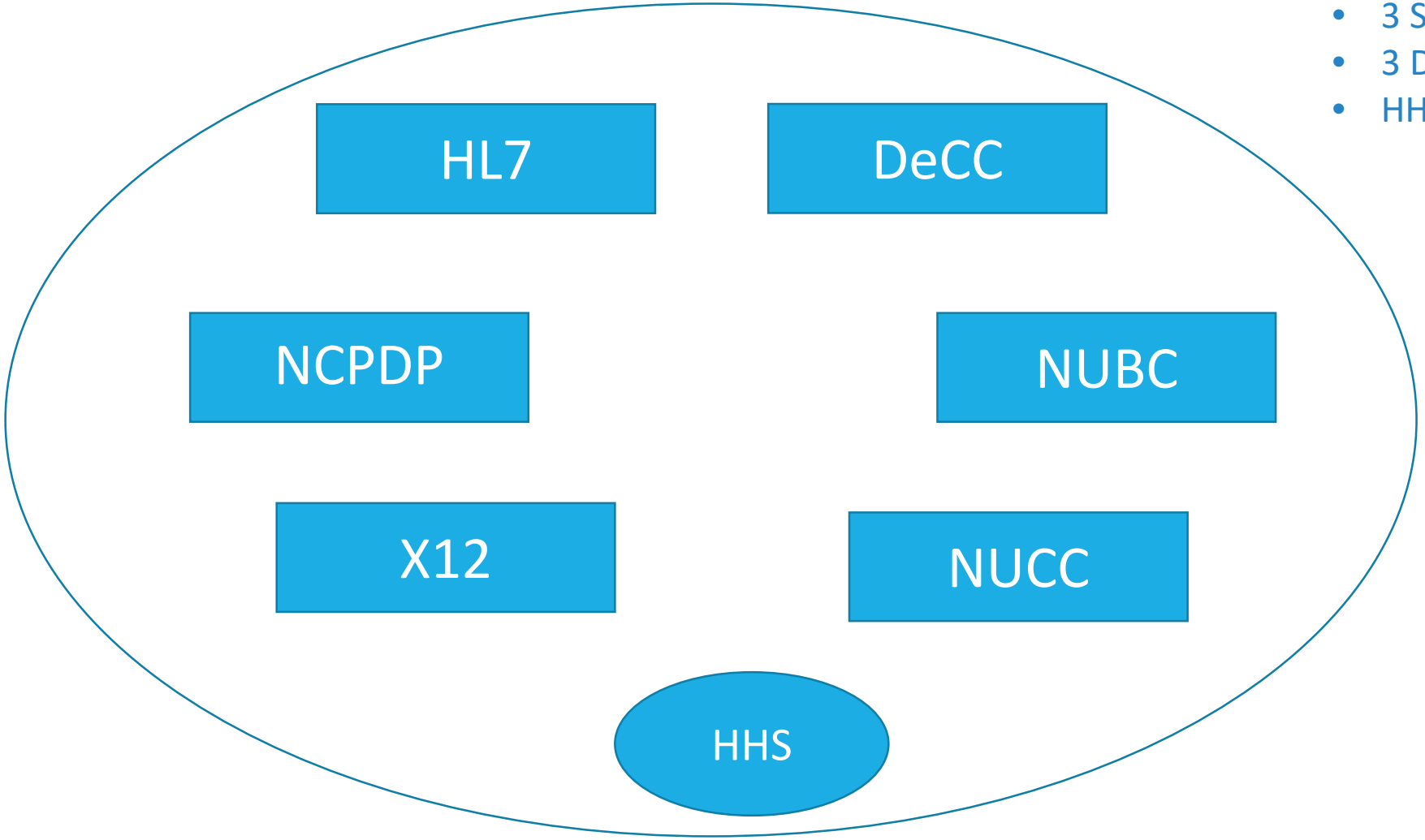
Theme 1: Governance - History

The Designated Standards Maintenance Organization

Named in Federal Register Notice 8/17/00

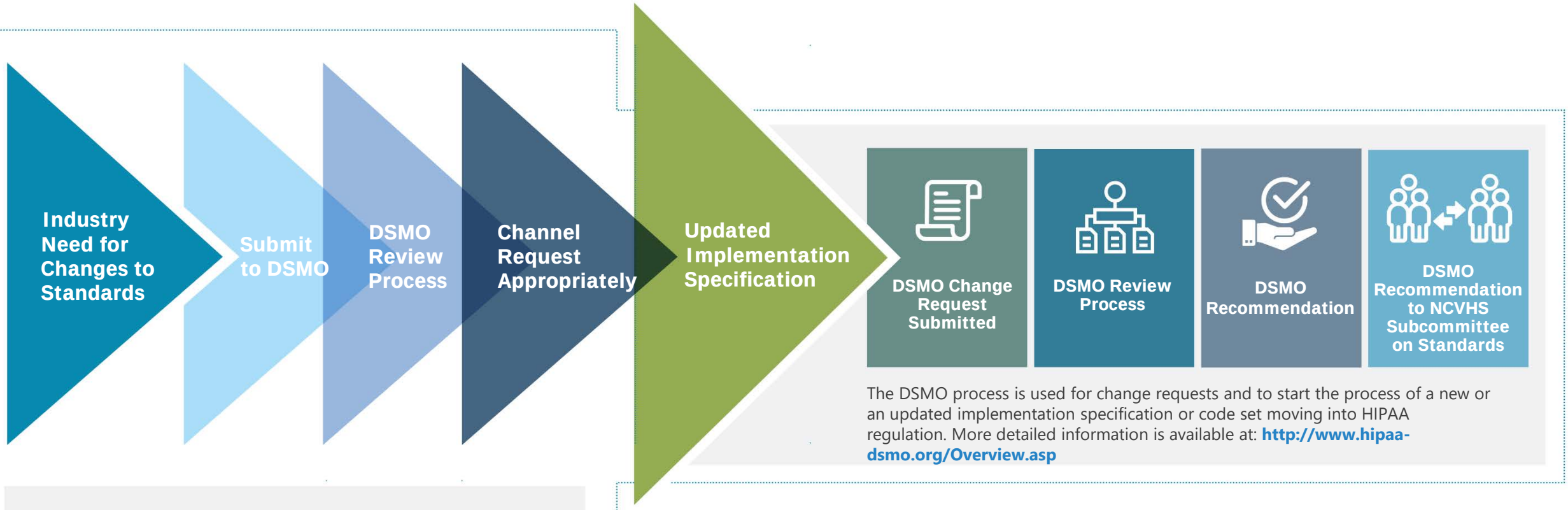
- Purpose: To work together to maintain the HIPAA Electronic Data Interchange (EDI) implementation materials named in the Final Rule(s)
- Includes requests for new code sets to be named as HIPAA code sets
- Process also requires that the NCVHS hear recommendations from the DSMO on an annual basis

Governance – DSMO MOU



- 3 SDO's (HL7, NCPDP, X12)
- 3 Data Content Committees
- HHS/CMS non-voting role

DSMO Process Handoff to NCVHS



Industry requests can come in through multiple entry points, depending on submitter familiarity.

The DSMO process is used for change requests and to start the process of a new or an updated implementation specification or code set moving into HIPAA regulation. More detailed information is available at: **http://www.hipaa-dsmo.org/Overview.asp**

Theme 1: Governance

PROBLEM STATEMENT: Current coordinating body (i.e. the DSMO) is charged with oversight of standards revision priorities but may be operating with too narrow a charter or lacking the authority and resources to be effective.

QUESTIONS:

- How does the review process work today from your vantage point?
- Where are the opportunities for improvement? How might the process be different?

Discussion of the Roadmap Themes

1. Governance

2. Standards Adoption

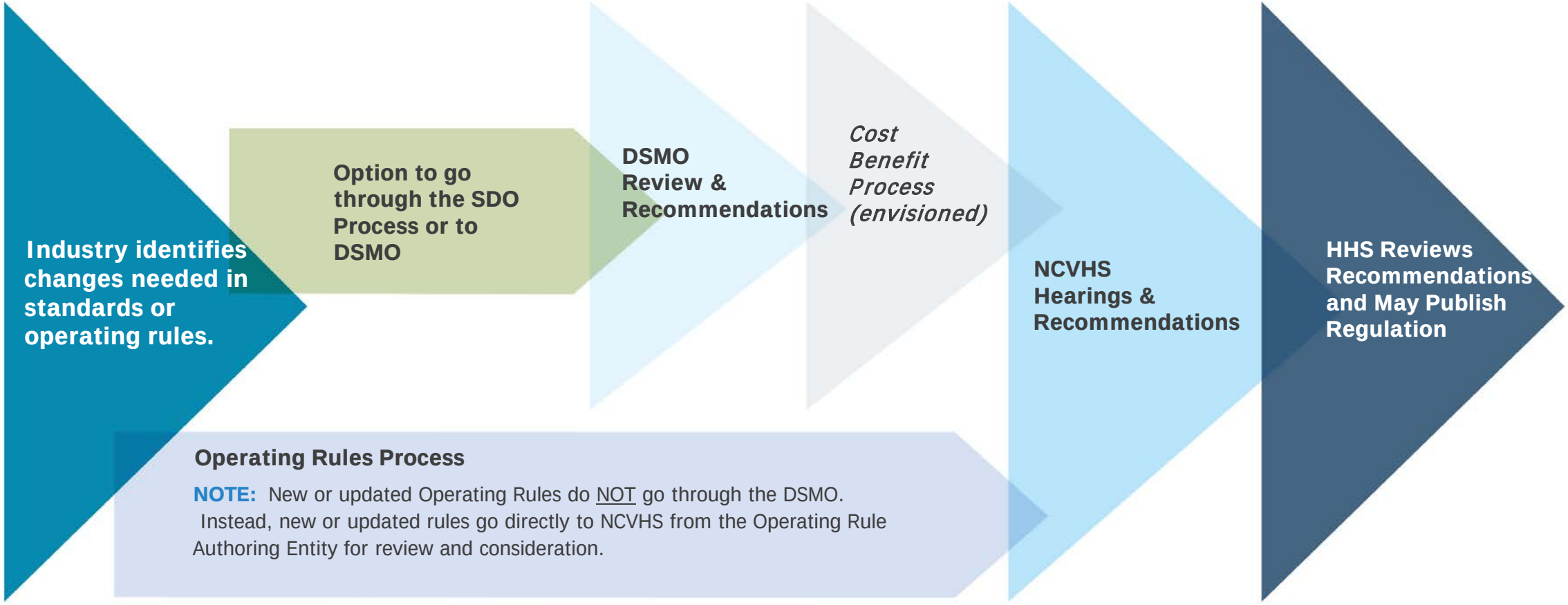
3. Regulatory Process

4. Data Harmonization

5. Third Party Entities

Standards Update Process - Overview

Current Process for Receiving Recommendations for Updates to Standards and Operating Rules



WEDI Policy Advisory Groups Help Industry Analyze HHS Policy After Regulations Have Been Published

Theme 2: Standards Adoption

PROBLEM STATEMENT: Frequency of updates to standards and operating rules is not aligned with industry business and technical changes and does not enable covered entities, trading partners, or business associates to take advantage of technology developments.

QUESTIONS:

- How do the current cycles for updating the standards support industry operational and technical transformation?
- Does your team participate in any standards work groups? Is that engagement effective for your organization? What are the best practices you see?
- What changes in the current processes of updating standards would be beneficial to industry as it is evolving?
    - Process, timing, incremental updates, type of updates, method of updates etc.

CIO Forum

LUNCH

12:10 p.m. to 1:10 p.m.

BLS Café
Union Station

Discussion of the Roadmap Themes

1. Governance

2. Standards Adoption

3. Regulatory Process

4. Data Harmonization

5. Third Party Entities

Federal Regulatory Process

Initiating Events
Request for rulemaking

1

Determination whether rule is needed
Administrative Procedures Act provisions include Information about forms, agency organizations and methods of operation

2

Preparation of Proposed Rule
Administrative Procedures Act provisions require steps 3 through 6 to be completed before rules may be established

3

OMB Review of Proposed Rule
90 days allowed

4

Publication of Proposed Rule

5

Public Comments
OMB requires 60 days

6

Preparation of Interim or Final Rule

7

OMB Review of Interim or Final Rule

8

Publication of Interim or Final Rule

9

NCVHS Role in the Regulatory Process

1. DSMO presents recommendation to upgrade adopted transactions or code sets to NCVHS
2. NCVHS reviews request and conducts hearing
3. NCVHS reviews testimony and makes recommendation to HHS
4. HHS reviews NCVHS recommendation and determines next steps
5. Rulemaking process begins at HHS

Theme 3: Regulatory Process

PROBLEM STATEMENT: The Federal process for adoption of standards and operating rules is lengthy, of unpredictable duration and contains numerous checks and balances that arguably duplicate similar processes within the standards development organizations.

QUESTIONS:

- How does the regulatory process advance or hinder your business model and strategic goals?
- What opportunities could improve the regulatory process?
- Can or would you use standards without regulations?

CIO Forum

BREAK

Discussion of the Roadmap Themes

1. Governance

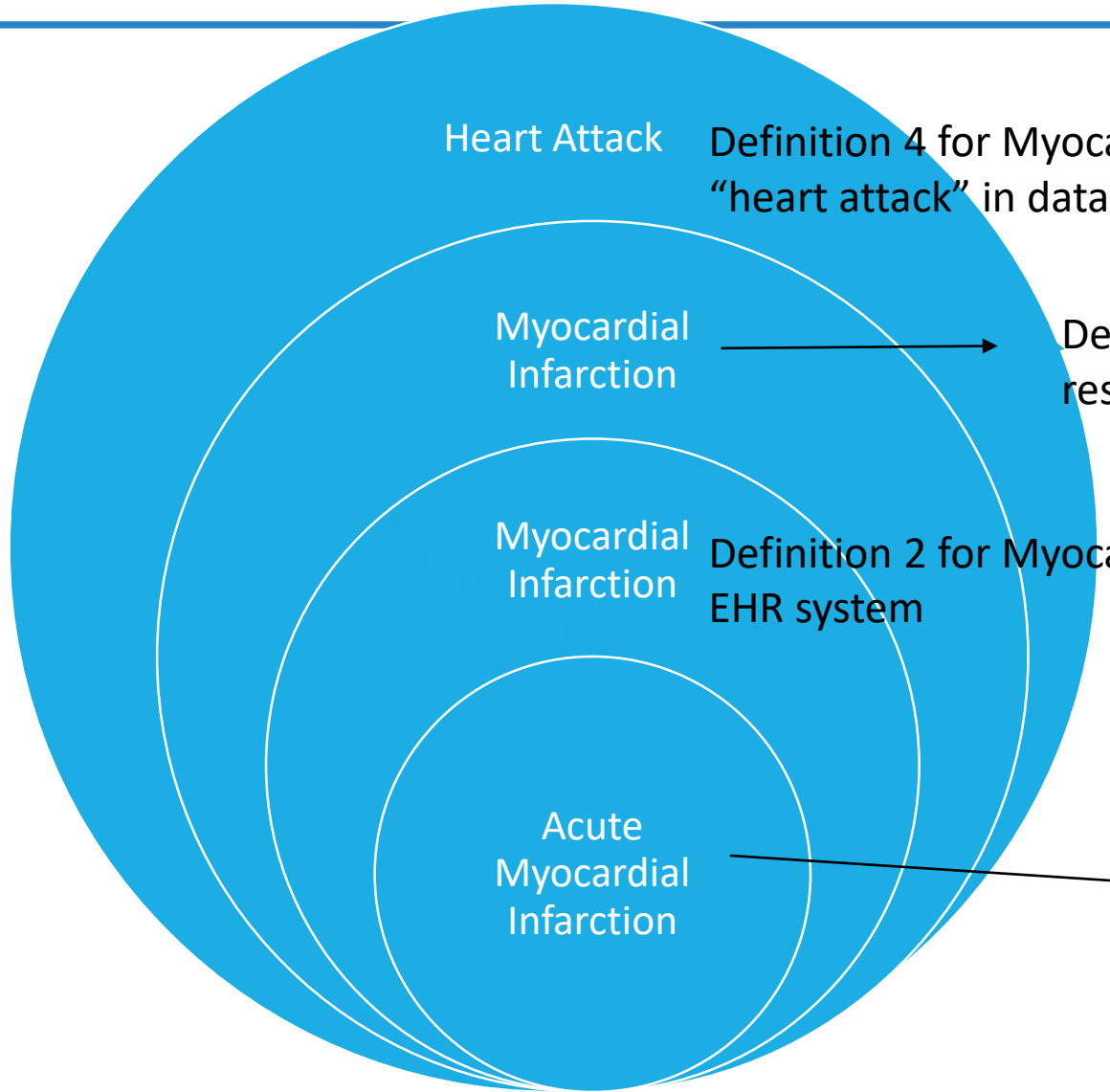
2. Standards Adoption

3. Regulatory Process

4. Data Harmonization

5. Third Party Entities

Theme 4: Data Harmonization



Definition 4 for Myocardial Infarction as "heart attack" in data dictionary

Definition 3 for Myocardial Infarction in research office

Definition 2 for Myocardial Infarction in EHR system

Definition 1 for Myocardial Infarction in Provider office

Theme 4: Data Harmonization - levers

US Data Harmonization Levers:

- Named health terminology and vocabulary standards under HIPAA: ICD-10-CM, ICD-10-PCS, LOINC, CPT, CDT, RxNorm, etc.
- ONC's 2018 Interoperability Standards Advisory
- ONC's draft US Data Content for Interoperability initiative (USCDI)
- Meaningful Use
- Quality metrics
- Patient registries
- Administrative standards and operating rules (HIPAA/ACA)

*ONC is the Office of the National Coordinator

Theme 4: Data Harmonization

PROBLEM STATEMENT: The lack of data cohesion jeopardizes interoperability due to inconsistencies in data dictionaries and data elements across SDOs.

QUESTIONS:

- Can you describe ways in which data harmonization has aided implementation of a standard; when it has impeded or complicated implementation of a standard?
- How would you describe the impact of the current status of data harmonization on operating costs, on integrity/quality of information and its usefulness?
- Should we persist in distinguishing between “clinical” and “administrative” data content standards (i.e. an HL7 CDA/FHIR/XML system for clinical and a separate X12/NCPDP EDI system for administration and payment)?

Discussion of the Roadmap Themes

1. Governance

2. Standards Adoption

3. Regulatory Process

4. Data Harmonization

5. Third Party Entities

Theme 5: Inclusion of Third Party Entities

A Covered Entity is one of the following:

A HEALTH CARE PROVIDER

This includes providers such as:

- Doctors
- Clinics
- Psychologists
- Dentist
- Chiropractors
- Nursing Homes
- Pharmacies

...but only if they transmit any infromation in an electronic form in connection with a transaction for shich HHS has adopted a standard.

A HEALTH PLAN

This includes:

- Health insurance companies
- HMOs
- Company health plans
- Government programs that pay for health care, such as Medicare, Medicaid, and the military and veterans health care programs

A HEALTH CLEARINGHOUSE

This includes entities that process nonstandard health information they receive from another entity into a standard (i.e., standard electronic format or date content), or vice versa.

Who is NOT A Covered Entity...

- Software vendors
- Practice Management Systems
- Third Party Administrators and Pharmacy Benefit Managers
- Companies involved in claims processing
- Property & Casualty Insurers
- Worker's compensation
- Employers (Unless providing self-funded /self-administered health insurance)
- Medical Transcription Services
- Health Information Exchanges
- Utilization Review and Management Companies
- Medical Billing Companies and Repricers
- Document storage and disposal

Theme 5: Inclusion of Third Party Entities

PROBLEM STATEMENT: Covered entities include providers, health plans and health care clearinghouses. Vendors and other business associates are not covered entities despite a role in the conduct of the adopted standards. The Federal Government is limited in its authority over non-covered entities. This impacts the use of standards in a variety of ways, from costs to actual utilization.

QUESTIONS:

- Do you think the list of entities on the prior slide should become covered entities under HIPAA? If so, why and how will this help industry use the standards and operating rules more effectively?
- If third parties who are not currently covered entities were to come under the umbrella of HIPAA, there could be implications for their compliance with the Privacy and Security rules. What barriers would that impose for those organizations?

PUBLIC COMMENT PERIOD

To Submit Public Comment to the Committee:

- **Send comments by email to NCVHSmail@cdc.gov**
- **Use the live WebEx broadcast dashboard**

Please include your name, title, and organization

WRAP UP

Next Steps

1. Consolidate findings from all activities, including the CIO Forum, into a draft set of recommendations and actions
2. Hold a hearing to review the draft recommendations and obtain additional feedback
3. Finalize recommendations
4. Send final set of recommendations to the Secretary