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

Update to the Health Information Technology Advisory Committee (HITAC)

Bill Stead, NCVHS Chair
Rich Landen, NCVHS & Member of Subcommittee on Standards
Rebecca Hines, NCVHS Executive Secretary/DFO

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Today's Presentation

- Review of NCVHS mandate
- Coordination between HITAC and NCVHS
- NCVHS Workplan
  - Predictability Roadmap – Draft Recommendations
  - Health Terminologies & Vocabularies
  - Beyond HIPAA
- Key Question Under Consideration
- Discussion

NCVHS Mandate

- Assist and advise the HHS Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues.

- Assist and advise the Department in the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA).*

- Inform decision-making about data policy by HHS, states, local governments and the private sector.

-- NCVHS Charter, approved January 2018

* Reiterated in Section 1104 of the ACA (2010)

Diverse Expertise

21st Century Cures Call for Coordination

Legislation: "The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies."

Benefit: Coordination and collaboration mutually benefits the respective work of both FACAs—enabling identification of opportunities for convergence or coordination of committee activities and deliverables, especially in the development of recommendations.

Key Point from Public Comment Recently Received by NCVHS

"It's important to consider the opportunity, as technologies advance, to move away from the currently dominant model of 'billing-system-with-clinical-bolted-on' and towards integrated systems that use one set of underlying standards (or, better yet, a single harmonized standard) that reflect the reality that this is all supposed to be about one goal: patient care.

Providers, public health, and billing/payors ultimately really need the same data—what care was given for what patient characteristics—abstracted at different levels. Reflecting that in base standards would do a lot to advance the technology field towards integrated/seamless systems."

2018 Work Plan Priority Areas

- Predictability Roadmap (Standards)

- Health Terminologies and Vocabularies (Standards)

- Health Information Privacy and Security Beyond HIPAA (Privacy, Confidentiality, Security)

- Next Generation Vital Statistics (Population Health)

- Small Area Population Health Data (Population Health)

- 21st Century Cures Collaboration with ONC and HITAC

The NCVHS Predictability Roadmap

- Standards development, adoption and implementation are not predictable and are not keeping pace with business and technology innovations.

- The Predictability Roadmap is an initiative to evaluate barriers to the update, adoption and implementation of standards and operating rules under the authorities of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act of 2010 (ACA).

- For the past 18 months, NCVHS has been collaborating with industry stakeholders to understand the challenges and develop actionable recommendations for the Secretary of HHS, covered entities, standards development organizations and operating rule authoring entities.

Development

Throughout 2017 – Information gathering efforts with:

Standards Development Organizations (or SDOs):

- ASC X12 (X12)
- CAQH's Committee on Operating Rules (CORE)
- Health Level Seven (HL7)
- National Council for Prescription Drug Programs (NCPDP)
- NACHA – The Electronic Payments Association (NACHA)

Regulators and governance entities:

- Designated Standards Maintenance Organization (DSMO)
- HHS/CMS/Division of National Standards (DNS)

August 2017 – An initial Visioning Workshop identified five core themes:

1. Governance,
2. Updates to standards,
3. Regulatory processes,
4. Data harmonization*, and
5. Third parties as covered entities.

* The theme of data harmonization will be addressed in the Subcommittee's Terminology & Vocabulary (T&V) project.

Development, continued

May 2018 – CIO Forum held with industry experts and end users from a variety of health care organizations yielded cross cutting themes of transparency, measurement and collaboration.

July 2018 – The Subcommittee compiled their findings into three (3) outcome goals with a set of draft recommendations, calls to action and measurement.

Recognizing the effort to make proposed changes, the outcome goals are broken into two year sprints.

Next steps – Outreach to stakeholders throughout the fall (Oct/Nov) leading to a hearing in December to obtain feedback on draft recommendations.

Emphasis of the Draft Recommendations

- **Improvements for the federal processes**
  - More visible enforcement of existing regulations
  - More frequent guidance and outreach to industry
  - Improve responsiveness to NCVHS recommendations and timeliness of regulatory activities

- **Improvements for SDO processes**
  - Increase diversity of industry participation in standards and operating rule workgroups
  - Improve timeliness of standards development to support innovation and evolving business and technology changes
  - Improve workgroup processes for productivity

- **Governance and Oversight (Stewardship)**
  - Transparency of processes (Federal and SDO)
  - Advancing industry needs and garnering value from standards

Roadmap Outcome Goals

1. Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.
    This goal supports the themes of Regulatory Processes and Third Parties as Covered Entities.

2. Policy levers will successfully support industry process improvement changes.
    This goal supports the themes of Governance and Updates to Standards.

3. Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules.
    This goal supports Updates to Standards and Regulatory processes.

    *Enforcement includes complaints and compliance reviews/audits

Input on Roadmap Recommendations

Submit Public Comment to the Committee to NCVHSmail@cdc.gov

In general,

1. Would these recommendations as a whole improve the predictability of the adoption of administrative standards and operating rules?

2. What additional recommendations are critical to achieve predictability?

And specifically,

3. What is the value proposition of each recommendation and what improvements to the current state do you believe will arise from each recommendation or group of similar recommendations.

4. Are there potential unintended consequences from any of the recommendations? What are those and how can they be mitigated with modifications to the recommendations?

Health Terminologies and Vocabulary Project Goals

A contemporary look at the health terminology and vocabulary landscape in order to advise the Secretary regarding:

1. The changing environment and implications for timing and approach to health terminology and vocabulary standards adoption,

2. Needs, opportunities, and problems with development, dissemination, maintenance, and adoption of health terminology and vocabulary standards,

3. Actions that HHS might take to improve development, dissemination, maintenance, and adoption of standards.

Areas of Opportunity

Near Term

Principles, policies and practices under control of Secretary

(to be addressed in Letter(s) to Secretary in 2019/20)

Mid Term

Deliberate and explicit pathway to convergence of clinical and administrative standards requiring public-private cooperation.
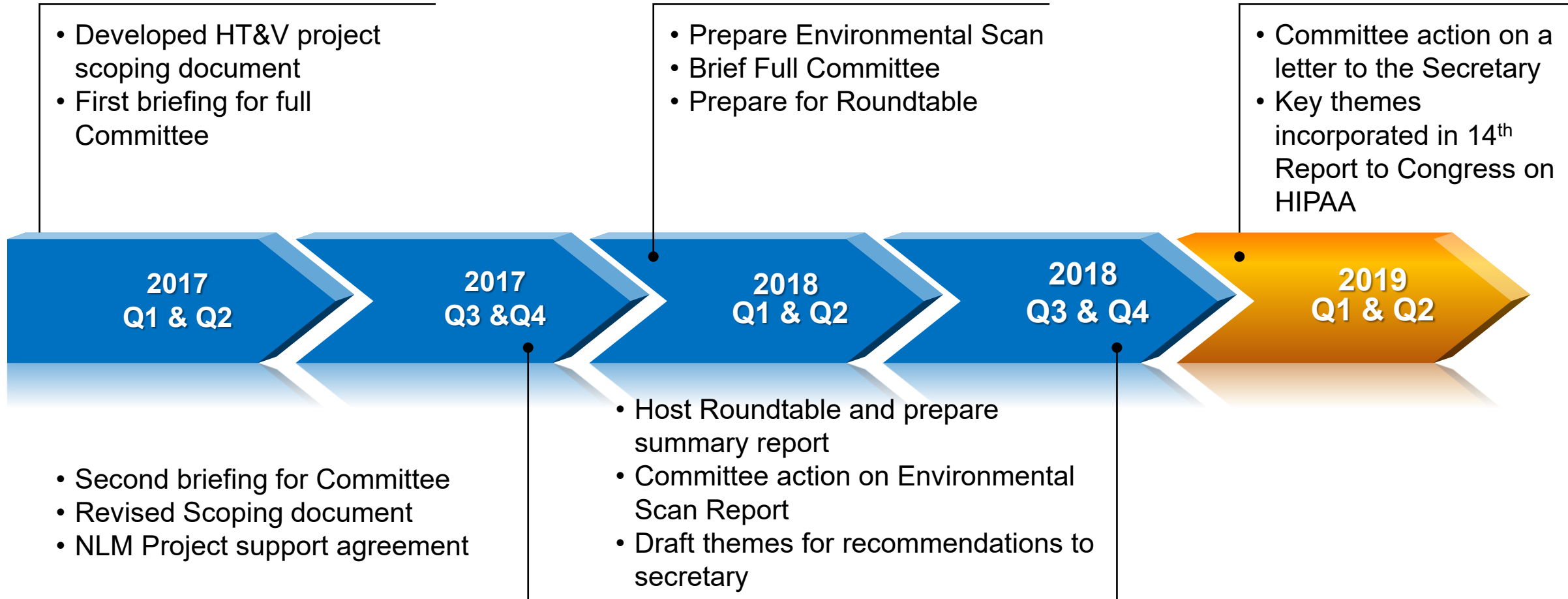
Long Term

Technology and research to realize terminology and vocabulary-based health data ecosystem

Near-Term Opportunities

1. Update principles to guide adoption of health terminologies and vocabularies

2. Develop principles for updates to health terminologies and vocabularies

3. Scope a project to evaluate ICD-11

Project Timeline

2017 Q1 & Q2
- Developed HT&V project scoping document
- First briefing for full Committee

2017 Q3 &Q4
- Second briefing for Committee
- Revised Scoping document
- NLM Project support agreement

2018 Q1 & Q2
- Prepare Environmental Scan
- Brief Full Committee
- Prepare for Roundtable

2018 Q3 & Q4
- Host Roundtable and prepare summary report
- Committee action on Environmental Scan Report
- Draft themes for recommendations to secretary

2019 Q1 & Q2
- Committee action on a letter to the Secretary
- Key themes incorporated in 14th Report to Congress on HIPAA

NCVHS

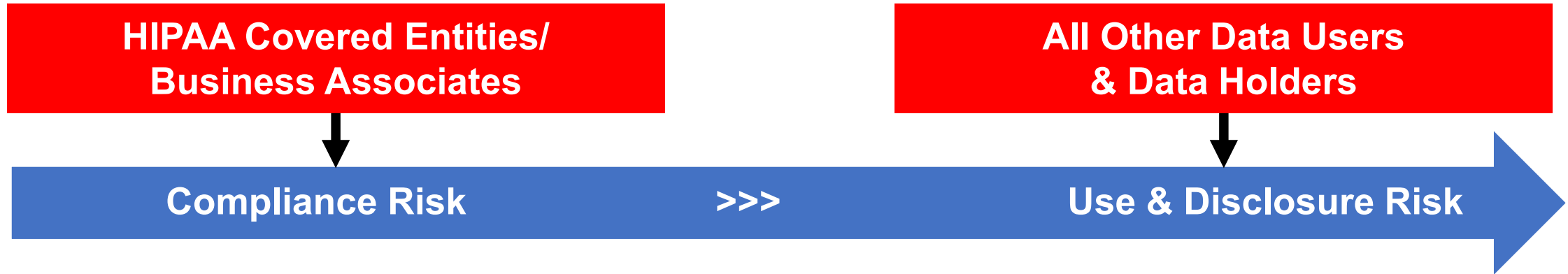# Health Information Privacy & Security "Beyond HIPAA"

A more comprehensive look at challenges beyond HIPAA and the range of policy options that may be available to the Department, to data stewards, and to the subjects of the information.
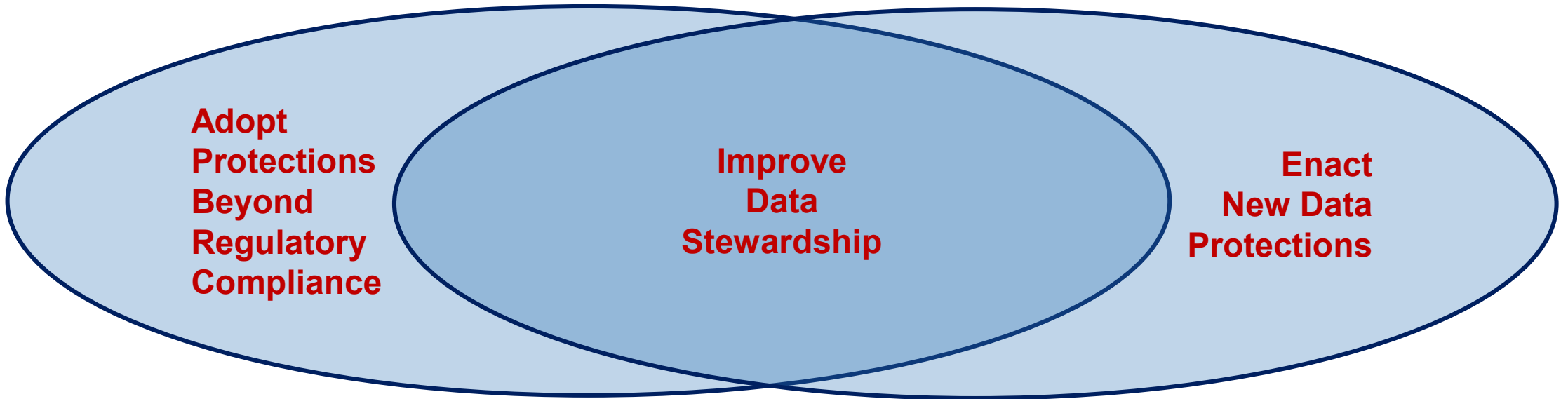
Goals

- 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

- Develop report for health data stewards

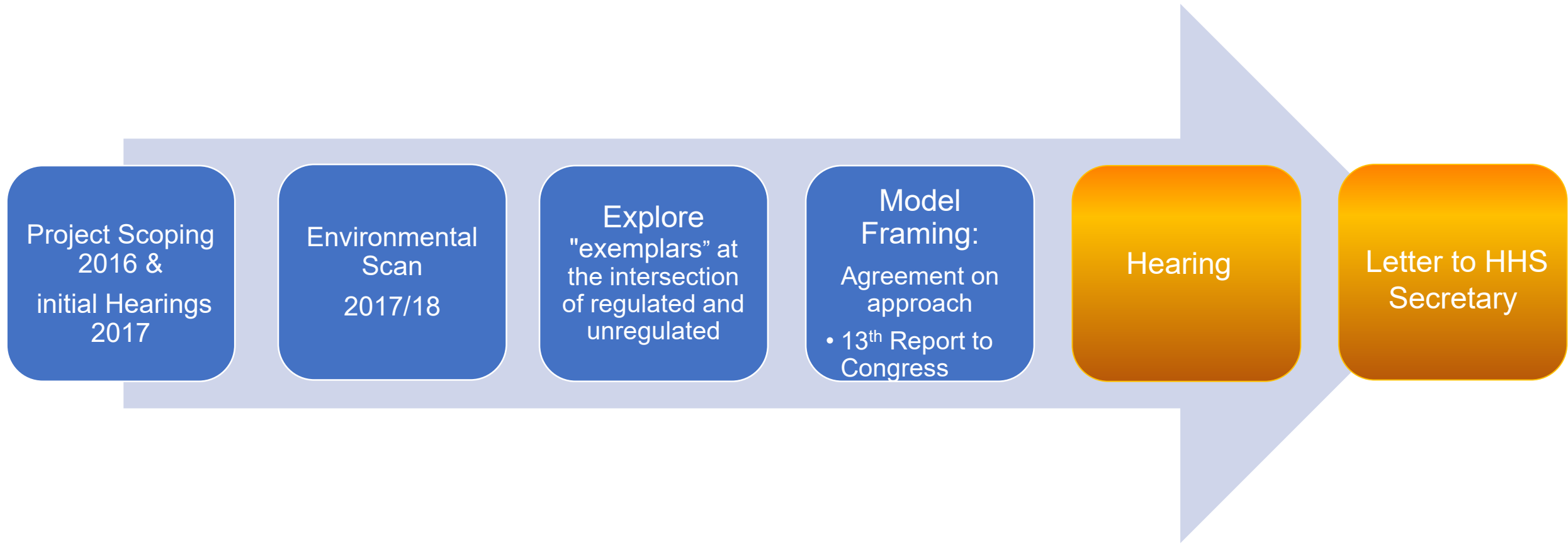# Beyond HIPAA: Health Information Stewardship Continuum

Use Case: Health Data Registries

NCVHS

	Leverage current mechanisms	Improve data stewardship	Enact new protections
Private	• Covered entities require data use agreements which include prohibitions against reidentification and redisclosure. • Covered entities offer patients opportunity to opt out of registries. • CEs strengthen management of de-identified data sets	Voluntary certification of registry sponsors	
Public	Office of Civil Rights issues guidance for registering Business Associates and Data Use Agreements	Mechanism for accreditation of registries for funding streams	Registries become covered entities

Beyond HIPAA Progress

NCVHS

| Project Scoping 2016 & initial Hearings 2017 | Environmental Scan 2017/18 | Explore "exemplars" at the intersection of regulated and unregulated | Model Framing: Agreement on approach • 13th Report to Congress | Hearing | Letter to HHS Secretary |

FY2018 NCVHS Reports and Recommendations

6 Reports – 3 Letters

- September 14, 2018 – Report: Health Terminologies and Vocabularies Environmental Scan

- September 14, 2018 – Report: Health Terminologies and Vocabularies Expert Roundtable Report

- July 23, 2018 – Report: CIO Forum Summary Report

- May 21, 2018 - Letter to the Secretary: US Vital Registration and Vital Statistics System Recommendations– Critical Challenges and Opportunities

- May 21, 2018 – Summary Report: Next Generation Vital Statistics—A Hearing on Current Status, Issues, and Future Possibilities

- May 17, 2018 - Letter to the Secretary: NCVHS Recommendations on National Council for Prescription Drugs Programs (NCPDP) Pharmacy Standards Updates

- March 15, 2018 - Letter to ONC: Proposed U.S. Core Data for Interoperability (USCDI) expansion process and emerging data classes

- January 10, 2018 – Report: Vital Records and Vital Statistics in the United States: Uses, Users, Systems, and Sources of Revenue

- December 13, 2017 – Report: Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges

Question for Consideration:
What is the Pathway to Harmonization?

An essential question on the road to harmonization is whether it is in the best interests of patients, the U.S. health care business community and health statistics and research to maintain an HL7 CDA/FHIR/XML system for clinical and an X12/NCPDP EDI system for administration and payment.

Questions & Discussion