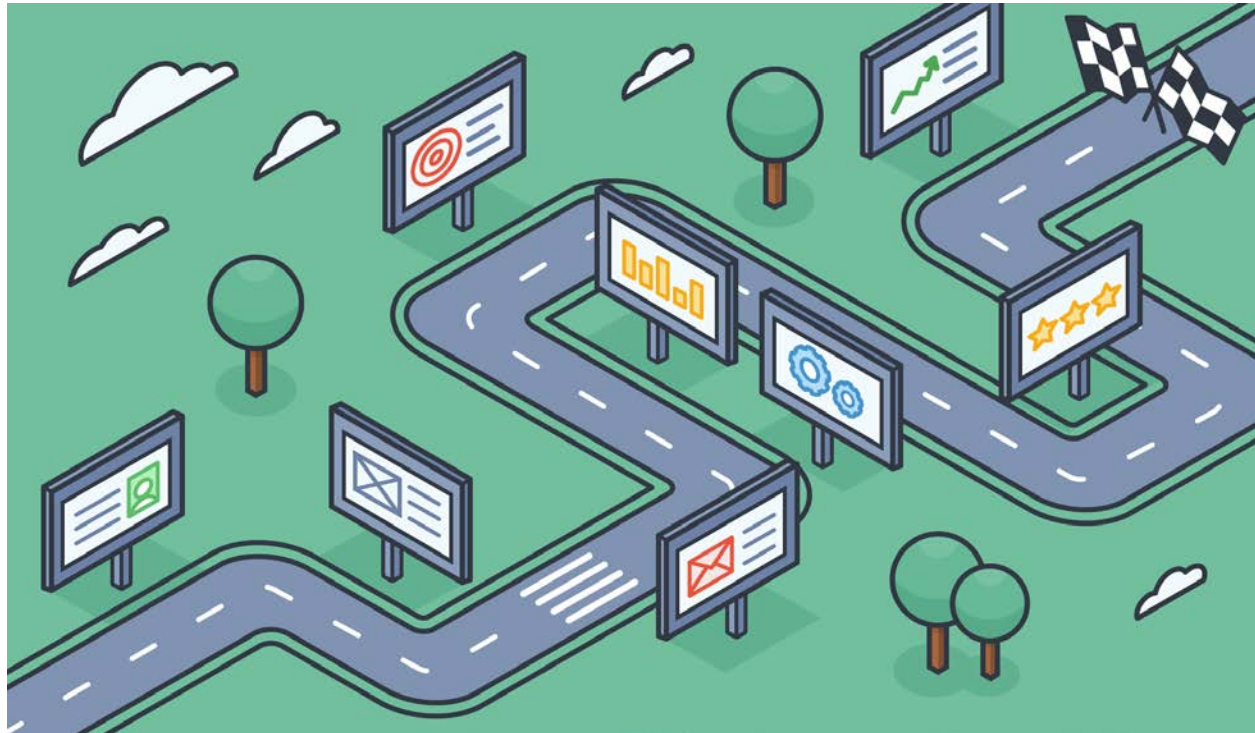




National Committee on Vital and Health Statistics  
Advising the HHS Secretary on National Health Information Policy



# Draft Recommendations for the Predictability Roadmap

October 2018

# Agenda



- Historical Review – how we got here?
- Draft recommendations
- Next steps and plan for fall hearing
- How you can provide feedback

# 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.

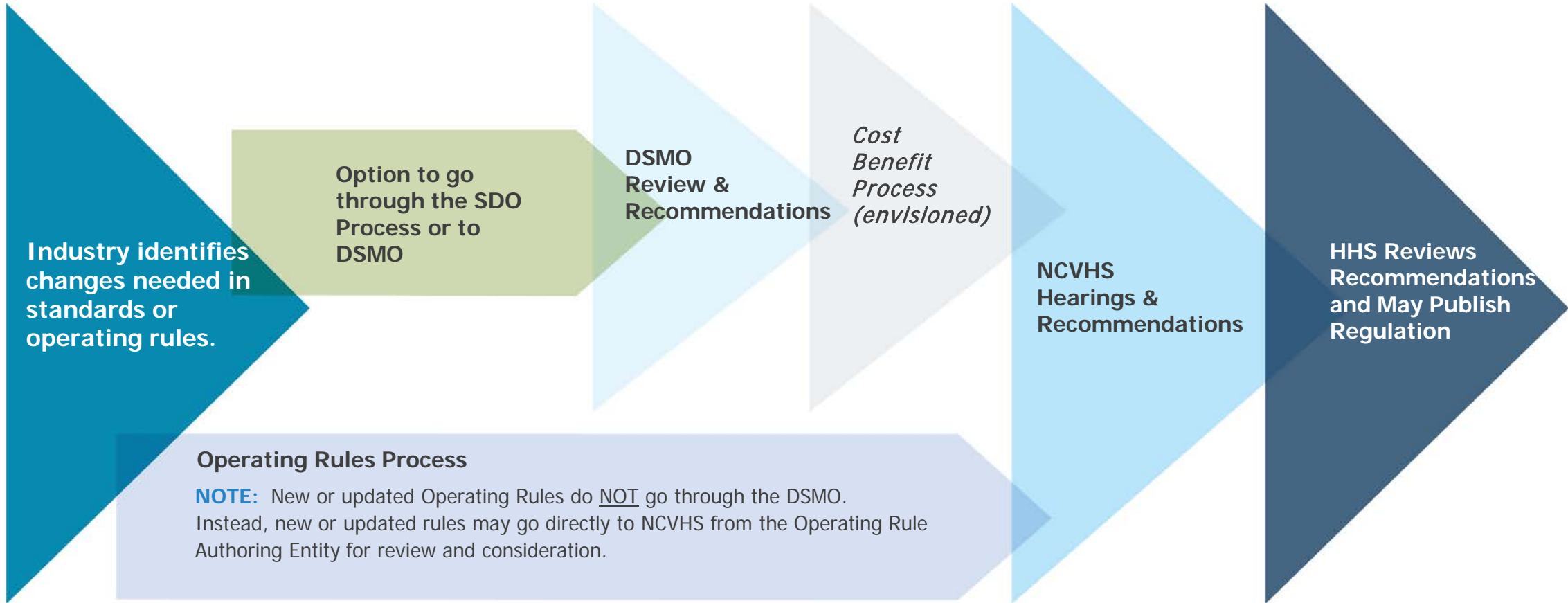
# Vision



For covered entities and business associates to be able to use up-to-date HIPAA standards consistently, garnering increased value from the standards by avoiding “one-off” work-arounds, and to reliably know when updated versions will be available and adopted in time to prepare systems, resources and business processes.

# Standards Update Process - Overview

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



# 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 time blocks.

**October 2018** – 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

# Draft Recommendations (1)



	<b>2019 – 2020</b> <b>Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.</b>	<b>2020 – 2021</b> <b>Policy levers will successfully support industry process improvement changes.</b>	<b>2021 – 2024</b> <b>Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules.</b>
<b>R e c o m m e n d a t i o n s</b>	<p><b>1.</b> HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry.</p> <p><b>2.</b> HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.</p> <p>*enforcement includes complaints, audits and compliance reviews as defined in statutory language.</p>	<p><b>3.</b> HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.</p> <p><b>4.</b> HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities.</p> <p><b>5.</b> HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.</p>	<p><b>6.</b> SDOs and ORAE should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years. Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCVHS.</p> <p>NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months.</p> <p>HHS should adopt the NCVHS recommendations on a regular schedule.</p>

# Draft Recommendations (2)



	<b>2019 - 2020</b> <b>Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.</b>	<b>2020 - 2021</b> <b>Policy levers will successfully support industry process improvement changes.</b>	<b>2021 - 2024</b> <b>Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules.</b>
<b>R e c o m m e n d a t i o n s</b>	<p><b>7.</b> HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.</p>	<p><b>8.</b> HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with what is permitted in §1174 of the Act).</p> <p><b>9.</b> HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.</p>	<p><b>10.</b> HHS should adopt incremental updates to standards and operating rules. In accordance with Sec 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCHVS, and if updates are available.</p> <p><b>11.</b> HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation.</p> <p><b>12.</b> HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.</p>

# Draft Calls to Action (1)



	<b>2019 - 2020</b> <b>Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.</b>	<b>2020 - 2021</b> <b>Policy levers will successfully support industry process improvement changes.</b>	<b>2021 - 2024</b> <b>Regulatory levers will enable timely testing, adoption and implementation of updated or new standards and operating rules</b>
<b>C a l l s  t o A c t i o n</b>	<p><b>A.</b> Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases.</p> <p><b>B.</b> The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.</p>	<p><b>C.</b> HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3<sup>rd</sup> parties to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.</p>	<p><b>D.</b> HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.</p>

# Draft Calls to Action (2)



	<b>2019 - 2020</b> <b>Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.</b>	<b>2020 - 2021</b> <b>Policy levers will successfully support industry process improvement changes.</b>	<b>2021 - 2024</b> <b>Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules.</b>
<b>C a l l s  t o  A c t i o n</b>	<p><b>E.</b> SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.</p> <p><b>F.</b> Leadership from the public and private sector should commit to membership in Standards Development Organizations, assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs.</p>	<p><b>G.</b> Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable policies regarding business practices, including policies for identifying and implementing best practices in such an organization.</p>	<p><b>H.</b> HHS should continue to publish a universal dictionary of clinical, administrative and financial standards that are or will be available for use, e.g. the ONC Interoperability Standards Advisory (ISA).</p>

# Recommendations for Measurement



	<p>2019 – 2020 Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.</p>	<p>2020 – 2021 Policy levers will successfully support industry process improvement changes</p>	<p>2021 – 2024 Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules</p>
<p>M e a s u r e m e n t</p>	<p><b>M1.</b> HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.</p>	<p><b>M2.</b> HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance.</p> <p><b>M3.</b> NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.</p>	

# Anticipated Timeline/Next steps



**September 14<sup>th</sup>:** NCVHS discusses draft recommendations with Full Committee

**Oct 1:** NCVHS finalizes and distributes slide deck, narrative document, and hearing questions

**Oct and Nov:** Stakeholders vet draft proposal and gather input

**Dec 12-13:** NCVHS Subcommittee on Standards holds hearing to gather industry input on draft recommendations

**Dec-Jan:** NCVHS incorporates feedback from stakeholders

**Feb 6 & 7:** NCVHS conducts Full Committee Meeting

**1<sup>st</sup> Quarter 2019:** NCVHS releases letter to HHS based on review and vote on final recommendations



# Where to send comments



- **Where to send comments:** [NCVHSmial@cdc.gov](mailto:NCVHSmial@cdc.gov) with the subject line: Predictability Roadmap.
  - Include your name, email and organization.
- Consider these questions when reviewing the recommendations:
  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?
  3. What is the value proposition of each recommendation and what improvements to the current state do you believe will arise from each recommendation/group of similar recommendations?
  4. Are there potential unintended consequences? What are those and how can they be mitigated with modifications to the recommendations?