# Hearing on the Predictability Roadmap

# Meeting Summary

## Held December 12-13, 2018

**Subcommittee on Standards**

**National Committee on Vital and Health Statistics**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This report was written by NCVHS consultant writer Lucas Smalldon and colleagues at Rose Li and Associates, Inc., in collaboration with NCVHS members and staff.

## NCVHS Members and Staff in Attendance

William W. Stead, MD, **NCVHS Chair**
Alexandra Goss,* Subcommittee Co-chair
Nicholas L. Coussoule,* Subcommittee Co-chair
Debra Strickland, MS*
Denise Love, BSN, MBA*
Jacki Monson, JD
Llewellyn J. Cornelius, PhD, LCSW
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Richard W. Landen, MPH, MBA*
Vickie M. Mays, PhD, MSPH

  *Member of the Subcommittee on Standards

Lorraine Doo, MSW, MPH, CMS, **Lead Staff to the Subcommittee**
Rebecca Hines, MHS, **NCVHS Executive Secretary/DFO**
Geanelle Herring, MSW, CMS, **Alternate Lead Staff to the Subcommittee**
Marietta Squire, NCHS
Geneva Cashaw, NCHS
Debbie Jackson, MA, NCHS
Michael Lincoln, MD, FACMI, VA

**Please refer to Appendixes, A, B, and C respectively for the agenda, complete list of invited participants, and text of all draft recommendations, calls to action, and measurement items discussed.**

The NCVHS website provides a complete membership roster:  **ncvhs.hhs.gov.**


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**The National Committee on Vital and Health Statistics**

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C. 242(k)] public advisory body to the Secretary of the Department of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C.242k[k]).  In this capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues. The Committee is composed of eighteen individuals from the private sector who are distinguished in the fields of health statistics, electronic interchange of health care information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing of health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the members are appointed by the Secretary of HHS for terms of four years each, with about four new members being appointed each year. Two additional members are selected by Congress.  **ncvhs.hhs.gov**

## Purpose of the Hearing

The National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards convened a hearing on December 12-13, 2018, to obtain stakeholder feedback on its draft recommendations to the Health and Human Services (HHS) Secretary as part of its goal of creating a Predictability Roadmap.  The purpose of the Predictability Roadmap is to outline a process of updating and adopting standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that would be more predictable and transparent. Feedback obtained from stakeholders during this hearing will help to inform the Subcommittee as it finalizes its recommendations for submission to the HHS Secretary in early 2019.

For further details on the proceedings, an audio recording and transcript of the hearing are available on the NCVHS website: https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting/

## Background of the Predictability Roadmap

*Alix Goss and Nick Coussoule, Co-Chairs*

For actors in the health care industry, standards development, adoption, and implementation have been unpredictable and have not kept pace with either business needs or technological innovation. The development of the Predictability Roadmap includes evaluation of the barriers to the update, adoption, and implementation of certain standards and operating rules, specifically those adopted under the authorities of HIPAA and the Patient Protection and Affordable Care Act of 2010. NCVHS has been collaborating with industry stakeholders to understand the challenges and to develop *actionable* recommendations. The recommendations emphasize the need to improve federal and Standards Development Organization (SDO) processes, as well as governance and oversight (stewardship) at both the federal and the SDO levels. The vision is for the recommendations to enable covered entities and business associates to: (1) use up-to-date HIPAA standards consistently, thereby garnering increased value from the standards by avoiding ad hoc workarounds, and (2) know when updated versions will be adopted—in time to prepare systems, resources, and business processes. The recommendations and expectations for next steps will be shared with the HHS Secretary, covered entities, SDOs, and operating rule authoring entities (ORAEs).

The Predictability Roadmap puts forth **three Outcome Goals**:

1. Increase compliance and use of the adopted standards and operating rules through greater education/outreach and enforcement. Greater visibility of enforcement and increased education will promote more appropriate use of the standards and operating rules.
2. Encourage process improvements to relevant industry activities through policy and operational changes.
3. Improve the regulatory process and timelines at HHS to enable timely adoption, testing, and implementation of updated or new standards and operating rules.

NCVHS's draft recommendations, calls to action, and measurement items were clustered thematically under the three Outcome Goals for hearing participants to discuss and provide feedback.

Over the course of the day and a half hearing, the Subcommittee co-chairs followed a structured agenda that enabled hearing participants to provide input into each of the 23 recommendations.  The hearing agenda was systematically structured – thus the order in which recommendations were put forth for input by participants was substantively thematic rather than by numeric order.

## Outcome Goal 1: Outreach, Education and Enforcement
*Panel Discussion*

### Outcome Goal 1
*Increase compliance and use of the adopted standards and operating rules through greater education/outreach and enforcement. Greater visibility of enforcement, and increased education will promote more appropriate use of standards and operating rules.*

**Recommendation 1**: *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.*

Several hearing participants agreed with this recommendation. Actors in the health care industry who receive complaints for not complying with standards should be publicly identified. This includes payers, because providers currently face greater harm for noncompliance (e.g., they risk having transactions rejected by payers). Providers must have confidence that noncompliant payers will be penalized, otherwise some providers will fear that their transactions will be rejected in retaliation and will be reluctant to register an official complaint. Enforcing the consistent use of standards and penalizing noncompliance will also improve predictability because providers will rightly *expect* payers to be compliant. However, some participants emphasized that the goal is compliance, not punishment, and that any penalties levied on noncompliant entities should have demonstrated effectiveness to improve compliance.

Indeed, the goal of making the adoption of new standards predictable is undermined without consistent compliance to existing standards across the whole health care industry. However, participants stressed that a slew of rejected payments is not necessarily evidence that payers are disproportionately noncompliant. Rejected payments must be investigated in detail to verify that the root cause is, in fact, some form of noncompliance. In order to uncover root causes, it may be fruitful to conduct detailed analyses of the *content* of complaints. Once the underlying causes of rejected claims are better understood, corrective measures can be developed and adopted. Claims are only one of the adopted transaction standards, but an important one as a point of reference for the rationale of this recommendation and the need for enforcement.

**Recommendation 2**: *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.*

Participants discussed the possibility of distinguishing tiers of noncompliance, such that actors in the health care industry that are found to be noncompliant beyond a certain well-defined threshold would be subject to public identification. Within the industry, there exist some bad actors who have voluntarily created barriers (e.g., charging transaction fees) that discourage the use of standard transactions. Such barriers do not fall strictly under the umbrella of "compliance to standards," yet they actively interfere with universal compliance, and therefore need to be addressed. It is critical that government agencies analyze these cases, understand the underlying motivations, and develop documentation to guide industry toward embracing "the spirit of the law."

**Recommendation 7:** *HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.*

Many participants agreed with this recommendation, with the proviso that the language should be modified to specify that SDOs should be involved in creating guidelines that have technical content because of their technical expertise. A prime example of how guideline development can be well executed with involvement of many stakeholders occurred when the Workgroup for Electronic Data Interchange (WEDI) established a workgroup, co-chaired by a provider and a health plan representative, to publish guidance for electronic payments policies. They developed a consensus set of principles and translated them into a guidance document that was posted to the Centers for Medicare and Medicaid Services (CMS) website (Note: this guidance document was removed from the website without explanation, and participants suggested that it be reposted). There is a broader need for similar guidance documents. Technical assistance could also be provided in the form of technical certifications.

Conversely, several participants expressed a preference for guidance documents that do not specify any technical pathway toward achieving a desired policy objective (thereby eliminating the need for SDO involvement), but instead specify only the policy outcomes themselves, and leave actors in the health care industry to implement those outcomes however they choose. This approach could help to promote innovation by allowing different organizations to develop unique approaches to implementing any given policy. Some participants suggested that HHS publish high-level reference materials to help organizations with implementation, along with a free validation system. Standards themselves must be affordable to implement, or enforcement will become much costlier and more difficult for regulators. In addition, regulations must strike a balance between being too restrictive (which can hinder innovation) and too general (which can undermine enforcement).

**Call to Action A**: *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.*

Several participants supported this call to action and recommended that WEDI be charged with convening the relevant stakeholders. Others noted that it will be important to involve providers in this call to action along with health plans and vendors because providers experience the barriers most directly and may be able to provide useful suggestions to reduce administrative burdens when processing transactions. In addition, including some providers that process transactions manually could reveal unknown yet significant barriers. In the past, NCVHS has found it difficult to involve providers because of the competing demands on their time. One approach to making it easier for providers to get involved might be to hold teleconferences, or focus groups at professional conferences, that are intended to cover specific topics that can be announced in advance, so that those providers who have something to contribute to those topics have a readymade and easily accessible forum to efficiently provide their input. The open-door forums held by the HL7 Da Vinci Project could be a model.

In addition, it was noted that NCVHS and SDOs must recognize that, for private actors within the health care industry, participating in standards development must be practically justified in terms of business incentives. Thus, some hearing participants favored carefully selecting organizations and individuals who should be involved in a given stage of standards and rules development, while others on the panel disagreed out of concern that this would vest disproportionate power in those making such selections. An alternative approach would be to promote community involvement as widely as possible and solicit input from any stakeholders who voluntarily participate. Either approach would be compatible with this call to action.

To supplement this call to action, one participant suggested adding another recommendation that would aim to align standards adoption with providers' business incentives.

**Call to Action 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.*

WEDI members are generally supportive of this call to action. One participant recommended that WEDI focus more on pharmaceutical transactions than it has in the past. Much of the discussion focused on the need to offer incentives for people to become involved in the standards development process. Volunteers need to be trained and educated as leaders in this field. However, adopting such leadership responsibilities often demands time and energy that is incommensurate with the incentives. Similarly, federal funding is needed for SDOs to perform all of their expected functions, (e.g., producing white papers). One participant noted that CMS supports SDO partnership initiatives, such as HL7's Da Vinci Project, that have *specific use cases* that are focused on interoperability. One participant suggested there is a general need for CMS to have a closer relationship with WEDI and the National Council for Prescription Drug Programs (NCPDP).

**Call to Action E:** *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.*

A potential model for promoting active collaboration are NCPDP's task groups, which meet via teleconference. Participants must register, but anyone is free to join. NCPDP actively recruits stakeholders whose input is especially sought. Another way to expand the reach of this call to action would be to encourage collaboration through professional associations such as the Healthcare Information and Management Systems Society (HIMSS). Collaborations among SDOs and providers may enable new operating rules and standards to better reflect the heterogeneity of different provider operating environments by helping SDOs better understand how transactions and other processes occur at the ground level. Vendors would also benefit from having a variety of stakeholders interacting directly with their products to become familiar with the available tools and to provide feedback. Additional important benefits of wider cross-sector collaboration would be (1) to establish test beds to help validate new standards and generate feedback before widespread adoption, and (2) to enable iterative analytical reviews of existing standards so that unforeseen problems can be regularly addressed. For organizations that are unable to make financial contributions to such collaborative efforts, in-kind contributions should be allowed.

**Call to Action F**: *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.*

Many participants agreed that support is needed from HHS to encourage leaders from various public and private stakeholder organizations to participate in standards development. One aim of the Predictability Roadmap is to "meet industry needs" which cannot be done if industry needs are not *known* by those developing new operating rules and standards. In addition, incorporating leaders from the health care industry into the standards development process could encourage industry needs to drive standards development, rather than vice versa. One participant stressed that industry leaders cannot be forced to participate productively, but that they will *choose* to if they see a business reason to do so. Moreover, establishing a predictable (perhaps annual) cycle of new standards rollouts could provide them with such a reason, because they will anticipate imminent changes and will want to keep up-to-date and influence the process. However, in order for participation in standards development to act as a business incentive, the resulting return on investment (ROI) must manifest relatively quickly.

**Measurement M1**: *HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.*

Participants questioned whether this is truly a measurement item, though some noted that it could help to establish baseline information on complaints that would enable monitoring of trends in complaints over time. In addition, complaints could be analyzed so that common problems are addressed sooner and more effectively. Another benefit of this effort would be that requests to clarify various HHS recommendations could be tracked, enabling HHS to identify particularly common issues and promptly publish the relevant clarifications.

Apart from the proposed measurement item, some participants advocated that HHS expand its enforcement program by conducting broader auditing. Currently, only certain covered entities, (clearinghouses and health plans only) that volunteer to receive an audit do so and such organizations tend to be compliant. Expanded auditing would also improve benchmarking, increasing awareness of what is happening across the health care industry. Noncompliant actors in the health care industry are unlikely to respond voluntarily to more passive alternatives to audits, such as questionnaires. Information gleaned from audits would also help HHS to determine whether costs are truly being lowered by the adoption of new standards, or whether they are merely being shifted among the various industry actors.

Several participants stressed that the goal of all the proposed measurement items is to increase transparency, educate actors across the industry, improve standards adoption, and promote administrative simplicity. (That is, punishing or shaming noncompliant entities is not in itself a valid goal.) Another benefit of increased transparency is that solutions to common problems can be more widely shared and applied, as organizations across the health care industry are able to share the benefits of each other's creativity.

## Outcome Goal 2: Process Improvements
*Panel Discussion*

### Outcome Goal 2
*Encourage process improvements to relevant industry activities through policy and operational changes. The recommendations and calls to action in this outcome goal focus largely on stewardship. The goal is to ensure that the process of standards updates is reliable, and that communication is transparent.*

**Recommendation 3**: *HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.*

Many participants agreed that the DSMO has outlived its original purpose—which it fulfilled very well—and that it is no longer needed in its current form. When the DSMO was formed, change requests were so varied and numerous that a single process was needed to manage them all. Now, however, SDOs have updated processes for accomplishing the same task, and industry actors are far more effective than they once were in handling change requests and suggesting new standards. There is also concern that the DSMO, or any analogous entity, would merely create an additional, unnecessary layer of bureaucracy that will stall efforts to develop and adopt any new rules or standards. Some participants pointed to the adoption of electronic health records (EHRs) as an example of successful standards adoption without the oversight of an entity such as the DSMO.

However, many participants advocated establishing a new, federally funded entity—perhaps under WEDI's oversight—to serve as an updated analogue to the DSMO. It would be preferable that this new entity exist outside of the regulatory process so that it can be empowered to: (1) review existing standards, (2) assess the constraints imposed by business needs, (3) perform cost estimates for new standards adoption, (4) conduct new standards reviews on a cycle of no more

than 2 years, and (5) review and approve or reject expiring standards, without being delayed by cumbersome regulatory structures.

Another possible course of action would be not to disband the DSMO, but merely to modify it to better suit current needs. That is, HHS could terminate some of the DSMO's current functions and add others that could help to resolve issues or optimize existing processes. Several participants emphasized that *some* entity is needed to perform various functions in standards development, such as benchmarking and piloting of new standards, as well as estimating ROI. These same participants cast doubt on the argument that the DSMO creates significant delays in the standards development process. Those participants who argued that the DSMO *does* create significant delays advocated that NCVHS adopt a more prominent role for itself in coordinating standards development and in acting as a review body.

After much discussion, hearing participants generally agreed that no decision can be made on whether to establish a new entity to replace the DSMO until a specific proposal is drafted that explains exactly what the purpose and responsibilities of such a body would be, and why its existence would be justified. Some recommended that this DSMO-replacement entity be charged with coordinating work across SDOs. This and other such proposals, which all dovetail with Recommendation 4, will require further discussion.

**Recommendation 4:** *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.*

This recommendation expands on Recommendation 3. NCVHS representatives explained that the shift in terminology from "governance" to "stewardship" reflects the changing focus from *control* to *coordination* of the standards development process. Generally, although actors in the health care industry now possess far more knowledge of standards development than they did when the DSMO was first created, this has itself created a variety of *new* needs among those industry actors (e.g., more industry knowledge can facilitate faster innovation, which in turn multiplies needs for new standards), which could be served by a specially designed entity to replace the DSMO. Echoing discussions of Recommendation 3, there was disagreement over whether establishing an entity to replace the DSMO is necessary or wise.

One widely acknowledged shortcoming of the DSMO's coordination efforts is that they occur too late in the standards and operating rules development process. Any new entity that is charged with multi-stakeholder coordination should begin active stewardship at the beginning of the process when new standards and operating rules are first being *considered* to avoid wasting resources on developing standards that will later be rejected because of a cost-benefit analysis that could have been conducted far earlier in the process. ROI analyses should also occur as early as possible.

One suggested function for a new entity would be to serve as a single shared hub through which the various SDOs could communicate, which could help to streamline coordination, improve efficiency, and reduce fragmentation. Such an entity could also serve as a hub through which industry could submit change requests or recommend new standards, rather than having to interact ad hoc with individual SDOs. Rather than adding a layer of bureaucracy, this could potentially *reduce* friction in the process if it were implemented effectively.

Should HHS ultimately decide to replace the DSMO with a new entity, it should establish, in advance, an agreed upon method of assessing whether this new entity is satisfactorily fulfilling its functions. This will help to (1) ensure that the entity is established for a specific and agreed upon purpose, and (2) provide a standard method of judging whether continued investment in such an entity is justified.

**Recommendation 5:** *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.*

This discussion was postponed, as any decision regarding Recommendation 5 depends on prior decisions regarding Recommendations 3 and 4, which remain unresolved (see above).

**Recommendation 8**: *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).*

The spirit of this recommendation received widespread agreement. However, because NCVHS can only make recommendations (i.e., NCVHS lacks authority to compel HHS), many participants were doubtful that a 1-year timeframe would be feasible. Yet several participants suggested changing "should" to "must" in order to make the recommendation stronger, and two participants suggested changing "and" to "if" because some of NCVHS's recommendations will be *rejected* by HHS. Despite the lack of confidence among participants regarding the feasibility of a 1-year timeframe, many strongly supported the idea of having HHS release new regulations on a regular (e.g., annual) schedule. This would significantly improve the predictability of standards adoption, because even in cases when a rule or standard is delayed across several release cycles, industry actors will be able to predict, each year, when new rules or standards will *in general* be released. HHS should also be required to respond to or provide an update on each recommendation within a designated timeframe; participants have sometimes felt that NCVHS's recommendations remain unaddressed indefinitely.

Participants discussed the idea of creating a "floor" or "baseline" standard that all actors in the health care industry would be required to implement. Organizations that wanted to innovate and layer additional standards onto that baseline standard could do so. In addition to standards development and adoption/maintenance, the third main component of standard-setting and enforcement is the regulatory process, and a baseline standard could help to (1) reduce the regulatory burden, (2) allow organizations more freedom to innovate, and (3) protect smaller organizations from being dominated by larger organizations that can afford to adopt more

sophisticated standards more quickly. In addition, allowing industry actors to innovate on top of the baseline standards could serve as an engine for producing and validating new standards.

These points received wide, though not universal, agreement. One issue is that establishing a baseline standard raises the question of how to construct a list of standards that are acceptable to build on. Another issue is how to distinguish whether an innovation built on top of the baseline standard is simply an add-on or if it could sometimes be regarded as noncompliance with the baseline standard itself. These and other complications—such as what is the appropriate timeline for enforcing regular baseline standards updates and how much variation should be allowed on top of the baseline standard—need to be discussed further before this possibility is pursued.

Another approach toward lessening the regulatory burden would be to delegate to SDOs the authority to self-approve, thereby bypassing cumbersome regulatory processes that can slow approval and adoption of new standards. Furthermore, different levels of change requests for existing standards should be distinguished so that, for example, simple language changes that are suggested only to clarify the intended meaning, but do not alter the intent or meaning of the standard, should not be required to go through the same unwieldy regulatory processes as changes to the standard itself. In addition, releases of new standards should be kept relatively lean to quicken the adoption process. However, although speed of release and adoption is a priority, it is critical that enough time and focus be spent on validating new standards before they are released, adopted, and enforced. All parties will be hurt if quality control procedures are unduly rushed just to streamline and expedite new standard rollout.

Some participants drew an analogy to the organic, market-driven development of Wi-Fi standards to stress that top-down regulations may be counterproductive in cases where market forces incentivize industry actors to be interoperable on their own. However, other participants demurred, noting that the analogy is flawed because Wi-Fi vendors have business incentives to adopt consistent standards, whereas the some health care industry actors have business incentives that *discourage* the use of such consistent standards, which implies the need for more active federal regulators in health care. Actors in the private sector may also be less incentivized to adopt new standards if doing so is not a predictable requirement that can be known in advance and built into their business planning.

**Recommendation 9:** *HHS should ensure that the operating division responsible for education, enforcement, and the regulatory process is appropriately resourced within the Department.*

Participants widely agreed with this recommendation, though some noted that the quality of education is not merely a matter of resources; specifically, it is critical that the educators themselves be experts in the field, which some currently seem not to be.

**Call to Action G:** *Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable polices regarding business practices, including policies for identifying and implementing best practices in such an organization.*

After NCVHS representatives explained that this call to action is intended to empower NCVHS to act as a steward and coordinate across the health care industry, several participants reported that they—and others at their organizations—had misinterpreted it, thinking that it suggested that public and private sector stakeholders should collaborate to develop policies to govern business practices. Because misinterpretation was widespread, the discussion was skipped.

**Call to Action C:** *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$^{rd}$ parties to qualify to conduct the validation testing by demonstrating their business value. HHS should look at successful precedents such as the ONC certification criteria developed for Promoting Interoperability, and the eRx requirements, a joint effort between HHS, NIST, and the SDO.*

Many participants agreed with this call to action. As a precedent, NCPDP has built a tool that is currently available for organizations to test new standards. Organizations submit transactions, and the NCPDP validation tool identifies syntax errors and other mistakes. The tool also offers interactive scenario-based testing so that organizations can validate their systems in realistic situations. However, the NCPDP tool does not certify organizations, and several participants recommended that a single tool should perform validation and certification—though they are distinct concepts and must not be confused—to streamline the overall process.

Organizations such as Optum 360 Group have invested heavily in such tools, and HHS should leverage those existing efforts where possible to avoid duplicating efforts. Indeed, some participants argued that the private sector should be solely responsible for developing such validation and certification tools—though HHS should need to approve of their official use—because the diverse functionalities that such tools must have in order to accommodate the heterogeneity of provider workflows will be easier to accommodate if the tool is produced in the competitive, private market, especially if providers are directly involved. It is critically important, however, that the cost of developing such tools not be passed on to providers.

Although a validation and certification tool may effectively facilitate *syntactical* interoperability, it will not facilitate *semantic* interoperability (i.e., agreement on the meanings of terms used in a transaction). Thus, these investments should be judged based on their ability to improving syntactical, but not semantic, interoperability.

**Measurement M2:** *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.*

Discussion of proposed Measurement M2 was delayed until a decision is reached on whether to establish a new entity to replace the DSMO.

**Measurement M3:** *NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.*

Proposed measurement M3 received widespread agreement.

## Outcome Goal 3: Regulatory Levers and Timelines
*Panel Discussion*

***Outcome Goal 3***
*Improve the regulatory process and timelines at HHS to enable timely adoption, testing and implementation of updated or new standards and operating rules.*

Before discussing the proposed Recommendations, Calls to Action, and Measurements under Outcome Goal 3, participants discussed the outcome goal itself in the context of the earlier discussion of Outcome Goal 2 Recommendation 8, which called upon HHS to publish new regulations within 1 year of receiving and approving NCVHS recommendations for updates to standards or operating rules. During that discussion, some participants had suggested separating the rollout of new standards and operating rules from the regulatory process. If that approach were pursued, it would contravene the purpose of Outcome Goal 3, and so required further discussion.

Participants highlighted several existing models for enforcing organizations' compliance with new standards. For example, NCPDP's current e-prescribing standard is not HIPAA-mandated, though it *is* mandated through Medicare Part D. However, once this standard was implemented in accordance with the Medicare Part D mandate, it naturally evolved into an industry-wide e-prescribing standard that is used even for prescriptions not covered by Medicare Part D. One drawback of this model is that, although it works well if industry has reached a broad consensus on a given standard, it cannot resolve difficult cases in which industry actors widely disagree. Meaningful Use presents an alternative model in the context of EHR interoperability, wherein providers are incentivized to use an EHR platform that is officially certified and to comply with other criteria concomitant with those incentives (reporting requirements, etc.).

It could become difficult for organizations—within both industry and government—to justify the resource investments necessary to adopt new standards early if such investments are not mandated by regulation. However, several participants repeatedly expressed concern that the regulatory process causes major delays in standards adoption. Thus, some participants suggested that statutes be used to specify a *process* for establishing new standards, rather than including specific standards in statutory language. This approach could help to shorten the time lag that separates ROI analyses for a new standard and implementation of that standard, which can sometimes be so delayed that the ROI analyses become obsolete because of intervening changes to the health care industry.

Should NCVHS attempt to improve the standards adoption process by influencing development of new legislation, there are four committees in the U.S. Congress (the Senate Finance and Senate Health, Education, Labor and Pensions Committees, and the House Energy and

Commerce and House Ways and Means Committees) that should be targeted for these efforts. These committees tend to be relatively bipartisan and, judging by the number of hearings they have held on the subject, have a marked interest in health information technology.

**Recommendation 6:** *SDOs and ORAEs 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. NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months. HHS should adopt the NCVHS recommendations on a regular schedule.*

Participants generally supported this recommendation, with members of some organizations, such as NCPDP and HL7, noting that they already conduct pilot testing on a regular schedule shorter than every 2 years. However, regarding the proposed 2-year update schedule, one crucial question is how to conduct end-to-end pilot testing for each new standard and operating rule update (i.e., who should define the pilot criteria, who should conduct the pilots?) For businesses to conduct such pilots (e.g., for the new 70/30 standard) they must either establish and maintain new test beds for that specific purpose or else interrupt their normal development process to commit one of their existing environments to testing the new standard. These are burdensome investments for companies, and companies should receive external support if they are tasked with conducting end-to-end pilot tests for standards and operating rules updates. In addition, any financial burden placed on providers to test updates will inevitably detract resources from patient care delivery. Thus, all standards and operating rules updates must be carefully vetted before burdening providers with any testing.

**Recommendation 10:** *HHS should adopt incremental updates to standards and operating rules. In accordance with Section 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCVHS, and if updates are available.*

Hearing participants agreed with this recommendation.

**Recommendation 11:** *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.*

Several participants suggested that a separate two-day meeting would be needed to discuss (1) what the baseline standard should consist of (in terms of both data content and structure) and (2) how much flexibility should be allowed for organizations to develop on top of the baseline standard. Regarding configuring baseline standards for transactions and data transmission, participants discussed the tension between consistency and flexibility, with many agreeing that standards documentation and implementation guides should be combined into a single resource to improve consistency and ease of reference. In addition, participants generally agreed that the most important benefit of establishing a baseline standard is achieving stability across the health care industry over time. (i.e., backward compatibility, though important, is secondary). As new standards have been introduced, the variability across the industry has not decreased in proportion but has instead driven increased use of clearinghouses. Indeed, some

transactions move through multiple clearinghouses before the payer receives them. Adopting baseline standards could reduce provider variation, thus decreasing reliance on clearinghouses.

One participant suggested that a possible root cause of the variability in transactions between covered entities is that too much information is being crammed into each administrative transaction, perhaps as a legacy of the old paper-based system, wherein a given piece of information either was captured in the transaction or was practically unavailable to the payer. In today's electronic transactions, it may be possible to simplify administrative transactions such that they are more easily standardized and require fewer updates while gleaning additional information from context-specific sources.

**Recommendation 12:** *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.*

Participants disagreed regarding whether testing of new standards should be regulated, with some arguing that regulating this process could stifle innovation. In contrast, those arguing in favor of regulation suggested that providers, payers, and vendors should collaborate to propose testing approaches that would require HHS approval. In addition, HHS could publish testing approaches that have already been approved, so that entities can easily join already-approved testing processes. A tension exists between interoperability (which regulations can improve) and innovation (which regulations can stifle). However, lack of regulations can also allow bad actors in the industry to act, for example, against the interests of providers and in favor of payers, under the putative rubric of "innovation" (e.g., as occurred with the "virtual credit cards" which required providers to incur processing fees for one-time transactions via fax).

This discussion prompted one participant to suggest combining Recommendations 11 and 12 to stipulate (1) that organizations must implement a baseline standard, which must be validated, tested, and certified to sustain a universal standard of interoperability, and (2) that innovation should be allowed on top of that baseline. In contrast, other participants stressed that the two recommendations should remain separate in order to distinguish innovation among certified entities and currently regulated transactions from those currently uncertified and unregulated entities and transactions. When encouraging innovation, distinguishing between those two categories could help to prevent an unintended increase in variability of transactions.

In certain cases, though it is counterintuitive, the predictability afforded by regulations can help innovators by allowing them to anticipate certain features of their dynamic market niche, which would otherwise evolve less predictably. One possible solution to the tension between the twin needs for regulation and innovation is to impose regulations at the *implementation* level, but not at the *innovation* level. As a resource for innovators, participants should refer to The Office of the National Coordinator for Health Information Technology's (ONC's) Interoperability Proving Ground, which enables health care organizations to join existing interoperability projects to promote collaboration and avoid duplicating efforts.

**Call to Action D**: *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.*

Participants generally supported this action, so long as it does not prolong the process and raise the administrative costs for any given standard. In addition, several participants recommended that SDOs conduct cost-benefit analyses as early in the standards development process as possible to minimize sunk costs. The results of these cost-benefit analyses, if they demonstrate ROI, can also provide a 'business needs argument' to incentivize private entities to test the new standards. Despite widespread agreement, participants acknowledged that securing funding for this call to action would be challenging. Other anticipated challenges include (1) the potential for cost-benefit analyses to become unreliable because of intervening changes to the industry, and (2) the need to distinguish between cost-benefit analyses that study incremental vs. full-scale adoption of a new standard (this distinction, though important, is not currently made).

**Call to Action H:** *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).*

Participants supported this action—including leveraging the ONC ISA to avoid establishing something new—with the caveat that it should refer to both mandated *and nonmandated* (voluntary) standards. According to participant comments, further discussion may be required to optimize ISA's process of incorporating public comments into its publications.

## Prioritizing Recommendations and Identifying Interdependencies
*Panel Discussion*

Participants did not suggest any additional recommendations. However, several potential topics for future discussion were offered, including: (1) the effects of artificial intelligence technology on the development and adoption of standards, (2) any similarities between health care and other industries that have successfully implemented standards, as a potential source for new ideas, (3) ways to quicken the process of obtaining HHS approval for NCVHS recommendations, as this process often stalls recommendations before they can move to the regulatory process, and (4) strategies to reduce the physician burnout that results from standards implementation. In addition, participants were encouraged to submit comments or feedback on their own before final recommendations are submitted by NCVHS to the HHS Secretary in early 2019.

## Public Comment

*Rebecca Hines, NCVHS Executive Secretary*

The following organizations submitted written testimony prior to the meeting, all of which can be accessed on the NCVHS website:

The Accredited Standards Committee X12 (ASC X12)
American Dental Association (ADA)
American Health Information Management Association (AHIMA)
American Hospital Association (AHA)
American Medical Association (AMA)
America's Health Insurance Plans (AHIP)
Blue Cross Blue Shield Association (BCBSA)
Cambia Health Solutions
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for
        Information Exchange (CORE)
Defense Health Agency (DHA)
Department of Veterans Affairs (VA)
Designated Standards Maintenance Organization (DSMO)
Electronic Healthcare Network Accreditation Commission (EHNAC)
Healthcare Administrative Technology Association (HATA)
Kaiser Permanente
Laboratory Corporation of America (LabCorp)
Lantana Consulting Group
Medical Group Management Association (MGMA)
Nachimson Advisors LLC
National Automated Clearing House Association (NACHA)
National Council for Prescription Drug Programs (NCPDP)
National Unions Claim Committee (NUCC)
Optum 360
Patient Provider Exchange (PPX)
Pennsylvania Medical Society (PAMED)
St. Luke's Health System
Surescripts
Utah Health Information Network (UHIN)
Workgroup for Electronic Data Interchange (WEDI)

In addition, several public comments were provided in person and via WebEx. These comments are summarized below.

**Laurie Burckhardt (WPS Health Solutions)** submitted the following comments: (1) many small providers do not have up-to-date technology, such as EHRs, and those who do often remain uncertified. In order to achieve industry-wide standards, these providers must somehow be accommodated to support interoperability of their clinical and administrative data. (2) It is

generally insufficient to test standards in environments that do not reflect the reality of a production environment (e.g., systems must be structured not only to receive transactions from providers but also to support timely and accurate payments). (3) Aggressive education and collaboration efforts across stakeholders is essential, yet this requires more funding than is currently available. (4) NCVHS should always assess which of its actions or recommendations might have unintended deleterious effects on patient care.

**Tara Gensemer (PAMED)** commented that, although predictability and the implementation of application programming interfaces (APIs) that allow seamless transactions among payers and providers will help small providers construct their budgets, it may also lead them to receive more requests for a la carte services, which could have an unintended negative impact on care delivery.

**Stanley Nachimson (Nachimson Advisors)** submitted the following comments: (1) when an entity is noncompliant, much of the cost is passed on to its trading partners, which is why standardization is crucial; (2) regulations mandated by CMS are necessary to enforce new standards adoption; (3) industry (including small providers) must accept that development, review, implementation, and enforcement of standards is part of the cost of doing business; (4) innovation is stifled by regulations, so labs that are exempt from normal regulations should be established to permit innovation; (5) vendors should be responsible for ensuring that their products meet standards; (6) regarding Outcome Goal 3 Call to Action D, cost-benefit analyses should be conducted for individual providers, payers, and vendors, as well as for the industry as a whole (as the latter alone will not yield actionable information).

**Sam Rubenstein (WEDI)** submitted the following comments: (1) to be considered compliant, health care organizations should not only have the capacity to process a specific set of transactions, but should also have to demonstrate that a transaction (or a combination thereof) can be used to accomplish a specific business objective; (2) transaction processing should be automated as much as possible, and actors within the health care industry should be required to periodically report on returned/rejected transactions; (3) because the term "provider" denotes many different types of user, and because their roles in processing transactions can differ significantly, more specific terms should be adopted when appropriate; (4) regarding Outcome Goal 2 Recommendation 3, WEDI should oversee the formation of a new entity to replace the DSMO; (5) Outcome Goal 3 is critically important to achieving predictability, and to reducing health care cost and complexity.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

04/22/2019

Chair                                                                Date

**Appendix A**

**Hearing Agenda**

**National Committee on Vital and Health Statistics**

**Subcommittee on Standards**

**December 12-13, 2018**

**Omni Shoreham Hotel, 2500 Calvert Street, Washington, DC 20008**

This hearing is a continuation of the Committee's work to identify the challenges regarding the update, adoption, and implementation of health care administrative standards and operating rules.  The Committee's overarching objective is to create a "Predictability Roadmap" to enhance the transparency and pace of change of the standards process under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).  The purpose of this hearing is to obtain stakeholder perspective on the Committee's draft recommendations developed with industry's input and released to the public on September 30, 2018.  This feedback will inform development of final recommendations for submission to the HHS Secretary in early 2019.

**Wednesday, December 12**

| | | |
|---|---|---|
| **9:00 a.m.** | **Welcome** | Alix Goss and Nick Coussoule, Co-chairs |
| | • Call to Order | |
| | • Roll Call | Rebecca Hines, NCVHS |
| | • Review Agenda | Designated Federal Official |
| **9:10 a.m.** | **Introductions** | Nick Coussoule, Co-chair |
| **9:40 a.m.** | **Background of the Predictability Roadmap** | Alix Goss & Nick Coussoule |
| | • History, actions and outcomes | |
| | • Proposed recommendations | |

| | | |
|---|---|---|
| **10:00 a.m.** | **Discussion of Outcome Goal 1**<br><br>**Outreach, Education & Enforcement – 8 recommendations/calls to action** | All participants in open discussion forum |
| **11:00 a.m.** | **Break** | |
| **11:15 a.m.** | **Continuation of discussion of Outcome Goal 1** | All participants |
| **12:00 p.m.** | **Lunch** | |
| **1:00 p.m.** | **Continuation/closure of discussion of Outcome Goal 1** | All participants |
| **2:00 p.m.** | **Discussion of Outcome Goal 2 Process Improvements – 9 recommendations & calls to action** | All participants |

*(with a break)*

| | | |
|---|---|---|
| **4:45 p.m.** | Wrap up and plan for day two | Alix Goss & Nick Coussoule |
| **5:00 p.m.** | Public Comment | Rebecca Hines, NCVHS Executive Secretary/DFO |
| **5:30 p.m.** | Closing Remarks & Adjourn | Alix Goss & Nick Coussoule |

## Thursday, December 13

| | | |
|---|---|---|
| **8:30 a.m.** | **Welcome** | Alix Goss & Nick Coussoule |
| | • Call to Order | |
| | • Roll Call | Rebecca Hines, NCVHS Designated Federal Official |
| **8:40 a.m. – 10:40 a.m.** | **Discussion of Outcome Goal 3** | All participants |
| | **Regulatory levers – 6 recommendations & calls to action** (break at 10 a.m.) | |
| **10:45 a.m.** | **Prioritizing recommendations and identifying interdependencies** | All participants |
| **12:00 p.m.** | **Public Comment** | Rebecca Hines, NCVHS Executive Secretary/DFO |
| **12:30 p.m.** | **Closing remarks, Next steps & Adjourn** | Alix Goss, Nick Coussoule |

### Advance Questions for Panelist Discussion

In general,

1. How do 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 (expected outcome) 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?

**Appendix B**

# Invited Participant List

## Standards Subcommittee
## Predictability Roadmap Recommendation
## Hearing Participant List
*December 12-13, 2018*

**Liora Alschuler**
President and CEO
Lantana Group

**Mike Barlow**
Vice President
Palmetto GBA

**Joe Bell**
Chairman
Cooperative Exchange

**Andrew Burchett**
Chief Information Officer
UHIN

**Janet Campbell**
Vice President, R&D Relations
Epic

**Tammy Banks**
Director, Optum Insight
Optum 360 Group

**Gary Beatty**
Chair, Accredited Standards Committee
X12

**Sue Bowman**
Senior Director, Coding Policy &
Compliance
AHIMA

**Laurie Burckhardt**
EDI Regulatory and National Standards
Administrator, WPS Health Solutions
Chairperson
Designated Standards Maintenance
Organization (DSMO)

**Melanie Combs-Dyer**
Director
CPI, Centers for Medicare & Medicaid
Services

**Laurie Darst**
Revenue Cycle Regulatory Advisor, Mayo Clinic
Chairperson of the Board
Workgroup for Electronic Data Interchange - WEDI

**Deborah Gash**
Chief Digital Officer
St. Lukes Health System

**Mark Gingrich**
Chief Information Officer
Surescripts LLC

**Brad Gnagy**
Information Technology Director
HealthPac

**Dr. James Goodyear**
Pennsylvania Medical Society

**Eric Heflin**
Chief Technology Officer
Sequoia

**Michael Herd**
Senior VP, ACH Network Administration
NACHA – The Electronic Payments Association

**Charles "Chuck" Jaffe**
CEO
Health Level 7 International, HL7

**Katie Knapp**
Veterans Health Administration

**Gail Kocher**
Director, National Standards
Blue Cross Blue Shield Association

**Suzanne Lestina**
Chair, NUCC
American Hospital Association

**Minil Mikkili**
Manager,
National EDI Business Operations
Kaiser Permanente

**Chris Muir**
Director,
Office of the National Coordinator for Health Information Technology (ONC)

**Jean Narcisi**
Director of Dental Informatics
Practice Institute
American Dental Association

**Arthur Roosa**
Chair, HBMA Government Relations Committee, CEO SyMed Corp

**Danny Sawyer**
Chief, Business Information Management
Department of Defense

**Nancy Spector**
Coding and HIT Advocacy Director
American Medical Association

**Dr. Walter Suarez**
Executive Director, Health IT Strategy &
Policy, Kaiser Permanente
Representing HIMSS

**Rob Tennant**
Director, Health Information Technology
Policy
Medical Group Management Association

**Patrick Tighe**
Bureau Chief Claims Operations
Ohio Department of Medicaid

**April Todd**
Senior Vice President
CAQH

**Rajiv Uppal**
CMS CIO
Office of Information Technology
Centers for Medicare & Medicaid Services

**Pat Waller**
Senior IT Staff Consultant
Cambia Health Solutions

**Margaret Weiker**
Director, Standards Development
NCPDP

**Martin Wilbanks**
Chief, Development Division
Financial Service Center
Department of Veterans Affairs

# Appendix C

# Complete Set of 2018 Draft Recommendations, Calls to Action and Measurement Items for the NCVHS Predictability Roadmap, organized by the 3 Draft Outcome Goals

**Outcome Goal 1:  Improved education, outreach, and enforcement to promote efficient planning and use of the adopted HIPAA standards and operating rules.**

**Recommendation 1.**  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.

**Recommendation 2.**  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.

**Recommendation 7.**  HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.

**Call to Action A**.  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.

**Call to Action 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.

**Call to Action E.**  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.

**Call to Action F.**  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.

**Measurement M1**.  HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.

## Outcome Goal 2:  Policy levers will successfully support industry process Improvement changes.

**Recommendation 3.**  HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.

**Recommendation 4.**  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.

**Recommendation 5.**  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.

**Recommendation 8.** 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).

**Recommendation 9.** HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.

**Call to Action C.** 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$^{rd}$ 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.

**Call to Action G.** 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.

**Measurement M2.** 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.

**Measurement M3.** NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

## Outcome Goal 3:  Regulatory levers will enable timely adoption, testing, and implementation of updated or new standards and operating rules.

**Recommendation 6**. 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 NCHVS.

NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months.

HHS should adopt the NCVHS recommendations on a regular schedule.

**Recommendation 10.** 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.

**Recommendation 11.** 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.

**Recommendation 12.** 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.

**Call to Action D.** 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.

**Call to Action H.** 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).