CIO Forum

Meeting Summary

Held May 17, 2018

Subcommittee on Standards

National Committee on Vital and Health Statistics

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICE

This report was written by NCVHS consultant writer Susan Baird Kanaan in collaboration with NCVHS members and staff.

NCVHS Members and Staff in Attendance

Nicholas L. Coussoule,* **Subcommittee Co-chair and Hearing Co-chair**
Alexandra Goss,* **Subcommittee Co-chair and Hearing Co-chair**
Debra Strickland, MS*
Denise E. Love, BSN, MBA *
Jacki Monson, JD
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Llewellyn J. Cornelius, PhD
Richard W. Landen, MPH, MBA*

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Suzie Burke-Bebee, DNP, MSIS, MS, RN, ASPE, OS, HHS
Debbie Jackson, MA, NCHS
Marietta Squire, NCHS

Others in Attendance (See Appendix B for complete Forum Roundtable Invited Participant List)

Margaret Weiker, NCPDP
Christine Gerhardt, CMS
Erin Weber, CORE, CAQH
Suzanne Niemeyer, Ketchum
Bill Finerfrock, Capitol Associates, Inc.
Nancy Spector, AMA
Michael DeCarlo, BlueCross Blue Shield Association
Yelena Balin, b.well
Gail Kocher, BlueCross Blue Shield Association
Tina Greene, Mitchell

The National Committee on Vital and Health Statistics
(NCVHS) serves as the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42U.S.C.242k[k]). The Committee also serves as a forum for interaction with interested private-sector groups on important health data issues. Its membership includes experts in health statistics, electronic interchange of healthcare information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing healthcare 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 18 members are appointed by the HHS Secretary to terms of four years each. Two additional members are selected by Congress. The NCVHS website provides additional information: **www.ncvhs.hhs.gov**

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Introduction and Background

The Subcommittee on Standards of the National Committee on Vital and Health Statistics (NCVHS) hosted a Chief Information Officer (CIO) Forum on May 17, 2018, in Washington, DC. The goal of the Forum was to elicit ideas for improving the standards development, update and adoption process, with the intent of identifying actionable steps to include in the Committee's forthcoming Predictability Roadmap, and to inform a set of recommendations to send to the Secretary of Health and Human Services (HHS). More specifically, the Subcommittee wanted to get a sense of how standards and operating rules need to evolve to support business requirements for the health care industry in the future. NCVHS is exploring options for providing the health care industry with a degree of certainty in the timing and sequence of the development and adoption of new or revised standards and operating rules that are required under the Health Insurance Portability and Accountability Act[1] (HIPAA) and other legislation. This report summarizes the discussion from this daylong Forum.

At the beginning of the day, each participant shared information about their organization's innovations, accomplishments, and specific strategic initiatives. They also shared their experiences in using the adopted (HIPAA) standards and operating rules, including successes and challenges. The 21 invited technology experts and senior corporate officers represented a cross-section of organizations that are end-users impacted by HIPAA and the Patient Protection and Affordable Care Act (ACA) administrative standards. The Forum agenda and participant roster are in Appendices 1 and 2.[2]

The CIO Forum was the latest step in the ongoing NCVHS Predictability Roadmap initiative. In this initiative, the NCVHS Subcommittee on Standards is working to understand the strengths and weaknesses of current processes for developing, updating, and adopting standards and operating rules and to develop actionable recommendations for improvements to inform development of a Predictability Roadmap. The initiative is a response to the ongoing concerns

[1] Health Insurance Portability and Accountability Act of 1996 (HIPAA)

[2] The comprehensive NCVHS slides used to structure the Forum are included in the Appendix. The transcript and speakers' slides are posted at: https://ncvhs.hhs.gov/meetings/standard-subcommittee-cio-forum/

expressed by a wide range of stakeholders about the need for greater predictability to enable the efficient and appropriate adoption of standards and operating rules. Prior to this Forum, the Subcommittee met with standards organizations to discuss their current practices (July 2017); conducted a daylong visioning workshop with multiple stakeholders to identify opportunities for action (August 2017); and interviewed HHS about the regulatory process (March 2018). After integrating the findings from the CIO Forum with those from its other explorations, the Subcommittee will develop provisional recommendations and hold a hearing to obtain feedback on them. The recommendations will be relevant to the Department, the private sector, and standards development organizations (SDOs). Subsequently, the Subcommittee will revise its recommendations and vet them with the full Committee. Once they are approved, NCVHS will send the final recommendations to the Secretary.

The CIO Forum--May 17, 2018

In their introductory remarks, Subcommittee Co-chairs Alix Goss and Nick Coussoule explained that through its discovery process, the Subcommittee had identified five themes related to the Predictability Roadmap. These themes provided the structure for the day's discussion, as follows: governance, standards adoption (the update process), the regulatory process, data harmonization, and third-party entities becoming HIPAA covered entities.

The Co-chairs then invited Forum participants to describe their organizations and share salient observations about standards. Throughout the day, participants brought forth perspectives based on their experiences in the diverse sectors of the health care ecosystem they represented:

- Health care providers
- Health plans
- Health care clearinghouses
- Health care delivery and integrated health systems
- Practice management system vendors
- Electronic health record systems
- Consumer vendor/personal health record applications
- Retail pharmacy and pharmacy benefit managers (PBM)

- Federal government agencies
- Health care Industry analysis
- Health information exchange networks

The participants' opening presentations reflected the five themes identified by NCVHS, confirming the relevance of these specific themes. Panelists agreed that the themes did represent significant challenges for the industry and merited being addressed. Speaking as end-users of the standards and operating rules, albeit from unique perspectives, they found broad agreement about the ways in which the reality of administrative standards today falls short of their potential, and about the types and urgency of improvements needed. All agreed that the HIPAA and ACA administrative standards have already enabled significant efficiencies with respect to pre-HIPAA paper processing and direct data entry, and positioned the industry for even more innovations for which a robust standards base is necessary. Discussions focused on how to close the gap between current reality and future potential.

Participants stressed that in their current state, and with current processes, standards do not support enough of their business needs or enable innovation. For example, the current standards adoption process actually stifles innovation. The pace of standards development and updates lags far behind the pace of technology and business change, still necessitating many manual processes and leading to what one participant called "technical debt" and another called "throwaway work." Several participants stressed the need to "put the patient in the process," noting for example the impacts of denials of coverage on patients as well as business entities that result from challenges with the standards that cause delays in payment. More than one participant indicated that 90% of denials are appealed and ultimately reversed and paid. Others agreed that denials and appeals could be addressed by the use of standards. As one part of the solution, the group, drawing on their functional and operational expertise, urged that the inputs of end-user organizations be better leveraged in the standards development and adoption processes. Participants also agreed that there is a visible path to the integration of clinical and administrative data and that it is no longer necessary to differentiate the two data streams in the ways now codified in administrative and payment systems.

The remainder of this meeting summary amplifies the comments and issues raised by participants in the context of the five themes referenced above. Each theme was discussed in a discrete session facilitated by a Subcommittee member. To provide context and stimulate discussion, each facilitator began by providing an overview of the theme, a problem statement, and a set of preliminary questions to generate reflection and dialogue. While the Forum was organized around five separate themes, many of the same observations and ideas arose in multiple sessions. The final sections of this summary highlight the major crosscutting messages and ideas that emerged from the day's discussions and outline the next steps that NCVHS plans for the Predictability Roadmap initiative, based on the inputs it has received.

Theme 1: Governance

To launch discussion on this theme, Rich Landen gave a brief overview of the existing governance process, explaining the origin and role of the Designated Standards Maintenance Organization (DSMO), which was established by regulation in 2002. He explained that NCVHS receives recommendations from the DSMO and then the Committee conducts its own hearings and makes recommendations to the Secretary regarding adoption of new or updated standards. Mr. Landen stressed that this process and structure was created over 15 years ago and was intended to provide ground rules and build trust within the industry to help it move toward administrative simplification. The oversight process conducted by the DSMO does not include a review process for the operating rules, which are brought directly to NCVHS by the authoring organization itself. After NCVHS makes its recommendations, HHS may choose to implement the rulemaking process.

He then posed a problem statement and set of questions for discussion—a format that was used for each of the five discussion segments.

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

QUESTIONS:

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

Participants identified a number of problems in the area of governance, along with possible improvements. One person observed that while the process is working as designed, it is a design for a ten-year iteration cycle that is too slow for today's conditions and business needs. Further, the process is too bureaucratic, and it excludes people playing key leadership roles in standards development and standards implementation today. Indeed, some participants of the Forum seemed unfamiliar with the existence or function of the DSMO.

There was ready consensus among the group that the DSMO process had outlived its original purpose and could be eliminated, re-designed or re-purposed to accommodate a digital world. One participant raised the suggestion that the current consensus-based governance process, which is qualitative and opinion-based, could lend itself to a data-informed process, using advanced analytics, testing and modeling and other tools. The data would include elements of the business process, the status of adoption, and what works and does not work, along with other appropriate factors. The participants explored this general vision in various contexts throughout the day's discussions.

<u>The de-facto extra-regulatory environment and the alternatives to regulation</u>

There was some discussion about the fact that much of today's industry business needs outpace the standards and regulatory processes. The slow pace of standards development was cited as a major reason for the extra-regulatory activity. The representative from the Office of the National Coordinator (ONC) pointed to the existence of tools such as ONC's cooperative agreements and certification as alternatives to regulatory action.

<u>Enforcement</u>

There was also discussion of how the inconsistent and non-standard use of the standards impact the full and effective use of the transactions. While operating rules were envisioned to address

business rules to improve use of the standards without hampering individual business processes, it was apparent through participant comments that this combination of standards and operating rules has not yet had the full beneficial impact that was intended.

Most participants agreed that some form of enforcement is needed to limit the need to deviate from use of the adopted standards, even though many segments of the industry find such deviation necessary to conduct day-to-day business. Some of those deviations are workarounds to address deficiencies in the standards, common-sense ways to improve transaction flow, and innovation necessary to support changing business demands or to provide an impetus for full and timely adoption. One person noted that enforcement is needed across all players in order to get return on investment (ROI). This is especially important in cases when there is no ROI for adopting a given standard by one type of covered entity whose business needs do not require the full functionality of that standard. Participants agreed, though, that whenever possible, the process should be structured to demonstrate ROI through pre-adoption experimentation and testing, thereby documenting ROI and encouraging adoption and the successful use of standards.

There was strong agreement that regulations and enforcement should be structured to provide a floor but not a ceiling for standards, so that early adopters could move ahead and innovate, and later adopters could benefit from their experience. It was also noted, however, that any optionality around a standard automatically creates an obligation on other parties to support and maintain multiple versions of the standards, which tie back into the ROI and enforcement themes. There was consensus for regulations to provide a standards floor. This topic pertains to discussions of extensibility and versioning covered elsewhere in this meeting summary. One person noted that "because regulations are blunt instruments," they should be kept at a high level, setting policy and direction and providing incentives while leaving the details of implementation to communities of interested parties. Over the course of the day, it was repeatedly stressed that testing is needed to determine what works and what doesn't so that standards can be refined based on evidence rather than on expert opinion.

Extensibility, innovation, and interoperability

One running theme of the discussions was the tension between the need for extensibility, fluidity and flexibility for innovation, on the one hand, and the problems with interoperability and predictability that the resulting variations can create for partners. Some proponents of extensibility said standards could be structured to allow for such an iterative process, allowing some room for innovation and flexibility. A later discussion of versioning explored one such approach.

Alignment and consistency across federal agencies

Another point made in this session and echoed throughout the day concerned the need for greater alignment across federal agencies with respect to standards. Participants indicated that consistency across agencies would send an important signal to industry about stability of conditions. The Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), the Veterans Administration (VA), and Department of Defense (DoD) were cited as examples.

Theme 2: Standards Update Process[3]

Deb Strickland described the current standards update process, using the X12 EDI standards development organization as the example, and noted where actual practice differs from the original plan. She then presented the problem statement and questions for discussion of this topic. In this section, standards adoption refers to the development of the standards in preparation for their review by the DSMO and NCVHS, and subsequent adoption by the Federal Government.

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

[3] The session title and terminology used here (standards update) has been revised from that in the agenda (standards adoption) to more precisely represent the topic addressed.

QUESTIONS:

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

Update cycles

Participants described the standards update cycles as infrequent and irregular, when what is needed is a regular, predictable and reliable schedule. This challenge is exacerbated by frequent delayed and postponed deadlines that had been specified in the rulemaking process. These delays or postponements can put CIOs in the position of "crying wolf" to their organizations about the imminent need for resources to prepare for adoption. Participants characterized the use of deferments as a "culture" at HHS and urged that it be changed.

Nick Coussoule asked for specific suggestions about the desirable pace and cadence and what to change in a given phase. Like many topics, this one was revisited in other Forum sessions. One participant later suggested that two years was a reasonable period of time to implement a new or updated standard. Another cited the consensus-based three (3) year implementation convention of the National Council on Prescription Drug Programs (NCPDP) as a possible model for the cadence of updates. Another person wondered simply what could be done to make adoption easier. There was general consensus around the need for more frequent, smaller updates to the standards, with longer intervals between major revisions.

Participation in standards work groups

Two or three attendees shared their experiences participating in standards workgroups, and their descriptions were honest and candid regarding the myriad difficulties and challenges, including time and workgroup organization. Participants explained that their organizations

wanted to help move things forward for the common good, but that there were a number of barriers to effective engagement. One said she joined X12 in order to include a provider voice at the table, but found that the work was cumbersome; it took too much time, and the process took too long to produce results to justify to her management her continued participation. While the participants stressed the importance of involving end-users in the standards development and update process, these individuals also called attention to the problems inherent in a voluntary process and urged that a way be found to fund it properly. Both of these ideas received broad support from Forum participants and surfaced often in the discussions. The absence from the development process of people with content expertise was also noted.

Possible improvements

Several individuals made suggestions about ways to improve the process for updating standards. Ideas included phased approaches to transaction-set implementation and beta testing before finalizing standards. After one participant shared a vision for joint pilots by providers and plans to show ROI and stimulate adoption, another immediately offered to have his organization host such a pilot. One individual pointed out that agility is only positive when surrounded with a good deal of planning, based on clear criteria for prioritizing and measuring. Another wondered about the possibility of oversight over *all* the changes. Again, the need for testing and iterative approaches was a strong theme. There was general recognition of cost inequity for first movers and for free riders.

Monitoring and evaluation were another cross-cutting theme of the day's discussions, toward the goal of devising a more evidence-driven system. There was agreement about the need to measure the extent of standards adoption and effective use, with the ONC and CMS representatives stating their agencies' interest in this information. Further, information is needed on what problems people are having with adoption, yielding insight into why some standards get adopted and others do not.

One participant shared his concern about the prospects for the long-term use of X12 because of the time involved in updates; he called for "a bridge to the future." Another pointed to the X12 278 (referral and authorization) transaction as "low-hanging fruit" whose adoption could and

should be accomplished this year. Finally, there was discussion of the growing trend toward use of APIs (Application Program Interface) as standards in addition to or in lieu of traditional EDI or XML transaction standards, with one person pointing out the need to use a consistent definition when talking about APIs.

Theme 3: Federal Regulatory Process

Denise Love reviewed the NCVHS role that precedes rule-making. She outlined the importance of industry engagement and the steps in the ensuing federal regulatory process. She noted that like a huge ship, the process does not turn quickly or easily, and Alix Goss added that it can take 4 to 12 years to go from a recommendation to a final rule. Participants were reminded that operating rules follow a different and somewhat less complex path than the X12 and NCPDP standards, from the standpoint of not having change requests submitted to the DSMO,[4] although operating rules still must receive a recommendation from NCVHS to the Secretary, and be adopted through the federal regulatory process.

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

QUESTIONS:

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

[4] Industry may submit change requests directly to the individual standards development organizations for consideration. However, the final product of an updated or new standard should still come to the DSMO for final submission to NCVHS.

Regulatory process impact on business model and goals

To the first discussion question, the participants had a straightforward response: The regulatory process does *not* advance their strategic goals; it only hinders them. One person cited the example of the attachment regulations, a process that has been so slow that several states have moved ahead with their own regulations, including Texas and Minnesota.

Besides the issues around the slow pace of the regulatory process, attendees had a lot to say about the lack of transparency and government accountability inside the rulemaking process. Several individuals expressed appreciation for the quality of NCVHS recommendations to the Secretary, but noted with frustration that these recommendations then sometimes seem to go into a "black hole" after which "nothing happens." While acknowledging that "the federal government is never going to be Apple," people wondered how the government's decision-making and actions could be made more transparent and predictable.

The solutions put forward for expediting the use of standards without waiting for regulation involved a combination of greater federal accountability and a shift toward a funded, public-private model, such as Cooperative Agreements and funding of pilots with SDOs to test new concepts. Argonaut and the DaVinci Project were cited as examples.

A federal representative described the policy timelines and other factors that affect the rulemaking process in different agencies, noting that the timing "windows" are not always clear. He added that this is a good time to be having this conversation. Alix Goss suggested that NCVHS and ONC work together to promote greater alignment within government in these areas.

Enforcement

Having discussed enforcement in a previous session, participants also mentioned the lack of enforcement in the context of this regulatory process discussion. It was noted that some health plans are not compliant with the adopted standards, and that there does not appear to be a mechanism for addressing this problem. Some participants expressed concerns about the issues that arise if organizations use the standards "in their own way."

Opportunities for improvement

Turning to opportunities for improvement in this area, the Subcommittee Co-chairs again asked the participants to be specific about dates and cadence for standards updates. Much of the ensuing discussion in this session concerned ways to make the regulatory process faster and more cost-effective for the benefit of both the regulator and covered entities. One person proposed that two years for implementing an updated version of a standard was a realistic cadence, given that many processes and cycles are under way at once. Another individual suggested that regulations specify sunset dates for use of an adopted version of a standard. The group again considered the need for funding – for updates, pilots, and evaluations — given that volunteer-driven processes are inevitably slow, and it was noted that the testing and pilots being proposed would only increase the need for funding.

There was support for the idea of getting existing transactions working properly before introducing new ones. To that end, participants asserted that the standards development life cycle is much like that of the software life cycle and involves essentially the same steps. The implication is that like software development, standards development should involve quality assurance (QA), attention to the business case, and checklists. There was considerable support in the group for a versioning approach in which early adopters would do the QA and modifications would then be introduced into the standard in time for its later adoption by others. At the same time, though, participants expressed varied points of view about how much flexibility to build into the process. One person called for mindfulness of provider burden, noting that cross-compatibility helps. Others stressed that workflow and policies must drive technology, rather than the other way around. Finally, it was reiterated that all of the relevant stakeholders—including patients/consumers—must be at the table and have their interests taken into account during the development process.

Alix Goss observed that in the scenario just sketched by the Forum participants, the industry would drive the process and say when it had completed its checklist and was ready, at which point NCVHS would be asked to concur that the standard was ready for adoption.

Are regulations needed?

Participants were in general agreement that some form of regulation with enforcement is needed to induce covered entities and their business associates to use the adopted standards correctly. The participants expressed concerns about transparency and follow-through in the federal process; one person pointed to "the gap between [NCVHS] recommendations and the procedures behind the scenes with HHS."

Theme 4: Data Harmonization

Linda Kloss, who also chairs the NCVHS Subcommittee on Privacy, Confidentiality and Security, told the group that NCVHS is taking a broad look at the vocabulary landscape in its Health Terminologies and Vocabularies project, and an environmental scan will be available early summer 2018. She indicated that the narrower focus for the present discussion is the existing levers for data harmonization, which include HIPAA, ONC's draft US Data Content for Interoperability initiative (USCDI), Meaningful Use, and other efforts at standardizing and defining data content.

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

QUESTIONS:

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

Patient safety and data harmonization

This topic, which stimulated a wide-ranging discussion, revealed the considerable concern among the Forum participants about today's lack of semantic interoperability. One person characterized the challenge of data harmonization and lack of exchange as "the number one source of frustration and distrust, and a top priority" for her industry. She offered to share her organization's survey findings on the matter. Several participants stressed that the lack of data harmonization endangers patient safety. The Subcommittee was receptive to the suggestion that its problem statement be expanded to include the consequences for patient safety.

The ideas for achieving standardization in this area included the need to eliminate artificial boundaries between clinical and administrative data. The importance of defining metadata in data element standards was also suggested, as was creation of a repeatable governance process based on use cases.

This discussion moved one participant to remark on the "drastic" oversimplification that had happened with respect to the complex information systems that are actually needed to encompass clinical data exchange and payment and to take standards into account. He called, instead, for recognition of the need for an architected solution able to manage "a massive web of dependencies" that includes but is not limited to standards. This, he said, would require a validation program and a trusted exchange environment for an operational, deployed production system that iterates over time.

A government representative observed that in a streamlined governance process, it would be important to "involve the SDOs at the front end." Another participant suggested that an approach of governance by use case may be needed, and another individual reiterated the importance of building in empirical testing as early in the process as possible, with repeats.

Clinical and administrative data content

Participants agreed that in view of the convergence of clinical and administrative data, which serve the same purpose of describing and serving the patient, it is no longer meaningful to distinguish the two data streams in the ways now codified in administrative and payment

systems. Some participants expressed a sense of urgency about "forcing the issue" and changing the status quo in this regard.

Theme 5: Third Parties as Covered Entities

To begin this session, Alix Goss asked for a show of hands by participants, which reflected that participants represented a cross-section of HIPAA covered entities, non-covered entities, and business associates. She noted that the list of non-covered entities is extensive (see slides 34 and 35 in Appendix C).

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

QUESTIONS:

- *Do you think the list of entities on the prior slide should become covered entities under HIPAA? (referring to slide 35 in Appendix 3) If so, why and how will this help industry use the standards and operating rules more effectively?*
- *If third parties who are not currently covered entities were to come under the umbrella of HIPAA, there could be implications for their compliance with the Privacy and Security rules. What barriers would that impose for those organizations?*

This topic stimulated a lively discussion in which the varied perspectives and interests of the participants came into play somewhat more than with the other themes. The discussion identified criteria that might be used in considering who should or should not come under the HIPAA umbrella. The first criterion focused on leveling the playing field and sharing the risks; the second emphasized simplification to make it easier for patients to understand the HIPAA status of all who touch their data. A physician in attendance asserted that all those who touch patient data should face the same requirements. In contrast, some other participants laid out the

reasons why they thought their sectors should remain as third-party, non-covered entities and hence beyond HIPAA. One in that category described the extent of his company's work, as a business associate, to secure data and protect patient privacy and confidentiality.

The group also discussed this question in terms of specific entity types. Those named as candidates for coming under the HIPAA umbrella included worker's compensation, auto insurance and other third-party liability companies; ERISA plans; practice management; and registries and other clinical measure aggregators. The participants were not always in agreement about whether certain entities were indeed already covered, in some cases stemming from differing legal opinion.

Finally, a participant pointed out that in Texas, "basically almost every type of organization is a covered entity" because of the broad definition of a covered entity in the Texas Health and Safety Code.[5]

Public Comment

Margaret Weiker, Director of Standards Development, National Council for Prescription Drug Programs (NCPDP)

Speaking based on her long history with standards development organizations, Margaret Weiker provided some historical context and commented on several of the Forum themes and questions:

- Governance: The reason the DSMO was created was to provide a structured, formalized way to request changes to standards. Today, however, the DSMO process no longer has value. Some type of organized governance may be of potential value, depending on its purpose and goals, but not the DSMO.

[5] Texas Health and Safety code, Title 2. Health, Subtitle I, Medical Records, Chapter 181. Medical Records Privacy, Subchapter A. General Provisions 181.001 (b) (2)

- Standards adoption: As one example of the frequency of standards adoption and review, NCPDP set a three-year cycle for review, with variations and flexibility.
- Some of the practices of SDOs stem from their ANSI-accredited status, which requires them to adhere to certain procedural requirements.
- Regulatory process: The regulation process takes too long, and something must change. She also noted that many NCVHS recommendations have not been acted on.
- Versions of standards: There needs to be a better transition process and naming convention with versions so that versions can change. Specifically, she suggested not specifying version numbers in the regulation and not including the number in the name of the version, and allowing obsolete iterations to sunset without regulatory action.
- Data harmonization: Ms. Weiker asserted that it is no longer possible to distinguish clinical and administrative data.

Erin Weber, Director, CAQH-CORE

Erin Weber explained that CAQH-CORE was founded as a voluntary initiative to develop operating rules. She described the development of operating rules before and after publication of the Affordable Care Act in 2010, noting that her organization is a model of the industry coming together to work collaboratively. It can be more nimble because it is not ANSI-accredited, and the requirements that apply to it are less rigorous.

Suggested Topics for Future Consideration

Various participants asked NCVHS to give attention in the future to the following topics, at a Forum such as this and/or in another manner:

- The future of X12 and opportunities for using more progressive technology for data transfer;
- Consumers' right to correct things in the EHR and any upstream or downstream uses; and
- Standards for when and how to use electronic signatures.

Summary: Overarching Themes

The CIO Forum accomplished the Committee's goals for a focused discussion with business process stakeholders to gain the benefit of their perspectives. In summary, the following major themes arose through the Forum discussions and will inform NCVHS' process going forward (as described in the next section).

- The rulemaking process for the HIPAA/ACA administrative transactions, code sets, and operating rules is not functioning adequately to meet industry's business needs. The current process is too lengthy, unpredictable, unaccountable, inconsistent, and constraining. It stifles innovation, cannot keep up with changing business requirements or changing technology, and is not aligned with standards development on the clinical side of the business.
- As a result of the mismatches between business needs and the pace of technology development, on the one hand, and standards development, updates, uptake and regulation, on the other, the health care industry's strategic needs are not being met.
- Standards development and governance should involve end-users, organizations of different sizes, and content experts.
- Consideration should be given to making funding available for the standards development process instead of continuing to conduct it on a voluntary basis.
- The standards development/update process should involve smaller iterations, have a predictable cadence, and include reasonable backward compatibility.
- More iterative and agile models, based on ample planning, are needed for governance, standards adoption/updates, and regulation. These should set a floor but not a ceiling, be based on versioning, and include a sunset.
- The standards development process should become more evidence-based; that is, it should incorporate empirical testing and pilots that generate learning and demonstrate ROI, thereby encouraging adoption.

- The types of entities that handle patient information subject to HIPAA should be expanded. Most, though not all, participants favored a significant expansion of organizations to be considered as covered entities, or the creation of some equivalent process to bring other actors under the standards use umbrella and data protection obligations.
- There is no longer any meaningful differentiation between administrative and clinical data, so the standards development processes for both HIPAA and HITECH/Meaningful Use appear ready to be aligned.

Next Steps in the NCVHS Predictability Roadmap Initiative

To conclude the Forum, Standards Subcommittee Co-Chair Alix Goss thanked participants for their thoughtful contributions to the Predictability Roadmap initiative. She indicated that the Subcommittee would remain in communication and looked forward to their further inputs at a forthcoming NCVHS hearing on provisional recommendations once developed. The end-user inputs and suggestions shared during the CIO Forum will be used, along with other inputs, to generate opportunities for the Predictability Roadmap as they pertain to HHS, the private sector, and the SDOs.

NCVHS plans the following steps as it continues its work on the Predictability Roadmap:

- Consolidate findings from all Predictability Roadmap activities, including the CIO Forum, into a draft preliminary set of recommendations and actions.
- Hold a hearing to review the draft recommendations and obtain additional feedback.
- Finalize NCVHS recommendations for HHS, private sector and SDOs.
- Send the final set of recommendations to the HHS Secretary.

APPENDICES

A. CIO Forum Agenda
B. Participant List
C. CIO Forum Presentation

Appendix A

AGENDA

National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards
CIO Forum
May 17, 2018
Bureau of Labor Statistics, Janet Norwood Conference and Training Center
Postal Square Building, 2 Massachusetts Ave, NE, Room G440
Washington, DC 20212

Background

This CIO Forum will continue the Committee's work to obtain stakeholder input into the current challenges regarding the update, adoption and implementation of health care administrative standards and operating rules. The Committee's overarching objective is to help foster a "Predictability Roadmap" which seeks to improve the visibility into and increase the pace of change of the standards process. As a continuation of this effort, NCVHS is convening a group of Chief Information Officers (CIOs) who work with the standards and operating rules as end users and with leaders from the health care technology field. Agenda topics will include identification of changing business and technology needs specifically as they pertain to the standards adopted under HIPAA and ACA such as claims, eligibility, referrals and authorizations, and operating rules. Topics related to the predictability roadmap challenges will include the standards development and update process; governance and oversight of the standards review process; the Federal regulatory process to adopt new versions of standards; data harmonization; and inclusion of non-covered entities under HIPAA. Stakeholder input generated at this meeting will be considered to further inform the Committee's predictability roadmap leading toward a letter outlining recommendations to the HHS Secretary.

9:00—9:10 am	**Welcome** Call to Order Roll Call	Rebecca Hines, MHS NCVHS Executive Secretary
9:10—9:30 am	**Review of the Agenda and Introduction to the Predictability Roadmap**	Nick Coussoule, Co-Chair Alix Goss, Co-Chair Standards Subcommittee
9:30—10:20 am	**Participant Introductions with Brief Summary of Standards Initiatives** (5 minutes each) Q&A with Subcommittee (1st group of 10)	Co-Chairs

10:20—10:30 am	Break	
10:30—11:20 am	**Participant Introductions continued** Q&A with Subcommittee (2nd group of 10)	Co-Chairs
11:20—12:10 pm	Interactive Panel Discussion led by Subcommittee **Theme 1: Governance**	Rich Landen Subcommittee Member
12:10—1:10 pm	Lunch Break	
1:10—2:00 pm	Interactive Panel Discussion led by Subcommittee **Theme 2: Standards Adoption (Update) Process**	Deb Strickland Subcommittee Member
2:00—2:40 pm	Interactive Panel Discussion led by Subcommittee Theme **3: Federal Regulatory Process**	Denise Love Subcommittee Member
2:40—2:50 pm	Break	
2:50—3:30 pm	Interactive Panel Discussion led by Subcommittee **Theme 4: Data Harmonization**	Linda Kloss Subcommittee Member
3:30—4:10 pm	Interactive Panel Discussion led by Subcommittee **Theme 5: Third parties as covered entities**	Alix Goss, Co-Chair
4:10—4:20 pm	Public Comment	Rebecca Hines NCVHS Executive Secretary
4:20—4:30 pm	Wrap up and Next Steps	Co-Chairs
4:30 pm	Adjourn	Co-Chairs

Appendix B

Standards Subcommittee
CIO Forum List of Invited Participants
May 17, 2018

Jon Arends Director, Electronic ePrescribing Walgreens Co. Email: Jon.Arends@walgreens.com	**Mike Barlow** Vice President of Operations Palmetto GBA Email: mike.barlow@palmettogba.com
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Mark Gingrich Chief Information Officer Surescripts LLC Email: Mark.Gingrich@surescripts.com	**Brad Gnagy** Information Technology Director HealthPac Email: brad@healthpac.net
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Eric Heflin Chief Technology Officer Sequoia Email: eheflin@sequoiaproject.org	**Liz Johnson** Chief Information Officer Acute Care Hospitals & Applied Clinical Informatics- Tenet Healthcare Email: liz.johnson@tenethealth.com

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

NCVHS Standards Subcommittee CIO Forum

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

May 17, 2018

Bureau of Labor Statistics

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Agenda

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

2

Goals for the Day

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

3

History of the Predictability Roadmap

- HIPAA Legislation was enacted more than 21 years ago to promote administrative simplification efficiencies and effectiveness of the health care system through the use of standards for electronic transactions between health plans, clearinghouses and certain health care providers.
- The Patient Protection and Affordable Care Act included provisions to support HIPAA, both reinforcing certain requirements (adopt attachment standard), and adding new ones (adopt operating rules), increase enforcement.
- Industry feedback to NCVHS indicated the need for predictability in how standards are developed, adopted and implemented.
- We undertook a project engaging the industry in developing a predictability roadmap. We met with the following: Standard Development Organizations, Operating Rules Authoring Entity, Federal regulators, and industry stakeholders.

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History of the Predictability Roadmap

Pre-2012

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

2016

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

2017-2018

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

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What We've Accomplished

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

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What Happens After Today?

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

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What Has HHS Adopted to Date?

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Adopted Standards

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

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Adopted Operating Rules

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

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

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

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Participant Introductions

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CIO Forum

BREAK

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Participant Introductions

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Before we begin…Logistics

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

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Discussion of the Roadmap Themes

1. Governance
2. Standards Adoption
3. Regulatory Process
4. Data Harmonization
5. Third Party Entities

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Theme 1: Governance - History

The Designated Standards Maintenance Organization

Named in Federal Register Notice 8/17/00

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

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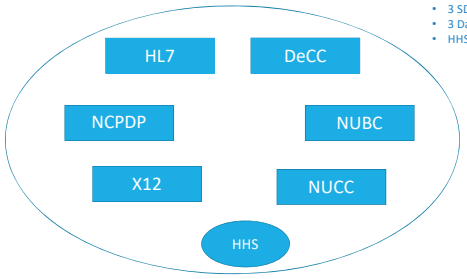
Governance – DSMO MOU

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



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DSMO Process Handoff to NCVHS

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Theme 1: Governance

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

QUESTIONS:

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

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Discussion of the Roadmap Themes

1. Governance
2. Standards Adoption
3. Regulatory Process
4. Data Harmonization
5. Third Party Entities

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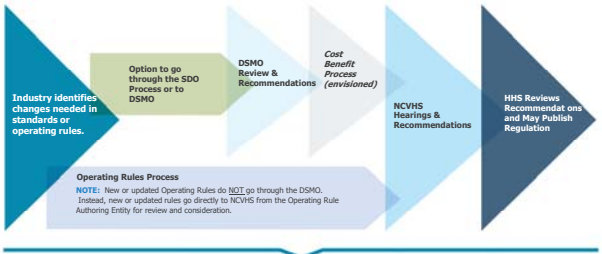
Standards Update Process - Overview

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



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

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Theme 2: Standards Adoption

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

QUESTIONS:

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

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CIO Forum

LUNCH

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

BLS Café
Union Station

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Discussion of the Roadmap Themes

1. Governance
2. Standards Adoption
3. Regulatory Process
4. Data Harmonization
5. Third Party Entities

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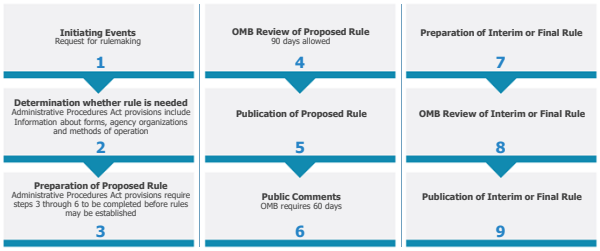
Federal Regulatory Process



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NCVHS Role in the Regulatory Process

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

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Theme 3: Regulatory Process

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

QUESTIONS:

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

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CIO Forum

BREAK

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Discussion of the Roadmap Themes

1. Governance
2. Standards Adoption
3. Regulatory Process
4. Data Harmonization
5. Third Party Entities

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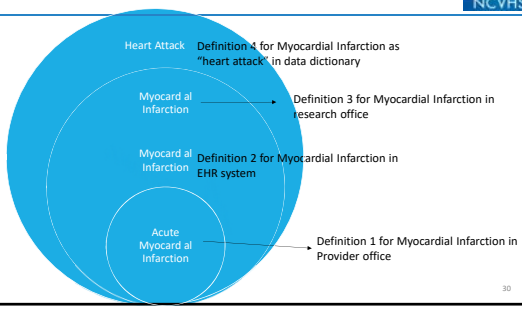
Theme 4: Data Harmonization



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Theme 4: Data Harmonization - levers

US Data Harmonization Levers:

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

*ONC is the Office of the National Coordinator

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Theme 4: Data Harmonization

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

QUESTIONS:

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

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Discussion of the Roadmap Themes

1. Governance
2. Standards Adoption
3. Regulatory Process
4. Data Harmonization
5. Third Party Entities

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Theme 5: Inclusion of Third Party Entities

A Covered Entity is one of the following:

A HEALTH CARE PROVIDER	A HEALTH PLAN	A HEALTH CLEARINGHOUSE
This includes providers such as: • Doctors • Clinics • Psychologists • Dentist • Chiropractors • Nursing Homes • Pharmacies ...but only if they transmit any infromation in an electronic form in connection with a transaction for shich HHS has adopted a standard.	This includes: • Health insurance companies • HMOs • Company health plans • Government programs that pay for health care, such as Medicare, Medicaid, and the military and veterans health care programs	This includes entities that process nonstandard health information they receive from another entity into a standard (i.e., standard electronic format or date content), or vice versa.

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Who is NOT A Covered Entity…

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

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Theme 5: Inclusion of Third Party Entities

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

QUESTIONS:

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

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PUBLIC COMMENT PERIOD

To Submit Public Comment to the Committee:

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

Please include your name, title, and organization

CIO Forum

WRAP UP

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Next Steps

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

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