National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards Predictability Roadmap Hearing

Defense Health Agency (DHA) Response to NCVHS Predictability Roadmap Recommendations, and Related Panel Participation

For: December 12 – 13, 2018

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I. **Introduction**

    A.   Thank you for inviting me to present today about the Predictability Roadmap, on behalf of the Military Health System (MHS) and as a representative of the Defense Health Agency. My name is Danny Sawyer and I am the Chief of Business Information Management and HIPAA Transactions, Code Sets, and Identifiers Lead for the Defense Health Agency (DHA).

    B.   A Quick Background on DHA: The Defense Health Agency is within the United States Department of Defense (DoD). We function as both a healthcare provider entity and a health plan and payer. Our beneficiary population is about 9.5 million people; including but not limited to active duty, dependents of active duty, retired military personnel, and dependents of retired military. The DHA works to ensure compliance with the HIPAA Transactions, Code Sets, and Identifiers requirements where they apply to our military treatment facilities (MTFs) and our TRICARE Health Plan.

    C.   The DHA also participates in and monitors the development of standards to ensure DHA interests and business processes are represented and considered; while also seeking to contribute to and benefit the broader U.S. healthcare industry use of the standards.

II. **Position on the Predictability Roadmap**

    A.   We specifically support predictability roadmap recommendations that provide for a smaller number of changes per version, with those smaller versions adopted and implemented more frequently ("smaller/faster").

    B.   Benefits of "smaller/faster" are expected to include predictability (i.e., to have adoptions and implementations on a defined and regular schedule), providing the ability to adapt more quickly to accommodate changes in U.S. healthcare insurance requirements, and to improve the ability to plan and budget for resources (for example: I can't submit for budget resources to implement HIPAA initiatives until I have a Final Rule in hand. As a result, HIPAA initiatives can't be planned during development of 5 year budget plans, but rather have to be funded in year of execution).

    C.   We recommend an effort to fix and use existing organizations (e.g., the DSMO) and processes in a "smaller/faster" construct, rather than disbanding or dismantling existing and starting from scratch.

    D.   All components of the start-to-finish (end-to-end) standards development, adoption, and implementation process need to be streamlined, adjusted, and institutionalized to support the "smaller/faster" construct. This includes the Federal Government adoption process.

    E.   See Appendix A for MHS' perspectives about each recommendation

    F.   See Appendix B for more specifics related to "smaller/faster"

III. **Possible Impacts and Suggestions for Improvement**

    A.   Here are some recommendations to consider that could help improve the current standard development, adoption, and implementation process to achieve greater process efficiencies. (See Appendix B for more information/talking points)

        1.   *Adopt a prioritization strategy*: Lack of change request prioritization has delayed review process in the past.

        2.   **"*Encourage greater industry input:*** As the need for Health IT support grows, it is essential to ensure industry functional user needs are identified and their priorities are considered throughout the standards development cycle.

        3.   *Utilize an Agile-like or incremental process:* Agile AND nimble/flexible processes are necessary to meet emergent industry needs, which might be adapted or created due to national policy changes." (Mr. Chris Brancato, contracted subject matter expert to DHA)

        4.   *Perform detailed risk analyses so that mitigation strategies are in place:* SDOs or DSMO might need to evaluate the risks (to their organization and the industry) of any changes to the change request review process. This suggestion is essential if the SDOs adopt a change request prioritization strategy or incorporate agile-like processes.

    B.   Possible opportunities of the predictability roadmap recommendations:

        1.   Regular re-targeting and prioritizing of high priority work

        2.   Increased efficiency with streamlined and standardized processes

        3.   Increased predictability of releases to improve estimates and plan for budgetary needs

IV. **Thank you**

    A.   Thank you. It's been my pleasure to present this information to you today on the topic of the Predictability Roadmap, and on behalf of the Defense Health Agency. We are a Medically Ready Force and a Ready Medical Force. Thank you.

Appendix A: NCVHS Recommendations and DHA Perspective

V.   NCVHS Questions to Consider -- Panelist Discussion, questions to discuss during the hearing:

In general,

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

B. What additional recommendations are critical to achieve predictability? And specifically,

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

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

VI.   NCVHS Roadmap Outcome Goals

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

Goal 1's anticipated date range is 2019 – 2020. The recommendations associated with goal 1 are the following:

1. HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. All appropriate means available should be used to share (de-identified) information about complaints to educate industry.
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 about the status of complaints should be publicized to the extent permitted by the law.
7. HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.

B.   Goal 2: Policy levers will successfully support industry process improvement changes.

Goal 2's anticipated date range is 2020 – 2021. The recommendations associated with goal 2 are the following:

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

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.

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.

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).

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

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

Goal 3's anticipated date range is 2021 – 2024. The recommendations associated with goal 3 are the following:

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.

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.

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.

12. HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. The purpose of this recommendation is to enable early adoption and innovation by willing trading partners and be consistent with the existing ONC policy framework.

VII. Defense Health Agency (DHA) Responses to the Recommendations

#	NCVHS Recommendation	MHS Response (responses *italicized*)
1	HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. All appropriate means available should be used to share (de-identified) information about complaints to educate industry.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. We do not see this as a factor in what we understand the "predictability roadmap" to be.* **2. What additional recommendations are critical to achieve predictability?** *The recommendation is fine in a different context.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Informs Industry of incorrect practices or processes* **4. Are there potential unintended consequences from this recommendation? What are they and how can they be mitigated with modifications to this recommendation?** *Yes. Don't see how this recommendation relates to improvement of predictability of developing, adopting, and implementing healthcare industry EDI-related standards, but would more so improve appropriate use of the standards. Mitigate by applying this recommendation in a different context and setting.*
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 about the status of complaints should be publicized to the extent permitted by the law.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. We do not see this as a factor in what we understand the "predictability roadmap" to be.* **2. What additional recommendations are critical to achieve predictability?** *The recommendation is fine in a different context.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Informs Industry of incorrect practices or processes* **4. Are there potential unintended consequences from this recommendation? What are they and how can they be mitigated with modifications to this recommendation?** *Yes. Don't see how this recommendation relates to improvement of predictability of developing, adopting, and implementing healthcare industry EDI-related standards, but would more so improve appropriate use of the standards. Mitigate by applying this recommendation in a different context and setting.*
7	HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes, this will be essential when we get to a process of more frequent adoption and implementation of standards.* **2. What additional recommendations are critical to achieve predictability?** *We suggest this recommendation appears to be primarily a function of WEDI.*

#	NCVHS Recommendation	MHS Response (responses *italicized*)
		3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation? *The healthcare industry current and future users of EDI-related standards would be better informed, and results should be improved use, compliance, and benefit for end users.* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Yes. This recommendation would not, of course, ensure full and proper use of the standards. Will need to keep guidance at a common level, as adoption strategies and tactics may vary in organizations depending on size, complexity and capabilities, the hardware and software, and other factors.*
3	HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. We rather recommend specifically identifying, documenting, and fixing (addressing) gaps in current structure and processes.* **2. What additional recommendations are critical to achieve predictability?** *We would recommend a way to modernize and streamline the DSMO function and processes to support and enhance a predictable model of EDI-related standards development, adoption, implementation, and compliance.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Perceived value of the stated recommendation appears to be that a new entity will work better than the current entity. Unknown as to if or what improvements would result.* **4. Are there potential unintended consequences from this recommendation? What are they and how can they be mitigated with modifications to this recommendation?** *Yes. We recommend improving DSMO instead of disbanding to save time and funds. Standing up a new entity would likely add complexity to the standards process; it can take significant time and a significant level of effort to stand up a new entity and new processes; and without assurance that the new entity will work better.*
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.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. We rather recommend specifically identifying, documenting, and fixing (addressing) gaps in current structure and processes. Funding is one of the gaps which should be addressed.* **2. What additional recommendations are critical to achieve predictability?** *Modernize and streamline the DSMO function and processes to support and enhance a predictable model of EDI-related standards development, adoption, implementation, and compliance. Consider that national healthcare industry EDI standards development, adoption, implementation, and compliance is a private/public partnership and that each needs to contribute to meet needs and demands of the marketplace.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Perceived value of the stated recommendation appears to be that a new entity will work better than the current entity. Unknown as to if or what improvements would result.*

#	NCVHS Recommendation	MHS Response (responses *italicized*)
		4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation? *Yes. The new entity would conflict with DSMO's purpose and function. We recommend identifying what needs to be fixed (what are the gaps) with the current entities and processes and then applying those fixes (including how to appropriately fund as required).*
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.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. We rather recommend specifically identifying, documenting, and fixing (addressing) gaps in current structure and processes. Authority is one of the gaps which should be addressed.* **2. What additional recommendations are critical to achieve predictability?** *Modernize and streamline the DSMO function and processes to support and enhance a predictable model of EDI-related standards development, adoption, implementation, and compliance.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Perceived value of the stated recommendation appears to be that a new entity will work better than the current entity. Unknown as to if or what improvements would result.* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Yes. Consequences may include increased risks and resources (including time resource) to replace rather than fix and enhance DSMO. We recommend improving DSMO instead of replacing. This would give DSMO, as an existing jumping off point, the opportunity to enhance or create faster and effective processes.*
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).	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes, this would improve predictability* **2. What additional recommendations are critical to achieve predictability?** *All predecessor steps need to be synchronized, as well. The entire development, adoption, implementation, and compliant use process needs to be organized and managed to work effectively for smaller changes, made more frequently, and on a predictable schedule. Also, this "should" recommendation will need to be institutionalized in writing, with appropriate provisions and conditional statements.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Contributes as being a key factor and piece of a predictable and repeatable process for developing, adopting, implementing, and compliance with standards.* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Yes. All cylinders need to be firing and working together in a predictable, managed, and synchronized way. Need to allow for some loose coupling (not too tight of tolerances) while also working to maintain a continuous flow and process.*
9	HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes.* **2. What additional recommendations are critical to achieve predictability?** *(No response)*

#	NCVHS Recommendation	MHS Response (responses *italicized*)
		3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation? *Value proposition is that work to be done that is required, within HHS would be appropriately resourced.* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Not anticipated, as being appropriately resourced seems to be appropriate.*
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.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes.* **2. What additional recommendations are critical to achieve predictability?** *Must ensure management and control of the size (depth and breadth) of incremental updates. Must ensure management and control of backlog and pipeline future changes for flow and necessity. This will require increased and ongoing communication and collaboration to synchronize and harmonize.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *The value is having a known (predictable) and repeatable process cycle which will allow for planning, budgeting, and continuous execution. Value is smoothing out the process and making the process ongoing and regular.* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Yes. These recommendations would affect the workflows of the SDOs, ORAE, NCVHS, and HHS and may require resource adjustments to ensure quality is not lost to quantity. There may be unintended risks with resources or quality of work. To mitigate consequences, establish a process to prioritize and limit updates to standards at the SDO level, making certain timelines can and will be met. Assess risks of the potential process changes, test (dry-run), and ensure process mitigation strategies already in place.*
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 NCVHS, and if updates are available.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes.* **2. What additional recommendations are critical to achieve predictability?** *We recommend ensuring semantic interoperability (message sent is understood by the receiver, in the context and meaning it was intended by the sender) of terminology and words used. Need to define, "incremental updates" as it could be argued and perceived we already have incremental updates, though large and every many years.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *The value is having a known (predictable) and repeatable process cycle which will allow for planning, budgeting, and continuous execution. Value is smoothing out the process and making the process ongoing and regular.*

#	NCVHS Recommendation	MHS Response (responses *italicized*)
		4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation? *Yes. The entire process and all the entities involved and affected will have to adapt. The change may not be easy for some (possibly small provider entities), and nation-wide roll-out and implementation of the changed process needs to be well thought out, planned, and implemented.*
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.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *No. A floor may likely reduce predictability.* **2. What additional recommendations are critical to achieve predictability?** *Predictability needs to be predictable. Not having a ceiling implies that anything above the floor is acceptable, which seems to be unpredictable. Recommend that this recommendation (shown as #11) can be in conjunction with recommendation #12, so a regularly and frequently updated floor is put in place while also allowing for trial use testing of potential future upgrades/enhancements between willing trading partners.* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Perceived value of the stated recommendation appears to be that "Early adopters could move ahead and innovate, and later adopters could benefit from their experience" (NCVHS'CIO Forum Report)* **4. Are there potential unintended consequences from any of this recommendation? What are those and how can they be mitigated with modifications to this recommendation?** *Yes. Consequence may be increase in unpredictability. "Any optionality around a standard automatically creates an obligation on other parties to support and maintain multiple versions of the standards" (NCVHS' CIO Forum Report)*
12	HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. The purpose of this recommendation is to enable early adoption and innovation by willing trading partners and be consistent with the existing ONC policy framework.	**1. Would this recommendation improve the predictability of the adoption of administrative standards and operating rules?** *Yes. This may provide a benefit above an established floor, as long as for trial use testing and between willing trading partners.* **2. What additional recommendations are critical to achieve predictability?** *(No Response)* **3. What is the value proposition of this recommendation and what improvements to the current state do you believe will arise from this recommendation?** *Voluntary use of new standards would help with spreading out the adoption of new standards. Industry will have more flexibility to use a standard when it is needed instead of waiting for it to go through the rule making process, which has an unpredictable end.* **4. Are there potential unintended consequences from this recommendation? What are they and how can they be mitigated with modifications to this recommendation?** • *This recommendation may lead to more inappropriate and inconsistent use of the standards. It may be hard for covered entities, business associates, or others since there would be variation in the standards being used. There is not a way to enforce compliant use of a voluntary standard.* • *Mitigation may include requiring reporting by entities employing (using) trial use testing so HHS knows who is doing what, and so results can act as feedback toward development of future adopted versions.*

Appendix B: Supporting Information for DHA recommendations to NCVHS

VIII.   Adopting a Prioritization Strategy

Implementing a change prioritization strategy will classify the numerous change requests according to a set of criteria that are relevant to current and projected business needs. While most change requests may be valid, not every change request will have the same priority. For instance, requests may be categorized and balanced based on time sensitivity, industry drivers, complexity, cost, or other factors. Categorizing requests and ranking them will allow the industry and SDOs to focus on the requests that have priority according to established criteria. This strategy will also help entities involved with transaction development, adoption, and implementation processes to better target and focus on what really needs to be in upcoming transaction versions.

IX.   Adopting an Incremental Process for Guide Release and Adoption Cycles

Adopting an incremental process for the HIPAA transactions update, release, adopt, and implement process will keep versions smaller and more frequent; which will help accommodate evolving needs of the U.S. healthcare industry while providing the benefits of "predictability". An incremental process will allow for shorter development cycles and less change requests per cycle. Breaking down the processing cycles into smaller development windows would allow the SDOs to release guides more frequently. Using an incremental process and a prioritization strategy concurrently, the NCVHS and SDOs could designate a period of time for each new version to be ready and entered into the release, adopt, and implement process. A change request backlog will have to be maintained, prioritized, and evaluated for what will be included into the next and future cycles. This strategy would allow for fewer requirements per cycle, resulting in shorter review periods and faster implementations. With fewer requirements and a strategic timeframe, the SDOs and other entities involved will be able to execute based on shorter, more predictable cycles.

X.   Risks (Anticipate and Mitigate)

At a high level, implementation of a new process includes the risk of not proactively managing the change, including not getting buy-in from stakeholders, and the need for training. There are also risks associated with how the change is executed (e.g., single large roll out or phased approach). An analysis would need to be done to determine the appropriate strategy given the available time and resources. Risks should always be logged and evaluated prior to executing the change so that the mitigation strategies are in place to help avoid the risks from becoming issues, and mitigations are ready for when a risk becomes an issue. More detailed risk analyses are required.

XI.   Effect on the Industry

The time it currently takes to update, release, adopt, and implement a transaction version for HIPAA compliant use, lags behind the evolving needs of the industry. On July 7, 2009, representatives from the Standards Development Organizations (SDOs) published an update to an earlier white paper titled, "Proposal for the Modification of the HIPAA Transaction Implementation Specifications Adoption Process." This paper explained why improvements were needed in the adoption process for HIPAA standards and what needs were not being met in the health care industry under the current processes. The

authors wrote: "the net impact to the health care industry of an unpredictable schedule for both the update and adoption of standards negates the ability to conduct effective strategic planning and budgeting for staffing, new technology, or innovation." Of course, we anticipate that there will be costs for transition to, and compliance with, the Predictability Roadmap. Related costs for small covered entities (providers, health plans/payers, or clearinghouses) to keep up with smaller but more regular and frequent implementations have to be considered and reasonably addressed.