



December 4, 2018

National Committee on Vital and Health Statistics  
Subcommittee on Standards  
3311 Toledo Road  
Hyattsville, MD 20782-2002

Dear Ms. Goss and Mr. Coussoule,

I am writing on behalf of the Workgroup for Electronic Data Interchange (WEDI), the nation's leading nonprofit authority on the use of health IT to create efficiencies in health care information exchange. We want to commend you for the work the National Committee on Vital and Health Statistics (NCVHS) has undertaken over the past eighteen months which has resulted in the Predictability Roadmap Draft Recommendations. These efforts focused on identifying ways to make the process of development and adoption of standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) timelier and more efficient.

In response to the draft recommendations presented at the September 14, 2018 NCVHS meeting, WEDI held a Policy Advisory Group (PAG) to provide a forum for health care industry stakeholders to convene and discuss in detail the draft recommendations, calls to action and measurements identified by the NCVHS. The outcome of the discussions is a set of recommendations for moving to a more predictable development and adoption process of standards and operating rules, so that Administrative Simplification can be better achieved. The comments were reviewed subsequently and approved by the WEDI Executive Committee on November 27<sup>th</sup>. As WEDI recommendations, and on behalf of the WEDI Board of Directors, I send them to you for your review and consideration.

As NCVHS determines the best pathway for DSMO modernization pursuant to Recommendations 4 and 5, WEDI recommends that any new or modified entity should include all stakeholders and be capable of bringing together these groups to establish oversight of the standards development process to ensure efficiency, effectiveness, consistency, and timely improvement in accepting new versions of standards and operating rules. It will also be important for HHS to provide the financial and/or operational support to this process to ensure success.

WEDI was established in the mid-90s with such a governing structure and welcomes the opportunity to become the entity tasked with facilitating an effective intra-industry solution. As an advisor to the Secretary of the Department of Health and Human Services (HHS) and a multi-stakeholder organization comprised of payers, providers, vendors and SDOs, WEDI currently offers the stewardship structure for intra-industry collaboration. WEDI has proven leadership engaging the industry to address the most impactful changes and implementations of our time, including the National Provider Identifier (NPI), health plan ID card, ICD-10, National Health Plan Identifier (HPID), attachments, and prior authorization. We offer our expertise and multi-stakeholder input to be the entity that ensures the advancement of standards and operating rules.

WEDI appreciates the opportunity to collaborate with the NCVHS and stands ready to assist in clarifying the attached as needed. Charles Stellar, President and CEO of WEDI, or I would be pleased to answer any questions pertaining to WEDI's recommendations, which are enclosed herein.

Sincerely,

A handwritten signature in cursive script that reads "Laurie Darst".

Laurie Darst  
Chair, WEDI

cc: WEDI Board of Directors



## **About WEDI**

WEDI was formed in 1991 by then-Secretary of HHS Dr. Louis Sullivan. Named in the bipartisan Kassebaum-Kennedy HIPAA legislation as an advisor to the HHS Secretary, we have worked closely with every Administration. WEDI is a multi-stakeholder organization, whose membership includes ambulatory providers, hospitals, health systems, health plans, health information technology standards organizations, health care information technology vendors and government entities. We continue our role of working with both the public and private sectors to reduce health care administrative costs and facilitating improvements in information exchange through voluntary collaboration.

WEDI has been an instrumental force in establishing and later enhancing HIPAA standards for electronic administrative transactions, data privacy and data security; driving down the costs associated with manual, paper-based transactions and increasing the confidentiality of patient information. Our robust workgroups, white papers and other industry guidance, informative conferences, surveys and online webinars provide critical industry education and foster collaborative partnerships among diverse organizations to solve practical, real-world data exchange challenges.

We have also worked closely with both the Centers for Medicare & Medicaid Services and the Office for Civil Rights on industry outreach and education on critical HIPAA issues.

**Workgroup for Electronic Data Interchange (WEDI)**  
**WEDI Policy Advisory Group (PAG)**  
**NCVHS Predictability Roadmap Draft Recommendation Comments**

**As approved by the**  
**WEDI Executive Committee on November 27, 2018**

This document contains comments developed by the WEDI Policy Advisory Group (PAG) in response to the National Committee on Vital and Health Statistics (NCVHS) Predictability Roadmap Draft Recommendations and questions posed by the NCVHS Subcommittee on Standards to industry stakeholders.

Note that WEDI organized the recommendations and our responses according to the implementation timeframes which are not necessarily in numerical order.

**Roadmap Recommendation 1:** HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry.

**WEDI Response 1.1: WEDI supports** the concept of greater transparency, to include better context around the specific nature of the compliance review. After the enforcement action, the entities involved should be identified to the public.

WEDI encourages additional work be conducted to analyze compliance review data into helpful industry guidance. The focus should be on improving understanding across the industry regarding implementation and ongoing support of transactions and operating rules and the ability to track compliance issues. The goal should be to use compliance reviews to help shape industry best practices which ultimately creates greater administrative simplification.

**Roadmap Recommendation 2:** HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.

**WEDI Response 2.1: WEDI supports** HHS complying with the statutory requirements for handling complaints against non-compliant covered entities and processing enforcement actions against those entities and their business associates.

Greater transparency into the CMS process for handling complaints also feeds into the more helpful industry guidance noted above.

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

**WEDI Response 7.1: WEDI recommends** HHS provide guidance more directly around operational implementation and this guidance should be issued more proactively as industry education. HHS, however, should utilize the expertise of the entities that are responsible for the standards and operating rules in developing guidance on the standards and operating rules.

The goal of all these activities should be encouraging, promoting and enforcing broad-based adoption by all stakeholders (including all participants, commercial and government) in the industry regarding operating rules and standards.

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

**Roadmap Recommendation 4:** HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities.

**Roadmap Recommendation 5:** HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.

**WEDI Response 3.1/4.1/5.1: WEDI recommends** that if the DSMO is modernized, then the revised DSMO should be responsible for oversight and stewardship to improve the process of accepting new versions of standards and operating rules in a more timely and consistent manner.

**WEDI Response 3.2/4.2/5.2: WEDI recommends** that if there is a new entity, then it should be a coordinating entity responsible for the effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting.

Regardless of the outcome, ensuring there are no gaps created through any changes that would impact, i.e. hinder, the forward movement of any standards and operating rules is critical.

**Roadmap Recommendation 8:** HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with what is permitted in §1174 of the Act).

**WEDI Response 8.1: WEDI recommends** that HHS expedite the publishing of regulations once a recommendation has been 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).

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

**Recommendation 9.1: WEDI recommends** that the division(s) responsible within HHS for HIPAA have their resources increased to facilitate the timely review, maintenance and adoption of national standards, including education and enforcement.

**Roadmap Recommendation 6:** SDOs and ORAE should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years. Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCHVS.

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

HHS should adopt the NCVHS recommendations on a regular schedule.

**WEDI Response 6.1: WEDI supports** Recommendation 6 with the caveat that there needs to be a business need and cost analysis for updates to standards and operating rules.

Implementing new standards or operating rules or making updates to existing implementations comes with associated costs to implementers. These costs must be weighed against the resulting benefit. Prior to implementation of any new standard or operating rule, the business need must be established and cost analysis completed for any updates to standards and operating rules.

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

**WEDI Response 10.1: WEDI agrees** with Recommendation 10 with the caveat that there may be times that the industry may need to have the flexibility to make updates outside of the regulatory process. For example, the CORE-Required Code Combinations that are within Operating Rule 360 *Uniform Use of CARCs and RARCs (835) Rule*.

Our responses on Recommendations 6 and 8 are also relevant to Recommendation 10.

**Roadmap Recommendation 11:** HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation.

**Roadmap Recommendation 12:** HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.

**WEDI Response 11.1/12.1: WEDI supports** Recommendations 11 and 12 with the caveat that such implementations must occur between voluntary trading partners. The definition of voluntary trading partner is critical to the success of this recommendation (i.e. both parties in agreement without any undue pressure to be a voluntary party).

The desire and need for innovation should not create the situation where stakeholders are required to implement multiple, different versions of the same standard.

**WEDI Board Response:** The WEDI Board believes that the definition of floor (baseline) is critical to fully understanding Recommendation 11. The ability to adopt a baseline can have unintended consequences. The Board recommends that NCVHS solicit industry input and further clarify the definition of a floor (baseline).

**Call to Action A:** Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases.

**WEDI Response A.1: WEDI is willing and able to convene all** impacted stakeholders to identify best practices for mitigating barriers so that stakeholders can implement the effective use of the standards and operating rules. WEDI Workgroups and Subworkgroups actively identify best practices in an effort to determine current critical issues. This work is typically built upon prioritizing use cases, which is a component of best practice identification.

**Call to Action B:** The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.

**WEDI Response B.1: WEDI thanks** the NCVHS for recognizing the important role WEDI plays in the industry and we will continue to identify issues and solutions through our workgroup and committee structure. In addition, WEDI will continue to publish white papers advising on agreed upon policy implications and best practices related to the use of HIPAA standards and operating rules.

**Call to Action E:** SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.

**WEDI Response E.1:** WEDI believes that this collaboration exists today but strongly supports increased collaborative and innovative engagement with all stakeholder groups. We encourage the SDOs to explore and identify new and innovative opportunities to increase the level of participation from those currently under represented.

**Call to Action F:** Leadership from the public and private sector should commit to membership in Standards Development Organizations, assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs.

**WEDI Response F.1:** WEDI believes that through support from HHS, leadership from the public and private sector should commit to membership and participation in the SDOs

It would be beneficial to all stakeholders if the government encouraged greater participation in SDOs.

**Call to Action C:** HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3rd parties to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.

**WEDI Response C.1:** WEDI does not support this recommendation as drafted.

**WEDI Response C.2:** WEDI recommends that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

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

**WEDI Response G.1:** WEDI does not support this recommendation as drafted.

**WEDI Response G.2:** WEDI recommends that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

**Call to Action D:** HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.

**WEDI Response D.1: WEDI recommends and fully supports** that HHS apply any and all available resources to effectively quantify the full value of administrative simplification and automation and to leverage the existing industry efforts to achieve this goal.

**Call to Action H:** HHS should continue to publish a universal dictionary of clinical, administrative and financial standards that are or will be available for use, e.g. the ONC Interoperability Standards Advisory (ISA).

**WEDI Response H.1: WEDI recommends** HHS utilize and maintain the ONC Interoperability Standards Advisory (ISA), which includes the clinical, administrative and financial standards already.

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

**WEDI Response M1.1: WEDI does not support** this recommendation as drafted.

**WEDI Response M1.2: WEDI recommends** that NCVHS hold a hearing to further clarify this recommendation and solicit industry input.

**Measurement M2:** HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance.

**WEDI Response M2.1: WEDI supports** the recommendation that metrics be established for the new entity and that these metrics be developed by HHS after appropriate industry consultation. As well, we recommend that one of these metrics be a measure of efficiency. Understanding how a new process contributes to more efficient development and implementation for the industry is key to its success.

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

**WEDI Response M3.1: WEDI recommends** that NCVHS continue to conduct stakeholder hearings and seek industry input on a regular basis to continually evaluate the progress and success of the Predictability Roadmap.