



# NCVHS

## National Committee on Vital and Health Statistics

February 13, 2019

The Honorable Alex Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

### **Re: NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry**

Dear Secretary Azar:

This letter includes significant recommendations from the National Committee on Vital and Health Statistics (NCVHS) to reform the national standards process for the health care industry. These recommendations align with the Department's goals of promoting interoperability and reducing provider and regulatory burden. They also support the President's intention to roll back regulatory red tape and reform outdated and complicated rules and guidance. Certain regulations and current federal processes governing industry standards impose barriers to the convergence of administrative and clinical data exchange. If not improved, these will continue to create burdens and impede true interoperability. We provide specific solutions for administrative transaction standards and operating rules,<sup>1</sup> which apply to providers, health plans, and health care clearinghouses.

NCVHS is the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, and national health information policy, including the adoption and implementation of transaction standards, unique identifiers, operating rules and code sets adopted under the Health Insurance and Portability Act of 1996 (HIPAA)<sup>2</sup>. The five (5) recommendations that follow are the result of NCVHS' work over the past two years to evaluate barriers to the efficient and timely update and adoption of transaction standards and operating rules. To address these longstanding barriers, the Committee outlined a "Predictability Roadmap" to support industry's need for a clear and explicit pathway for standards that keep pace with changing business needs and opportunities to innovate. This work involved engaging with health care providers, health plans (private, State and Federal),

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<sup>1</sup> Transactions include claims, claim status, eligibility for benefits, prior authorization etc. Operating rules are the business rules to support standards such as use of the Internet, real time, response time (20 seconds) etc.

<sup>2</sup> The original HIPAA legislation (P.L. 104-191).

clearinghouses, Standards Development Organizations (SDOs), practice management and Electronic Health Record systems (EHR) vendors, pharmacies, health information exchanges (HIEs), and our Federal partners, such as the Office of the National Coordinator (ONC).

The recommendations, described in more detail on the following pages, address policy and procedural actions that the Secretary can take to materially improve predictability. The evidence shows that interoperability between administrative and clinical standards and the appropriate pace of adoption for useful transaction standards cannot be achieved by following current processes. Policy changes have not kept up with the technology; and over time, the constraints and complexities of the HIPAA regulatory process have become an impediment to progress.

Through its research, NCVHS also identified actions that SDOs and other stakeholders should take to contribute toward improvement; however, this letter focuses on the important Secretariat actions essential to improving adoption and use of transaction standards and operating rules to realize real efficiencies for health care administrative processes.

**Recommendation 1.**

Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.

**Recommendation 2.**

Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.

**Recommendation 3.**

Improve the visibility and impact of the administrative simplification enforcement program.

**Recommendation 4.**

Provide policy-related guidance from HHS regarding administrative standards adoption and enforcement.

**Recommendation 5.**

Re-evaluate the function and purpose of the Designated Standards Maintenance Organizations.

Background

HIPAA was enacted when the industry was transitioning from paper to electronic data interchange. At that time, its primary goals were to standardize and encourage the use of electronic transactions, to help the health care industry control administrative costs, and to protect the confidentiality and security of health care information. After 22 years, HHS can point to important achievements. Many in the industry agree that standardization is necessary, and that administrative simplification has made a quantifiable difference in the volume of electronic exchange. However, more work remains to improve system efficiencies. As industry and technology have evolved, some aspects of the process to develop and adopt standards

have become impediments to, rather than drivers for innovation. Simply stated, the processes take too long, contain unnecessary redundancies, are often opaque, and lack accountability to those impacted.

For example, while there has been a nationwide uptake on the usage of the electronic transactions for medical and pharmacy claims, eligibility and payment, the industry has not achieved benefits from other critical transaction standards, such as those supporting prior authorizations and attachments. This is due in large part to problems with the regulatory process and lack of regular communication from HHS. For both pharmacy and non-pharmacy standards, either some of the current standards development or federal rulemaking processes have impeded agile implementation of programmatic or system updates essential for providers and health plans to keep pace with value-based purchasing arrangements, opioid epidemic-related strategies and other innovation opportunities. These missed opportunities, if addressed, could have reduced burden, decreased costs, and improved care outcomes. NCVHS does not believe the current process is effective for either HHS or its stakeholders.

### Recommendation Development Methodology

Beginning in May 2017, the Committee conducted a series of interviews, workshops, forums, and hearings, and concluded our assessment with a final hearing on December 12 -13, 2018. In September 2018, the Committee released draft recommendations. These were posted for public comment and were the focus of the December 2018 hearing, where nearly 40 organizations and individuals representing the full range of stakeholders submitted oral or written testimony.

The final recommendations offered in this letter reflect the Committee's highly collaborative and transparent process. Each is actionable and supports the fundamental changes necessary to improve both the adoption and implementation of the administrative transaction standards and operating rules. The first three recommendations address predictability and pace of the standards adoption process. The last two recommendations address optimization of the standards environment to set the stage for the harmonization of administrative, i.e., HIPAA and the Affordable Care Act of 2010<sup>3</sup> (ACA), and clinical, i.e., HITECH<sup>4</sup> standards.

### Recommendations

#### **Recommendation 1. Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.**

Based on NCVHS' assessment, the Committee finds that the current regulation and proposed and final rule-making process must be modernized. HHS should mitigate the restrictions that prevent industry from using updates to a transaction standard or operating rule. The Committee suggests that HHS explore and implement ways to support use of updated

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<sup>3</sup> Patient Protection and Affordable Care Act of 2010 includes section 1104 for Administrative Simplification.

<sup>4</sup> Health Information Technology for Economic and Clinical Health Act of 2009.

transaction standards and operating rules when updates to named standards become available and industry supports the need and timing to upgrade. This would preclude the need for some regulations and mitigate the problem of delayed regulations. Instead of major updates every 5-10 years, HHS could enable smaller, more easily implemented updates supported by the industry. This would result in greater predictability and responsiveness to industry needs.

Based on consistent industry input, NCVHS has concluded that the current HIPAA regulations or rule promulgation process in this context are problematic and do not benefit HHS or its stakeholders. NCVHS recommends that HHS handle HIPAA and ACA transaction standard and operating rule updates in the same way it allows for some code set updates – whereby periodic, routine/known updates for code sets released by the responsible organization are automatically implemented. Today, versions of transaction standards (e.g., the X12 837-medical claim transaction Version 5010 or its equivalent NCPDP pharmacy claim Version D.0) are adopted by rulemaking with a proposed and final rule. Any update to a transaction, no matter how minor, currently requires rulemaking because it is considered a “modification.” The Committee recommends that subsequent updates to an adopted transaction standard (e.g., the claim transaction under the current NCPDP or X12 standard), or operating rule *not* require rulemaking. Instead, HHS could change the regulatory language to follow the approach used by HHS to handle updates on regulations for medical code sets, i.e., using the “as maintained and distributed” language of §160.1002 that allows the curating authority to determine when updates are necessary. Also, there should be a new process in which a finalized update for a specific transaction or set of transactions from the SDO or operating rule authoring entity would be cleared by an industry steering body (see Recommendation 5 regarding the evaluation of the Designated Standard Maintenance Organizations or “DSMOs” below), and implemented on an agreed upon timeline. HHS would publish guidance rather than a regulation based on information from the SDO and industry steering body. In other words, after clearance by the industry steering body, HIPAA-covered entities and their business associates would implement the updated transaction on a predetermined timeline appropriate to the update. HHS would provide appropriate communications and guidance to industry. The effect of this recommendation would be to enable timely use of updated versions of transaction standards and operating rules.

The current processes for modifications to a transaction standard do not accommodate the pace at which the health care industry needs to address changes in technology, payment models, and patient care delivery strategies. The Committee understands that this recommendation may require some analysis, a change to existing regulations, definitions and processes, and potentially sub-regulatory guidance and communication. However, we believe that this strategy will not only enable greater efficiencies and lower costs for the health care industry, it will also improve efficiency for HHS and reduce regulatory burden overall.

**Recommendation 2. Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.**

HHS should enable the voluntary use of new standards or updated transactions and operating rules prior to their adoption through sub-regulatory guidance. We strongly encourage the

Secretary to promote voluntary use of not-yet adopted or exceptions to adopted standards by more widely communicating the opportunity to test alternatives under the August 17, 2000 Final Transactions Rule<sup>5</sup> §162.940, Exceptions from standards to permit testing of proposed modifications. A good example of a new standard to test for HIPAA would be the HL7 FHIR standard, currently in pilot for various use cases, including prior authorization with various public-private sector organizations, including the Centers for Medicare & Medicaid Services (CMS). Testing its use for administrative transaction purposes and additional interoperability advancements might prove beneficial as well. If necessary, HHS should update regulations to communicate that any willing group of trading partners can register a project deviating from the standard; and that deviation would automatically be approved unless the Secretary rejects the registration within a defined period. Project registrations should be publicly available and easily accessible on an HHS website.

HHS is at a pivotal juncture of protecting the basic and critical value of standardization, while enabling innovation. The Committee recognizes that clearly defined parameters have been essential to the success of industry migration into a standards-based mindset in light of the state of the industry in 1996. However, now that a standards mindset has been widely demonstrated and become embedded in health care technology, NCVHS believes that relaxing that rigidity and promoting the evaluation process will go a long way to supporting innovation and reducing the time-to-market for standards development and adoption.

**Recommendation 3. Improve the visibility and impact of the administrative simplification enforcement program.**

HHS should enhance the implementation of the complaint-driven enforcement program in accordance with its statutory authority. HHS should publish relevant data and informative guidance for industry based on complaints and enforcement actions. Industry has testified numerous times that greater transparency into the enforcement program would support improvements in implementation of the transaction standards and operating rules, aiding in the predictability of their use and reduction in cost. We outline three actions related to this recommendation:

- a. Increase transparency of the complaint-driven enforcement program. Publicize de-identified summary information about complaint content and complaint volume on a regular basis.
- b. Where the evidence warrants, HHS should prosecute enforcement actions against willfully non-compliant covered entities and their business associates. Emphasis should be on shared learning for the industry but should also carry reasonably significant penalties against willful violators. While education and encouragement should continue to be at the forefront of enforcement efforts, penalties against willful and repeat violators should be significant and made public.

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<sup>5</sup> Health Insurance Reform: Standards for Electronic Transactions; Announcing Designated Standards Maintenance Organizations; Final Rule and Notice 65 FR 50369.

- HHS should use all appropriate means available to share information about complaints to educate industry, similar to the process used by the Office for Civil Rights, which oversees enforcement for the Privacy and Security provisions of HIPAA. (See <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/numbers-glance/index.html>.)
  - HHS should publish identified information about offending parties in closed complaints, unless HHS is precluded from doing so by statute, regulation or other governing order. (See <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>)
- c. HHS should consider working with stakeholders to improve enforcement communications and the on-line complaint system. Through its work, the Committee finds that both willful and unintentional non-compliance with the current HIPAA transactions, code sets, and operating rules is widespread. However, providers have expressed concerns about potential backlash from health plans as well as the administrative complexities of using the online complaint system, the Administrative Simplification Enforcement Testing Tool (ASETT). Additional outreach and collaboration may be helpful to mitigate these barriers.

**Recommendation 4. Provide policy related guidance from HHS regarding administrative standards adoption and enforcement.**

To promote transparency and improve communication, NCVHS recommends that HHS routinely publish educational information and guidance regarding policy. HHS should consider leveraging existing complaint information to provide educational information to the extent practicable, including case studies. This would not necessitate publishing the names of organizations, but rather information about the case to help other organizations correctly use the standards and operating rules. The Committee suggests that HHS be both proactive and responsive in providing policy interpretations for industry to demonstrate transparency and mitigate confusion. Technical guidance on the use of transaction standards and operating rules must be provided by the relevant standards organizations and operating rule authoring entity (ORAE) with an official HHS endorsement rather than HHS itself authoring the guidance. Greater collaboration between HHS and these organizations, including posting information on the appropriate HHS website, would ensure that more covered entities have access to the content.

**Recommendation 5. Re-evaluate the function and purpose of the Designated Standards Maintenance Organizations.**

The enabling regulation, which named the Designated Standards Maintenance Organizations<sup>6</sup> (DMSOs), was published on August 17, 2000.<sup>7</sup> This regulation set a process in motion for these organizations to collaborate, execute a Memorandum of Understanding (MOU), develop processes to evaluate modifications to standards and make recommendations to NCVHS regarding the readiness of updated standards for adoption. The Committee believes that the DSMO steering committee has accomplished its original mission and charter intended by the early rule. Changes in the health care standards environment and the need for harmonization of administrative and clinical standards require an updated mission for the DSMO. In the Committee's assessment, a new stewardship role will necessitate participation by additional organizations and wider collaboration among the SDOs and ORAEs. NCVHS plans to develop a new project including significant cross industry engagement to inform further recommendations to help support HHS in this evaluation.

Taken together, these recommendations lay the groundwork for renewed progress toward full adoption and widespread implementation of administrative transaction standards and operating rules. As envisioned by HIPAA, getting to a seamless electronic administrative system will reduce costs and administrative burdens on covered entities. The necessary pace of adoption for valuable industry desired transaction standards such as electronic prior authorization for pharmacy and pending updated administrative transactions cannot be achieved using the current processes. NCVHS recognizes that these recommendations may represent significant policy changes; however, action by HHS will be essential for an efficient and effective roadmap for predictability and innovation.

NCVHS is available to answer questions and provide any additional information that will help underscore this critical industry need. The Committee looks forward to supporting the Department's efforts to move these initiatives forward.

Sincerely,

/s/

William W. Stead, M.D., Chair  
National Committee on Vital and Health Statistics

CC: HHS Data Council Co-Chairs

**Attachment:**

Original NCVHS draft recommendations

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<sup>6</sup> The DSMOs include the three data content committees (dental content committee of the American Dental Association, the National Uniform Billing Committee, and the National Uniform Claim Committee) named in the HIPAA Statute and three standard setting organizations: Health Level 7 (HL7), the National Council for Prescription Drug Programs (NCPDP) and X12.

<sup>7</sup> Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule and Notice August 17, 2000 65 FR 50312.

## Original NCVHS Recommendations, Calls to Action and Measurements for the Predictability Roadmap – September 2018

### Recommendations

1. HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis.
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.
3. HHS should disband the Designated Standards Maintenance Organization (DSMO).
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.
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.
6. Standards Development Organizations (SDOs) and Operating Rule Authoring Entities (ORAEs) should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years.
7. HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.
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.
9. HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.
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.



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

## Measurement

M1. HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.
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.
M3. NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.