NCVHS
National Committee on Vital and Health Statistics

March 30, 2022

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

Subject: Recommendations to Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Burden Reduction

Dear Mr. Secretary,

The National Committee on Vital and Health Statistics (NCVHS) serves as your advisory body on health data, statistics, privacy, confidentiality, information security, and national health information policy. One key role for NCVHS is to monitor the continued effectiveness of adopted health data standards pursuant to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), including standards relevant for interoperability policy.

Through its convening capacity, the Committee periodically solicits stakeholder input. Industry stakeholders recently conveyed significant concerns regarding timeliness and substance of HIPAA transaction regulations. The Committee analyzed and deliberated that industry stakeholder input, including stakeholder requests for action regarding specific approaches to improve data exchange between patients, providers, payers, public health systems and other actors in health care.[1,2]

The Committee finds that HIPAA's regulatory structure for adopting national standards for transaction and code sets is out of date. Major remediation is needed to reflect the convergence of administrative and clinical data flows that have occurred over the last decade.

The Subcommittee on Standards is developing recommendations for a new, broader framework that will converge the HIPAA administrative simplification standards with clinical, public health systems and other wellness data standards, such as for social determinants of health and sexual orientation and gender identity data. In the near term, before any structural changes are made, updates to the HIPAA and related standards are still needed and required.

NCVHS identified four recommendations, three of which are designed to meet immediate industry needs. We believe the recommendations will help achieve the top health data priorities of this

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[1] NCVHS Subcommittee on Standards Listening Session on Healthcare Standards Development, Adoption and Implementation (August 25, 2022): https://ncvhs.hhs.gov/meetings/standards-subcommittee-listening-session/
[2] NCVHS Request for Public Comment on Healthcare Standards Development, Adoption and Implementation-Instructions for Submission (June 2021): https://ncvhs.hhs.gov/wp-content/uploads/2021/06/NCVHS-SS-August-25-2021-Request-for-Public-Comment.pdf

administration, including promoting interoperability, improving health equity, reducing provider and payer burden, and achieving greater efficiencies in health care administration.

- **Recommendation 1: Publish the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR[3] standard to support Application Programming Interfaces (APIs) to automate payer and provider prior authorization workflows.**
- **Recommendation 2: Adopt a standard or standards for electronic attachments as soon as possible to meet today's business needs.**
- **Recommendation 3: HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs).**
- **Recommendation 4: Streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely.**

The Committee provides additional detail below to explain its rationale for these recommendations.

Recommendation 1: Publish the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR standard to support APIs to automate payer and provider prior authorization workflows.

Publishing the Interoperability and Prior Authorization rule is necessary to enable the use of more current standards and API technology for the efficient exchange of data. It is particularly needed for remediating major obstacles to automating prior authorization workflows. Surmounting those obstacles could mitigate barriers to patients' timely care, reduce provider burden, ensure greater transparency of payer coverage policies, and incentivize both payers and providers to use newer and more efficient technologies.

NCVHS found industry statements to be compelling, including descriptions of excessive provider burden and patient care delays that plague the prior authorization process, which often is performed manually. Prior Authorization requirements vary both across payers and within payers, depending on specific insurance contract provisions. Standards for electronic Prior Authorization (ePA) are available from designated Standards Development Organizations (SDOs).[4]

[3] Fast Healthcare Interoperability Resource

[4] "Prior authorization is a utilization review process that requires health care providers to qualify for payment by obtaining approval from health insurers before performing a service. Despite the HIPAA standard 278 transaction for the completion of prior authorization, plans vary widely on accepted methods of prior authorization requests and supporting documentation submission. The most common method remains using fax machines and contacting call centers, with regular hold times of 20 to 30 minutes. In addition, plans offering electronic methods of submission most commonly use proprietary plan portals, which require a significant amount of time spent logging into a system, extracting data from the provider's clinical system and completing idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. For each plan, providers and their staff must ensure they are following the right rules and processes, which may change from one request to the next." -- Excerpt from the American Hospital Association public comment letter to NCVHS, August 2021.

We recognize that this CMS rule would be outside of HIPAA transaction standards, but the rule is built to utilize data definitions and code sets that are contained in the HIPAA-adopted transactions, and that it includes the use of the adopted HIPAA prior authorization transaction standard. Until such time as further development refines the HL7 Implementation Guides (IGs) to be adoptable as a HIPAA standard, this extra-HIPAA adoption will offer significant value to patients, providers, and the industry in general.

Recommendation 2: Adopt a standard or standards for electronic attachments as soon as possible to meet today's business needs.

One of the most frequent and emphatic comments that the Committee heard from industry was the need for HHS to adopt a standard for electronic attachments for claims, referrals, and prior authorizations. NCVHS had recommended adoption of a standard for attachments nearly ten years ago[5] and to date the regulation remains on the semi-annual Unified Agenda of Regulatory Actions; however no Notice of Proposed Rulemaking (NPRM) has been published. Since that time, the SDOs have updated their standards to incorporate current business needs, including the HL7 Clinical Data Exchange (CDex).

We recognize that there is ongoing debate and no definitive industry consensus about the role of attachments (i.e., documents) as opposed to data (i.e., a string of data elements not structured within a document). While the vision with APIs based on FHIR seem to be driving toward more of a data-driven transaction, we see more than sufficient industry demand for a document-based attachment standard, and we do not foresee any imminent demise of the utility of digital documents. We suggest short-term publication of an attachment rule, with consideration for emerging standards based on recent input from industry and other advisory group discussions. This could add immediate value for industry and could support future actions as HIPAA's procedural requirements may be updated to allow for non-document type digital attachment data.

Recommendation 3: HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs).

HHS should permit HIPAA Covered Entities to implement API-based standards such as HL7's FHIR standards for Prior Authorization when HHS adopts FHIR standards under authorities other than HIPAA. FHIR implementations should be permitted to utilize adjunct X12 HIPAA transactions but not required to do so whenever the FHIR standard is sufficient for the FHIR IG use case(s) without the adjunct X12 transaction(s), e.g., the X12 278 Health Care Services Review (prior authorization) transaction. HIPAA was enacted 25 years ago and the initial framework for transactions it established has been made obsolete by changed business requirements, changes to health data policy, evolving technologies, the growth of Value-Based Purchasing (VBP) programs and the inclusion of new actors in the routine flows of health data. HIPAA transaction constraints are stifling innovation and progress for these evolving uses. Ways must be found to allow HIPAA Covered Entities to use newer standards, such as HL7's FHIR, both alongside, or in lieu of, the adopted HIPAA transactions. Industry-wide availability of a suite of FHIR and X12 standards will mitigate inefficiencies in transaction processing systems and reduce costs and burden especially for providers.

[5] NCVHS Letter to the Secretary, "Attachment Standards for Health Care," (June 21, 2013): https://ncvhs.hhs.gov/wp-content/uploads/2014/05/130621lt2.pdf

Recommendation 4: Streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely.

In addition to the immediate actions in the first three recommendations, a reassessment of the HIPAA rule promulgation process is needed. Given changes noted above since HIPAA became law in 1996, its framework does not reflect current technologies, business processes and the diversity of business models. Industry needs an updated and streamlined standards update and/or rule promulgation process that produces a more nimble and responsive approach to standards adoption to better support federal policy objectives, industry business requirements and emerging technologies—for example, to incorporate new business requirements such as Universal Device Identifiers (UDIs) and VBP. HHS and CMS (in collaboration with ONC and other federal agencies) could identify an approach to modernize the standards adoption process under HIPAA to: a) ensure that updated versions of adopted standards are evaluated on a regular schedule; and b) make certain that appropriate updated standards are published on a reliably predictable schedule on which industry can rely for their budgeting and implementation resource planning. The vision and recommendations laid out in the November 2020 Intersection of Clinical and Administrative Data (ICAD) Task Force report[6] could be used as a reference for the streamlining. NCVHS is developing recommendations for a new, broader framework that we hope to be able to share with you this summer.

To be clear, Recommendations 1, 2 and 3 outline actions intended to address industry's immediate needs, while Recommendation 4 outlines a longer-term planning process to update future HIPAA rulemaking.

We urge you to consider these recommendations for action. As always, the Committee stands ready to assist HHS with a more detailed explanation of the recommendations and attendant implications.

Sincerely,

/s/

Jacki Monson, J.D., Chair
National Committee on Vital and Health Statistics

CC:
Micky Tripathi, ONC
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[6] ONC HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force Report, (Nov 6, 2020): https://www.healthit.gov/sites/default/files/facas/ICAD_TF_FINAL_Report_HITAC_2020-11-06_0.pdf