July 28, 2022

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

Re: Recommendations to Modernize Adoption of HIPAA Transaction Standards

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. A key role for NCVHS is to monitor the effectiveness of adopted health data standards pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

NCVHS has regularly submitted reports and recommendations to HHS pertaining to HIPAA in fulfillment of its charge.[1] Now, in response to certain persistent industry comments over many years regarding the adoption of HIPAA standards, and in recognition of new drivers in health care data exchange, the Committee has developed additional recommendations designed to support the transformative changes occurring in health care delivery systems, payment methodologies, standards development and rule adoption. The recommendations in this letter were informed by industry input received during the NCVHS Listening Session held June 9, 2022,[2] and letters of public comment.[3]

We recognize that new drivers of transformation in healthcare data exchange are within your purview, and include:

- Federal policy furthering interoperable data exchange, health data sharing and prohibiting information blocking; and
- Convergence of clinical and administrative standards as outlined in the vision of the Office of the National Coordinator's (ONC) Health Information Technology Advisory Committee, HITAC, and the Intersection of Clinical and Administrative Data (ICAD) Task Force Vision.[4]

[1] NCVHS reports and recommendations: https://ncvhs.hhs.gov/reports/recommendation-letters/
[2] NCVHS Subcommittee on Standards Listening Session on Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0" (June 9, 2022): https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting-3/
[3] Public comments received in response to Request for Comments, August 2021: https://ncvhs.hhs.gov/wp-content/uploads/2021/08/Public-Comments-Standards-Subcommittee-Listening-Session-August-25-2021.pdf
[4] ONC HITAC ICAD final report: https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

In this letter we are submitting four actionable recommendations for HHS consideration, which are intended to bring related health information data flows and HIPAA transaction standards into optimal configuration to regain the efficiencies envisioned in the original HIPAA legislation.

The four recommendations below are followed by additional background and context. Further detail is provided in an appendix that includes the rationale that led to these recommendations, including select industry comments in support of the recommendations.

Recommendation 1: NCVHS recommends that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.

- Specifically, task an HHS office to collaborate with NCVHS to develop a systematic approach to evaluate, plan and, if proven, implement multiple-standards for HIPAA.
- In the Committee's assessment, HHS needs to ensure that regulations allow multiple standards (i.e., one, two or three implementation guides or implementation specifications) to co-exist as they are tested and used by stakeholders to meet specific business needs and addressing gaps, while preserving ongoing use of widely used existing standards.
- CMS needs to ensure compatibility with HIPAA transaction and code set legislation and regulations, including making any modifications to the regulations to ensure that they achieve the policy objectives and business needs of current data exchange, interoperability, burden reduction and information blocking.
- An example of the usefulness of a multiple standards approach is the emergence of new standards to support electronic prior authorization (ePA). A second example, as pointed out in the American Dental Association public comment letter,[5] would be to allow some stakeholders to use Application Program Interface (API) standards based on Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) while other organizations could use X12 or National Council for Prescription Drug Programs (NCPDP) standards.

Recommendation 2: NCVHS recommends that HHS enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.

- Specifically, task an HHS office to collaborate with NCVHS to develop a systematic approach to evaluate, plan and, if proven, implement multiple versions for HIPAA.
- In the Committee's assessment, HHS needs to ensure that regulations allow multiple versions of standards (i.e., one, two or three versions of implementation guides or implementation specifications) to co-exist as they are tested and used by stakeholders to meet specific business needs and address gaps, while preserving ongoing use of widely used existing versions.
- We encourage HHS to continue working with the standards development organizations (SDOs) to ensure compatibility between versions of standards, and to enable the use of new versions through the regulatory process.
- An example of the usefulness of a multiple versions approach is the Device Identifier: specialty practices like cardiology routinely implant pacemakers and would have a business imperative to implement a new version that carries the Device Identifier data while specialty practices like dermatology may never implant a device and would not need that particular upgrade: that

[5] https://ncvhs.hhs.gov/wp-content/uploads/2021/08/Public-Comments-Standards-Subcommittee-Listening-Session-August-25-2021.pdf. See page 3 of the ADA letter.

means zero upgrade conversion cost for the dermatology practice and a reduced number of end-to-end testings for each provider-payer combination.

Recommendation 3: NCVHS recommends that ONC's existing authority be expanded to facilitate the coordination of Social Determinants of Health (SDoH) data standards efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), to include a formalized public process that would include non-federal entities (e.g., State, Tribal, Local, & Territorial Governments (STLTs), private health and healthcare systems) to align national standards with evolving and complex national and local reporting and information needs.

- This public process needs to include alignment of the data reporting requirements in federal programs and agencies (e.g., HRSA, SAMHSA, CMS) and in federally-funded data modernization investments in order to advance health equity in all jurisdictions.
- An important function of this process is to support ongoing work on data content, structures, and formats between diverse data sources, and establish a process to request modifications or propose new standards for additional specific use cases to meet evolving needs.
- To fulfill the intention of this recommendation, this public process needs to include provision of technical assistance and tools to STLTs and front-line health care workers. Such tools could include, for example, a virtual EHR for testing purposes, a centrally curated repository of SDoH definitions and formats. Other activities should be identified through this process to accelerate and improve new standards implementation and the integration of SDoH capable of supporting sub-population and social risk and social vulnerability analytics.

Recommendation 4: NCVHS recommends that HHS develop and publish a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

- The framework needs to include agreed-upon definitions, metrics, templates, test methods and procedures, publication of results for estimating standards readiness, standards costs, and overall value resulting from adoption.
- In order to streamline and facilitate the regulatory impact and fiscal impact analyses required as part of CMS' rule development processes, the framework needs to include as many of the data elements as possible that CMS needs to complete its analyses.
- Frameworks need to differentiate among base standards (e.g., X12 version 008020 or HL7 CCDA), implementation guides (i.e., specific use cases utilizing only designated sub-sets of the base standard), conformance requirements, and operating rules.
- An evaluation governance structure or framework could be a partnership between the public and private sector including appropriate HHS agencies, SDO's, industry stakeholders (i.e., payers, providers, patients, developers) supported with a regulation or sub-regulatory guidance from HHS.
- Periodic review of the future evaluation framework will ensure it maintains currency.

Background / Rationale for Recommendations

Recommendation 1: NCVHS recommends that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.

When HIPAA was signed into law in 1996, it marked the first introduction of the concept of national electronic standards for the health care industry. Due to constraints of technology and lack of experience around cooperation on standards (e.g., lack of trust across the HIPAA Covered Entities), the chosen tactic of moving all industry segments forward in lockstep was the only viable alternative for that environment at the time.

By 2022, technologies have evolved significantly, and HIPAA Covered Entities have more experience dealing with each other around standards development and implementation. Regulation providing carefully selected additional flexibility to industry now appears viable as a better alternative for achieving effectiveness and efficiency than the original "everyone-in-lockstep" model.

Some of the adopted standards (e.g., the X12 837 claims) enjoy adoption rates of over 90%,[6] indicating substantial value to industry users. On the other hand, some adopted standards (e.g., the X12 278 referral, certification and authorization) have very low rates of adoption by industry.

Public testimony and NCVHS review of input received suggests that, when adopted by regulation, new technologies (e.g., API-based standards like HL7 FHIR) could be more effective and efficient for certain of the HIPAA-named transactions. The advantages of FHIR for some stakeholders can include better workforce availability, lower total labor costs, or technical tooling compatibility. This recommendation protects the installed base so as not to disrupt the use of adopted transactions that are working well for industry but provides an on-ramp for a new generation of standards to replace those that are not well adopted or utilized by industry, e.g., prior authorization or attachments.

In an August 2021 comment letter, the American Dental Association (ADA) stated that the use and exchange of health data is fundamental for providing equitable high-quality care, and that the use of FHIR can help to make this contribution. In its letter to the Committee, the ADA wrote that the X12 standards are not working for dentistry, and that FHIR-based solutions should be developed and replace the HIPAA transactions for dentistry.

Recommendation 2: NCVHS recommends that HHS enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.

Updates and adoption of some standards under HIPAA are not meeting industry business needs. Relatively simple and non-controversial updates such as increasing dollar amounts in pharmacy transactions, adding a unique device identifier field, transmitting zero-dollar claims, and including state-requested data in transactions have not yet been adopted, although recommended by NCVHS and strongly supported by industry.

Allowing multiple versions of adopted standards could reduce the implementation cost and burden for updates over time. There are practical difficulties of moving to a new version of a standard in lockstep, or demonstrating industry-wide value of an updated field that is only required by some

[6] 2021 CAQH Index: https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf

sub-segment of the industry, and a pragmatic challenge of end-to-end testing with all trading partners within the regulatorily specified transition period.

By allowing multiple versions on a use case-by-use case basis, not all trading partners would be required to upgrade. That would eliminate the cost of upgrade for entities that had no need to update. It would also reduce the number of trading partners that would have to go through end-to-end testing for the upgrades. The installed base is protected; business imperatives are met; upgrade costs are minimized.

The role of contemporary interoperability is built upon a model in which things move incrementally; thus, standards should be developed in an agile fashion so that innovation would be robustly encouraged and backwards compatibility could be assured.

We point to the Office of the National Coordinator's Standards Version Advancement Process (SVAP) as a success story and a potential model.

Recommendation 3: NCVHS recommends that ONC's existing authority be expanded to facilitate the coordination of Social Determinants of Health (SDoH) data standards efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), to include a formalized public process that would include non-federal entities (e.g. State, Tribal, Local, & Territorial Governments (STLTs), private health and healthcare systems) to align national standards with evolving and complex national and local reporting and information needs.

The Committee notes, and panelists who spoke during the June 9, 2022, Listening Session confirmed, that collaboration and coordination on harmonization of data elements, data content and data exchange currently exists between a number of federal agencies within HHS, including CMS, ONC, OCR, and CDC. However, data also flows from providers and payers to other non-federal authorities and the existing inter-agency collaboration is not adequate to ensure that all uses (both federal and non-federal) are incorporated into any national collaboration.

Building on such expanded collaboration to attain other objectives for harmonization is complex – but has transformative potential. HHS could build on the momentum it has by considering establishment of a joint governing entity with authority to support additional work on data content, structures, and formats between diverse data sources, and development of new standards for emerging use cases, implementation and test tools.

This expanded ONC authority could provide national leadership and establish a centralized venue and process to achieve the objectives for a cohesive process and common base of standards across federal, industry, state, tribal, and local users to facilitate harmonization, develop needed tools, and provide educational resources for stakeholder engagement.

Testimony to NCVHS indicates that state and local authorities would welcome this formalized public process to avoid the cost and effort of developing local, (i.e., non-standard) solutions for their health-related data reporting needs.

<u>Recommendation 4</u>: NCVHS recommends that HHS develop and publish a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

The Committee received input from industry about the need to evaluate the value of and test updated, new and emerging standards before they are adopted under HIPAA to ensure they function as intended and meet identified business needs.

Some standards development organizations are developing projects and metrics to evaluate their standards with both quantitative and qualitative measures.

Some standards, such as HL7 FHIR standards and implementation guides undergo a process of testing in controlled environments prior to being implemented to demonstrate their capabilities, functionality and "fit for purpose."

As always, the Committee stands ready to assist HHS with a more detailed explanation of the recommendations and attendant implications.

Sincerely,

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

Enclosure

Cc: Chiquita Brooks-LaSure, CMS
Mary Greene, CMS
Micky Tripathi, ONC

Appendix

Part I. Select Industry Comments Submitted to NCVHS that Support the Four Recommendations[1]

NCVHS received written submissions with comments as part of its June 9, 2022 Listening Session, as well as significant information delivered orally by the Listening Session panelists. Below are selected nuggets reflecting comments received and NCVHS reaction to those comments.

Recommendation 1: NCVHS recommends that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.

Selected Comments submitted to NCVHS from industry and the public:

- Costs and benefits should be looked at holistically, including customer support and total cost of ownership, not just the additional implementation cost. Though organizations must spend some money to implement, the cost of ownership or the benefit of the overall increase in the experience outweighs the cost. For example, prior authorization, taking that from 17 minutes to a couple of minutes using a SMART on FHIR app much outweighs the cost of implementing that particular app as well.

- The theme on this concern and topic has consistently remained any adoption be done cautiously, with an eye towards "not breaking what works already," such as claims, and that it should address unmet business needs. This is precisely what the Committee's recommendation supports. Virtually every speaker mentioned prior authorization as an appropriate transaction which could be resolved by such an action almost immediately. With some additional investigation, it is possible that a standard for attachments could also fit this use case.

- The provider associations' comments (e.g., American Hospital Association, American Medical Association) indicated an on-going concern about the concept of "willing trading partners" and whether asymmetric market power might leverage providers into agreeing to terms they would otherwise not agree to.

Recommendation 2: NCVHS recommends that HHS enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.

Selected comments:

- There could be a tiered approach to standards updates. First, a pilot test for a new standard. Perhaps 6 to 12 months to prove that it works at least in a small set of plans, providers, and clearinghouses. The pilot would identify any glitches and provide an indicator that the new

[1] From the NCVHS Subcommittee on Standards Listening Session on Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0" (June 9, 2022): https://ncvhs.hhs.gov/meetings/standards-subcommittee-meeting-3/. Note: comments may be paraphrased, summarized or consolidated. They are not necessarily verbatim quotes.

standard would be scalable for more widespread implementation. And then move that forward to an option – not a requirement – for payers and providers to support. And then based on the experience that we have in both the pilot test and the use of that new standard as an option, consider that new standard to be eligible for adoption as the main standard (i.e., consider sunsetting the earlier version after an appropriate length of time) if it proves to be better than the existing standard. I think this gives more of an incentive to test standards because there is a pathway to move from the pilot test and the option to having adoption as a full standard.

- I think one of the benefits of this is that it does encourage the industry to innovate because you have folks that are on newer versions of standards that can establish an ROI from actual implementation that can be used to help move the rest of the industry forward and innovate.

- We do need to be investing and maintaining our systems of always moving, never being one more than one version behind so to speak or two or whatever the number is.

<u>Recommendation 3</u>: NCVHS recommends that ONC's existing authority be expanded to facilitate the coordination of Social Determinants of Health (SDoH) data standards efforts across HHS agencies and offices (e.g., CMS, ONC, CDC, NIH, IHS), to include a formalized public process that would include non-federal entities (e.g., State, Tribal, Local, & Territorial Governments (STLTs), private health and healthcare systems) to align national standards with evolving and complex national and local reporting and information needs.

Selected comments:

- There is an important distinction to be made between harmonizing or aligning data content and then trying to harmonize or align the data exchange method or exchange standard. With respect to data content, the value and benefits of having better alignment of the data content include reduction in reporting burden and improved data quality and utility. The goal is to establish a common base set of data elements that can be applied to all types of information exchange regardless of the purpose of the transaction. Public health and population health transactions rely on both administrative and clinical data elements. When data definitions and data elements are aligned across all data sources and types of exchanges, data submitters avoid having to tweak a particular data element to comply with reporting requirements that differ in formats and definitions. Content is very important. For example, USCDI is a good approach to promote alignment. But the USCDI data elements are not used or aligned completely with the administrative transaction. The next question is harmonizing the transactions and the method of exchange. The key element to understand is "goodness of fit." There will be some instances and some transactions where certain types of approaches, for example, FHIR-based API standards would make all the sense in the world while document-based approaches would be appropriate for other types of transactions.

- When it comes to the life cycle of standards, standards development adoption and implementation is one component. The regulatory process is another key component. The desire for more rapid-cycle standards adoption is a worthy goal but the realities of the regulatory process and timeline pose the most challenges to this goal. To shorten the HIPAA standards adoption process, alternative approaches such as ONC's standard version advancement process for EHR certification (SVAP) should be evaluated. The example above

provides a model to consider for other types of standards development and adoption in a more timely manner. For example, FHIR-based standards have demonstrated that the whole life cycle of standard development, adoption, implementation, and maintenance can be accelerated and can be compressed to fulfill the business need and the problem or the real constraints are the regulatory process.

Recommendation 4: NCVHS recommends that HHS develop and publish a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.

Selected comments:

- I think we still have here important work to be done in terms of aligning different types of, for example, social health need assessment forms and tools that are used because at the end, all these tools are generating data in different ways and are less comparable across systems. I think we are seeing it is very important. It is going to be part of the development of metrics that will help us set the performance of health systems in achieving health equity goals, the efforts that are being led by CMS, NCQA, and others.

- Another commenter suggested that the HL7 connectathons be expanded to include the X12 transactions. At present, HL7 organizes and supports these events specifically to test and evaluate the HL7 FHIR-based Implementation Guides, and participation in the testing tracks is dependent on volunteers from payers, providers, developers and vendors. X12 could consider developing a similar infrastructure.

Part II. Background for NCVHS Recommendations

The NCVHS Subcommittee on Standards is in a multi-year process of refining the vision for a much more broadly integrated network of health-related data systems. The above four recommendations are part of a series of recommendations intended to optimize the value of national standards as established by HIPAA and expanded by later legislation. The NCVHS vision originated in the HITAC/ICAD[2] report and is part of the Subcommittee's Standardization of Information for Burden Reduction and Post-Pandemic America project ("Convergence 2.0").[3] This vision encompasses and is supported by federal and other initiatives and lessons learned:

- Adoption of HIPAA administrative and financial transaction standards to achieve cost savings and efficiency in data exchange
- ARRA/HITECH clinical transactions and ONC policies to promote use of electronic health records, including federal policies on: interoperability, prohibition on data blocking, addressing disparities, privacy/security, burden reduction
- Lessons learned from the public health emergency
- State/territorial/tribal health data needs
- ONC's Integration of Administrative and Clinical Data (ICAD) Task Force: future vision to for patient-related data flow among traditional (e.g., HIPAA Covered Entities) and non-traditional (e.g., social service and community support) data systems to support patient services
- Integration and flow of patient-related data like SDOH and SOGI beyond HIPAA Covered Entities

The Committee understands there is a need to integrate HIPAA with HITECH and expand both to whatever data systems are in place at the point where the patient's needs touch those systems.

NCVHS "Convergence 2.0" Project Key Concepts:

- Protect the installed base while proactively supporting innovation
- Common data content/definitions across all adopted standards
- Reduce size of updates (smaller, more digestible bites)
- Improve speed-to-market for updates
- Make predictability/reliability of standards update process a high priority for HHS:
    - Ability to know upcoming adoption/implementation timetables
    - Ability to plan and budget (dollars, systems, vendors and personnel) for upcoming adoptions and implementations
- Burden reduction (to all entities, but especially patients and providers)
- How to ensure end-user input into standards development and testing while recognizing that end-users do not generally have the expertise, interest or financial wherewithal to participate in standards development
- Enforcement with meaningful analysis and feedback on common complaints/problems/issues

[2] ONC HITAC ICAD final report: https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf

[3] NCVHS Project Scope available at: https://ncvhs.hhs.gov/wp-content/uploads/2021/07/NCVHS-SS-project-scoping-convergence-2021-06-21-508.pdf