# National Committee on Vital and Health Statistics
# Roundtable Hearing on Predictability Roadmap to Accelerate the Update, Adoption and Use of Administrative Standards and Operating Rules
# December 12-13, 2018 – Washington, DC

## Kaiser Permanente Written Comments
## December 7, 2018

My name is Walter G. Suarez, MD, MPH, and I am the Executive Director of Health IT Strategy and Policy for Kaiser Permanente. I am also a member of the Board of Directors of HIMSS North America, and Chair-Elect of the Board of Directors of HL7 International. I am submitting the following written comments on behalf of Kaiser Permanente, in response to the National Committee on Vital and Health Statistics (NCVHS) Proposed Predictability Roadmap. The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with 12.2 million members in eight states and the District of Columbia.

**Overarching Comments**

- Kaiser Permanente applauds NCVHS efforts to develop a Predictability Roadmap to accelerate the updating, adopting and use of electronic standards for administrative transactions by the health care industry
- The current process for developing, adopting, using and updating standards was developed in the 90's and early 2000s, and has not been significantly changed since then
- We agree that two of the main challenges that exist under the current process are 1) enhancement of standards and operating rules cannot keep up with business needs and technology innovations; and 2) the changes are not predictable to allow for effective planning by the health care industry
- In addition to these challenges, we believe there are four other major challenges that affect the agility, efficiency, effectiveness, technology innovation adoption and use of electronic standards: 1) the standards development and maintenance process is long, complex, cumbersome, and inflexible; 2) some adopted standards do not fully meet business needs, or are too complex to achieve fulfillment of business needs; 3) the review process for completed new or revised standards (including DSMO process and NCVHS review) is long; and 4) the regulatory framework and process created and currently used to adopt and implement standards is also lengthy, complex, too granular in detailing standards, and inflexible. These four additional challenges result in a process that cannot meet rapid and timely changes in business needs and new technology capabilities.
- Overall, we strongly believe there is a need not only for a Predictability Roadmap, as described by NCVHS. However, we also believe there is a need for a new paradigm in the standards development, maintenance, adoption, and implementation, a paradigm that includes the following three elements 1) a new, more agile processes for voluntary consensus standards development and maintenanc; 2) a new, more efficient process for reviewing and recommending finalized standards for adoption; and 3) a new regulatory framework for adopting standards. These three components of the new proposed paradigm are further explained below.
- We are also concerned that the proposed Predictability Roadmap does not seem to acknowledge innovative alternative payment models that shift away from the traditional fee-for-service, transactional, claims-based model. As new payment models are implemented, new data needs and

new processes for information access and exchange will be needed, with a new breed of standards and new technology approaches already available, such as open APIs and FHIR.

- It is not clear why the Predictability Roadmap ties the three major goals with consecutive timelines. In other words, why would Goal 1 – Education, Outreach and Enforcement be only relevant to 2019-2020, Goal 2 – Process Improvement be tied to 2020-2021, and Goal 3 – Regulatory Levers be set for 2021-2022? All goals have elements that can be achieved during each of the three 2-year periods defined in the Roadmap

**Standards Development and Maintenance Process**

- As noted above, the current development and maintenance processes for voluntary consensus standards used in administrative transactions is simply too long, complex, cumbersome, and inflexible.
- We are concerned that regulations dating back to August 2000 established a detailed process for adoption of new standards, and maintenance and adoption of modified existing standards; this process has limited the development of newer, alternative, more efficient and effective processes to implement standards in the industry.
- Specifically, the establishment and use of the Designated Standards Maintenance Organizations (DSMO) process, and the identification of its specific members has created a series of additional steps with limited value.

    - *We recommend that this process be revisited, with consideration to defining a different process to bring forward recommended standards for adoption*

- We are also concerned about the time it takes to complete the development, vetting, testing, re-vetting, and finalizing of standards, particularly those developed and maintained by X12N. Since 2003, there have been two versions of the X12N standards adopted and in use: Version 4010 (with errata), which was effective between 2003 and 2011; and version 5010, which has been effective since 2012. The next version of the X12N standards likely to be recommended for adoption under HIPAA, Version 7030, is not expected to be finalized until 2019, and with the NCVHS review process, proposed rulemaking, comment period, final rule issuance, and period for transition to new standard, this version would not be formally required to be implemented until 2022 at the earliest. In the meantime, implementing important, necessary changes to the existing standard is very limited.

    - *We recommend that the Standards Development Organizations (SDOs) such as X12N, NCPDP, HL7 and others, revisit their standards development process to identify opportunities to gain efficiencies, reduce complexity and elapsed time, and improve the standards outcome.*

- We are also concerned about the limited implementation of documented standards testing and evaluation after the development or maintenance process, as well as the limited measurement of how well the standards achieve organizational goals and business needs.

    - *We recommend establishing publicly available formal evaluation of standard testing with documentation of how well each standard achieves the goals and business needs for which it was created.*

- The development and implementation of Operating Rules, which runs through a parallel process to that of standards development, has been mostly done through voluntary industry adoption (except for some operating rules adopted back in the 2000s). Voluntary adoption of non-regulated operating rules has provided an important example of how the industry can pursue non-regulatory actions to achieve administrative efficiencies.

    - *We recommend that NCVHS and regulatory bodies consider pursuing increased voluntary adoption of standards, through the use of appropriate program incentives and policy levers.*

**Complexity of Standards**

- We are pleased that the evolution of the standards from version 4010 to version 5010 and beyond demonstrates increasing reduction in the variability, interpretability, optionality and inconsistencies in many loops, segments and data elements that form the standards, as well as improving their implementation.

- We are concerned, however, that the level of complexity in the transaction standards, may limit their usefulness to achieve transactions. These complexities in structure, format and content have in some cases rendered the standard costly to implement and have resulted in organizations pursuing allowable alternatives. An example of this is the Prior Authorization transaction standard.

    - *We recommend that SDOs, particularly X12N, look into their standards and identify opportunities for simplification*

**Review Process for Adoption of Completed New or Revised Standards**

- Once a standard has been finalized, the current review process for the adoption of new or revised standards generally includes the following steps: 1) a DSMO review process; 2) a letter sent to NCVHS recommending the adoption of a standard; 3) NCVHS review process; 4) NCVHS submission of recommendation to HHS. This process can take anywhere from 9 months to a full year.

- We believe the industry needs a new paradigm for achieving this process. As recommended previously, the DSMO process, while initially a good approach as he first round of standards were being defined, has lost value and should be changed. The process followed by NCVHS to review standards for adoption and develop recommendations to HHS should include a more deliberate and structured evaluation of how well the new or revised/modified standard meets the business needs of the industry, achieves simplification, improves cost-effectiveness, efficiently meets the goals of the transaction, and is usable, simple, and adoptable by the industry.

    - *We recommend that NCVHS explore ways to simplify its own review process, and include a more structured evaluation process and documentation about the adoption of new or revised standards.*

**New Regulatory Framework for Adoption of Standards Needed**

- As mentioned above, a new regulatory framework and process for the adoption and implementation of electronic standards for administrative transactions is urgently needed. The current process takes too long, is too prescriptive and granular, represents a 'ceiling' rather than a

'floor' for standard requirements, and impedes or stifles development and use of new and innovative technologies that offer more efficient and effective ways to achieve the goals of the transactions.

- The current regulatory environment for HIPAA administrative transaction standards does not allow the use of simpler (simplification principle), less costly, more efficient and effective new and innovative technologies and approaches. – for example, the use of new Open APIs and FHIR-based transaction standards to achieve transactions such as Eligibility and Prior Authorization.

    - *We recommend a new regulatory policy framework that 1) avoids prescribing the process for developing and adopting standards; 2) allows for voluntary use of newer standards and approaches to achieve the goals of the transaction in addition to named standards; and 3) avoids requiring a single, specific, unique and exclusive standard (with version and date) that is adopted for each specific transaction.*

**Addressing NCVHS General Questions**

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

    - The recommendations included in the draft Predictability Roadmap will help the adoption of administrative standards and operating rules to follow a predictable path
    - However, the Roadmap should do more to restructure the development, maintenance, evaluation, adoption, and implementation processes of voluntary consensus standards, as well as to promote a new regulatory framework to support these changes

2. What additional recommendations are critical to achieve predictability?

    - See above

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

    - See above

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

    - One significant possible unintended consequence is the adoption of a standard that is inefficient or ineffective, and not used by the industry to achieve the goals of the transaction or the business needs of the industry
    - Another related consequence is stifling the adoption and use of new technology innovations and approaches that would result in better, more efficient, less costly ways of achieving a transaction

**NCVHS Goal 1 – Outreach, Education and Enforcement – Recommendations and Calls for Action (2019-2020) |** *(R=Recommendation; A=Action; M=Measurement)*

- [R] HHS to increase transparency of their complaint-drive enforcement: While this might help the industry understand points of pressure, its value as a mechanism to improve predictability is limited and not well defined
- [R] HHS should comply with statutory requirements for handling complaints: While there might be some informative value to the industry, its specific value toward predictability is limited or not well defined
- [R] HHS should regularly published guidance regarding appropriate use of standards and operating rules: We do not believe that the role of the regulatory agency is to provide guidance on technical implementation of standards. Such detailed, granular, technical guidance should be the responsibility of the industry, though groups such as SDOs or WEDI
- [A] Health plans and vendors should identify and incorporate best practices to mitigate barriers to the use of standards: We believe it is not just the responsibility of health plans and vendors but also providers to identify, through appropriate industry groups, barriers to effective use of transactions and the corresponding standards.
- [A] WEDI should continue to identify issues and solutions: We support this recommendation
- [A] SDOs should consider collaboration to plan outreach campaign: We support this recommendation
- [A] Leadership from the public and private sector should commit to membership in SDOs: We support this recommendation
- [M] HHS should publicly and regularly disseminate result of its enforcement program: As noted above, this dissemination might be informative to the industry, but its value as a mechanism to improve predictability is limited and not well defined

**NCVHS Goal 2 – Process Improvement and Policy Levers – Recommendations and Calls for Action (2020-2021) |** *(R=Recommendation; A=Action; M=Measurement)*

- [R] HHS should disband the DSMO: We support this recommendation
- [R] HHS should enable creation of a new entity tasked with oversight and governance (stewardship) of the standards development process; HHS should provide financial support: While we believe that a national organization should provide stewardship and coordination of the standards development process, we are concerned that this will simply create and introduce yet another layer of complexity into the process, or simply replace the current DSMO process. This process should be worked out within the industry and not through the establishment or designation of an organizations in legislation or regulation. We believe the industry should consider forming a national coordinating cross-SDO body, with representation from all SDOs. Its function should be limited to coordination of standards development across SDOs, and neither policing nor evaluating accreditation functions. We understand that currently NCVHS does not have the expertise or the resources to perform standards evaluation before considering adoption. This function should be fulfilled through contracted support by NCVHS on an 'as needed' basis.
- [R] HHS should conduct appropriate rulemaking activities to give authority to a new governing body replacing DSMO to review and approve maintenance or modifications to adopted or proposed standards: We strongly oppose utilizing regulatory actions to establish/name and authorize an organization to sit above the SDOs, which have the expertise in developing standards. This would be similar to establishing a process to accredit or certify finalized standards by an ANSI-accredited SDO.

- [R] HHS should publish regulations within one year of a recommendation being received and accepted by the Secretary for a new or updated standard: We understand this to mean the following steps: 1) SDO develops new/modification of standard; 2) New governance organization evaluates and recommends to NCVHS; 3) NCVHS evaluates and recommends to HHS; and 4) HHS evaluates and determines whether to accept or not recommendation, and if so, they would have one year to issue regulations. This process does not seem to simplify or reduce time or predictability, but rather complicate the process by increasing the steps and the length of time needed.
- [R] HHS should ensure that the operating division responsible for education, enforcement and the regulatory process is appropriately resourced: We support this recommendation.
- [A] HHS and SDOs should identify and fund a best of class third party compliance certification/validation tool; HHS should develop and test criteria for certification and develop a program to accredit third party certifiers: While we support the development of best-of-class third party validation tools, at this point. no certification program is needed to validate compliance with standards. Creating such a program will be costly - and the cost will be undoubtedly passed on to providers and payers.
- [A] Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable policies regarding business practices: While we agree that an industry group facilitating coordination across SDOs would be valuable, we recommend against granting such an organization the powers and authority proposed in this recommendation, for example enforcement of policies on SDO and/or covered entities.
- [M] HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity: We agree that the right set of metrics should be defined to evaluate the level of adoption and use of standards.
- [M] NCVHS should continue to conduct stakeholder hearings: We agree with this recommendation. However, with all the previous recommendations, it is not clear what NCVHS' new role would be.

**NCVHS Goal 3 – Regulatory Levers – Recommendations and Calls for Action (2021-2022) |**
*(R=Recommendation; A=Action; M=Measurement)*

- [R] SDO and ORAE should publish incremental updates to their standards and operating rules to make them available to NCVHS on a schedule no greater than every 2 years: We generally support this recommendation.
- [R] NCVHS should align its calendar to the SDO/ORAE updates: We support this recommendation
- [R] HHS should adopt the NCVHS recommendations on a regular schedule: While we agree with this recommendation, HHS can accept or reject a recommendation made by NCVHS. It is common that some recommendations are accepted, while others get no response, which means NCVHS submits repeated recommendations to HHS. We encourage HHS to commit to respond within a certain timeframe to all the NCVHS recommendations, whether they are accepted or not.
- [R] HHS should adopt incremental updates to standards and operating rules: While explicitly permitted in HIPAA, incremental changes to standards have rarely been adopted. This is primarily because a new version of the standard is frequently pursued = a process that depends on the SDO. SDOs should explore ways to adopt incremental updates to an existing standard within the 2-year proposed timeframe if a new version of the standard is not feasible or advisable.
- [R] HHS should publish rulemaking to enable the adoption of a floor (baseline) or standards and operating rules: We strongly agree with this recommendation. It should explicitly state that

regulatory floor in this context means that, at a minimum, entities must use the named base standard.

- [HHS should enable voluntary use of new or updated standards prior to their adoption through rule making: We support this this recommendation
- [A] HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment: We strongly agree with this recommendation, and propose moving it to the 2019-2020 timeframe
- [A] HHS should continue to publish universal dictionary of clinical, administrative and financial standards: We support this recommendation and propose moving it to the 2019-2020 timeframe