December 20 2018

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

Submitted electronically at: NCVHSmail@cdc.gov

RE: Predictability Roadmap Recommendations

Thank you for this opportunity to provide NCVHS feedback on its draft Predictability Roadmap to advance the administrative and financial standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act of 2010 (ACA).

As an electronic health records developer based in Verona, Wisconsin, we at Epic have significant experience working with stakeholders across the industry, both payers and providers, to improve the electronic exchange of information to support the administrative and billing processes of health care. In addition, our software is used to support other types of information exchange, from integration with devices and instruments to the sharing of patient information for the coordination of care. We have extensive experience with the advancement of standards through regulation and certification, and it is this experience that informs our recommendations to NCVHS.

Overall, we are supportive of NCVHS's intent to advance the speed at which standards proliferate and to encourage their adoption through a more predictable deployment schedule. However, we disagree with the Roadmap's recommendation to enforce standards use via certification. In our comments below, we explain our reasoning and also offer some smaller recommendations to help pave the path for successful adoption across the industry.

Thank you for your consideration. We look forward to continuing work with NCVHS and other industry stakeholders to provide cutting edge information technology resources that increase operational efficiencies and reduce waste.

Sincerely,

/s/

Janet Campbell

Epic

Comments on the proposed recommendations, calls to action, and measurements

Overall, we support the move to a more predictable cadence of standards updates and adoption. In our experience, where standards do not exist, the industry improvises. Custom codes and extending existing standards can sometimes provide workable, though suboptimal, solutions. However, more common is the use of less efficient manual processes, such as uncoded and non-computable information accessed through payer portals.

While a transition to more regular updates of requirements may be challenging, it will be far more beneficial than remaining in the current state.

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.

We support this recommendation, provided that there are clear standards and procedures for publishing valid complaints, and that such information is publicized with the intent of improving overall industry compliance and understanding.

At the hearing held December 12-13, 2018, some participants called for the publication of identified complaints. We would only support such a recommendation if publication was reserved for particularly egregious cases, such as a repeated pattern of non-compliance or willful disregard for correction.

Recommendation 6: SDOs and ORAE should publish updates to their standards and operating rules and make them available for recommendation to NCVHS on a schedule that is not greater than 2 years.

As currently worded, this recommendation implies that standards *must* be updated at least every two years, without consideration of whether updates are necessary or appropriate.

In our experience, setting a mandatory timetable for standards updates without other specifics can have unintended consequences. It could encourage superfluous updates for updates' sake, which introduce churn and disruption to industry processes without appreciable benefit. In order to keep current with these updates, technology providers in the industry need to create software updates, which then need to be distributed to and installed by providers, payers, clearinghouses, and others. This process should be reserved for those times when meaningful updates are necessary.

We recommend that Recommendation 6 be updated to read "SDOs and ORAE should provide NCVHS with information as to whether updates to standards and operating rules are available and necessary, on a schedule that is not greater than 2 years."

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).

We appreciate the recommendation to provide a more explicit path for recommended standards to become adopted in regulation, and we will leave the question of whether a year provides adequate time to others. However, we note that no recommendation in the draft Predictability Roadmap was made to set an expectation of the time between when a standard becomes codified into regulation and when the regulation goes into effect.

The process of updating to accommodate a change in standards differs depending on the size of the change. Small changes can often be accommodated via a "patch" to technology, which is applied similar to other fixes within live systems. Larger, more complicated changes may be too disruptive to apply safely, and thus may require an organization to upgrade to a newer version. The largest of changes may require changes not only to technology, but to practices' processes and procedures.

Regardless of the size of the change, however, a longer "runway" (the period between when standards are codified in regulation and when the regulation goes into effect) lessens the risk of disruption to the industry. An 18-month runway not only allows for thorough testing of any changes, it also reduces the likelihood of needing to patch systems, as organizations simply incorporate any necessary changes as part of their regular planned upgrade cycle. Similarly, given the overhead costs of making changes, it is safer to group smaller changes to standards into one larger change, rather than implementing them separately.

As NCVHS considers the appropriate timing for standards enforcement, we also urge it to align with other regulatory requirements that affect health information technology. An aligned cadence not only makes it easier for technology developers to test changes in a more reliable way, it also helps organizations in planning when they will upgrade their technology.

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.

We support the call for validation tools, especially automated validation tools that can be used by technology developers on an ad hoc basis to verify that their implementation of the standards is correct, or to settle disagreements about how standards should be interpreted.

While certification has been used in the past as a tool to enforce compliance with standards, such as via the ONC's HIT Certification program, our experience has shown that the cost of certification to the industry as a whole – in time, energy, opportunity cost, and tax-payer dollars – outweighs the benefit.

The draft Predictability Roadmap already covers a number of recommendations, from education to enforcement, that are very likely to result in increased compliance with standards, by removing the barriers to their adoption and catching bad actors. A call for certification is premature given the other Roadmap recommendations.

Therefore,

- We recommend that Call to Action C be updated to read “HHS and the SDOs should identify and fund a best of class third party compliance validation tool recognized and approved by each standards development organization to eliminate ambiguity in both defining and assessing compliance.”
- We recommend that a Call to Action E be added to the 2021-2024 timeframe, reading “HHS, with extensive input from all stakeholders, should conduct an in-depth study that assesses rates of noncompliance to established industry standards, and reviews the costs and benefits of introducing a certification program that conducts validation testing.”

Measurement 3: NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

We have appreciated the efforts of NCVHS to involve stakeholders throughout the drafting of the Predictability Roadmap and thus recommend that this measurement be moved to the 2019-2020 timeframe.