Comments to IOM on ONC Health IT Standards Progress

Jamie Ferguson, Kaiser Permanente

Introduction

First, thank you for accommodating my ability to speak to you today instead of tomorrow.

Kaiser Permanente represents an integrated system providing health care for over 8.7 million people. In Kaiser Permanente we seek to integrate and coordinate the efforts of medical groups, health plans, hospitals, research and other organizations with a focus on prevention and care management to consistently provide high quality, affordable health care conveniently and with a personal touch.

The stated goals of ONC's health IT efforts are to improve the nation's quality, affordability and access to care, as well as to make health care more personal, through interoperable health information technology. The overall goal of achieving broad nationwide interoperability, for these reasons, is the main focus of my remarks and serves as a touchstone for assessments of the elements of ONC programs relative to the adoption and implementation of health IT.

Executive Summary

We have been asked to comment on how effectively the ONC processes are working and whether they are proceeding at an appropriate pace. My remarks intend to support the conclusion that the ONC standards process is making good progress toward these goals. ONC is to be congratulated on their progress in making standards available for the industry to use in defined use cases. Despite this overall positive assessment, my comments will focus on areas where ONC programs could be improved. The relatively rapid pace of standards development in ONC programs is very positive and should be continued, but the overall program could benefit from more resources being applied to the coordination of its parts and to testing and implementation of the standards. Also, this pace of standards development and implementation will be sustainable only if the scope of each ONC use case is much narrower both now and in the future.

Pace/Speed of Standards Efforts

Overall it is positive that the pace is very rapid compared to historical healthcare standards work. This is one of the great successes of ONC. By comparison, the current pace of standards development in the ONC program is about three times faster than HIPAA administrative transaction standards

and about twice as fast as industry initiatives such as claims-based personal health records. Where the HIPAA standards development process has taken about six years, the ONC process takes about two years from start to finish. As a result of ONC programs, the involved Standards Development Organizations (SDOs) have become much more responsive to the need for standards, both in response to priorities defined by AHIC and to market needs. These organizations rely almost exclusively on volunteer resources. For example, the volunteers in Health Level Seven (HL7) responded to HITSP requests for standards needed in the 2006 AHIC use cases with unprecedented speed.

It has been easier for some industry participants and SDOs to adapt to this pace than others. My own observation is that this appears to follow an 80/20 rule, where about 80% of market participants welcome this faster standards development pace and think it is reasonable. They have adapted to it and expect to be able to implement the standards in a reasonable multiyear period.

There are other risks associated with this pace of standards work. The combination of this speed with the breadth of scope of the ONC efforts presents risks of participant burnout and other resource issues for the SDOs as well as HITSP and CCHIT. Further, this combination of speed and breadth of efforts quickly will exceed the industry ability to implement new standards in a timely manner if the scope of each new effort is not narrowed materially from the current and proposed use cases. There are limited resources for these activities in any healthcare organization and the combination of competing priorities from HIPAA and other sources will exceed the capacity of this implementation bottleneck if the scope of each use case is not made materially narrower.

Coordination Of Related Federal Efforts

Initially there was relatively poor coordination across ONC efforts but it appears to be improving. An example is the memorandum of understanding recently executed between CCHIT and HITSP. At the same time, greater coordination still is needed between AHIC and each ONC effort, as well as between CCHIT, HITSP, and NHIN efforts

Overall there has been relatively poor coordination with HIPAA standards and HIPAA processes. Although analysis of the compatibility of HIPAA administrative simplification standards with HITSP standards was conducted and found no conflicts, data flows from the clinical use cases to administrative use cases has not yet been well coordinated in these efforts, nor has there been detailed integration of standards for HIPAA privacy and security rules with HITSP standards development.

Coordination with related program and project efforts in other departments and agencies also should be improved. For example, Homeland Security reporting requirements should be better coordinated with HITSP emergency responder standards development through the application of Homeland Security resources in the HITSP process and through HITSP representation in the development of Homeland Security requirements.

The slow progress of security and privacy policy development that affect HIT standards is troublesome. Developing and implementing technical standards that must accommodate multiple consent and privacy policies has the potential to overwhelm the available volunteer resources as was already described.

Testing and Implementation Concerns

Standards must be tested before implementation. By comparison with the HIPAA standards testing process, which it could be argued is excessively time consuming, the ONC process currently includes no real world testing of the new standards before they are to be implemented as requirements in federal contracts. Implementers would benefit from some real world testing and refinement of the standards to reflect what is learned in testing. A one year testing period for each new interoperability specification is suggested prior to their introduction in contractual implementation requirements.

Implementation time must be built into the timeline for interoperability standards for both agencies and contractors. The currently-proposed Federal Employee Health Benefit Plan (FEHBP) contract implies immediate implementation of the recognized interoperability standards, however, in reality these IT projects can take two years or longer to complete.

Since implementation of the interoperability standards by contractors is to be required in annual contracts, but implementation projects may in many cases take multiple years, a mechanism still needs to be determined to bridge the annual contracts across the actual implementation period.

Interoperability Standards In Federal Contracts

Contract language to require implementation of interoperability standards may work well overall, but this approach still needs a lot of work.
Contractual obligations may result in unplanned or uncoordinated implementation of standards as well as rapid adoption of technologies that may compromise business strategies.

Federal contracts provide limited opportunities for negotiation and the timeframes contemplated cut current industry cycles by more than half.

It is also unrealistic for contractors to carve out parts of their systems and comply only for projects that are the subject of the contract. Essentially, these provisions force a broad application of technology adoption or upgrade.

At the same time, since the goal is broad interoperability between entities and organizations, as contracts terms are developed it is important to be very thoughtful about what they may mean for internal communications inside a single company or organization.

Level Playing Field

Contract terms should seek to create a level playing field across different business models, i.e., the contract terms should not be of particular benefit to either an integrated model or a fragmented model for the overall system of care. This implies that the contractual requirements should apply to federally funded health plan carriers and their contracted providers alike.

To support the goal of broad interoperability and gain the benefits of quality, access and affordability it is important that there should be an even-handed migration to the interoperability standards in local, regional and national health data exchange implementations. Exceptions, carve-outs, variations, or the creation of grandfather rights in the implementation of these standards would defeat the purpose of these standards programs.

Another aspect of creating a level playing field is to consider both the needs of those who have not yet made an investment in technology to achieve these benefits, along with those who now have an considerable installed base of health IT and are already achieving some of its benefits. The overall standards process should seek not to advantage or disadvantage either of these groups.

Use Cases

The current use case process is much improved since these programs started. With public comment periods there are ample opportunities for involvement of all interested parties.

Still, the scope of each use case is overly broad and it is not possible to specify interoperability standards and implement them fully in the time allotted. For example, the new Personalized Care use case is mostly about the use of genetic information to improve the direct care of an individual patient in a clinical care setting, but it also includes secondary use of genetic information for research, de-identified genetic information reporting to public health agencies, and disease management considerations. It would be much better to focus this use case exclusively on the active care of the individual

patient, and to leave the secondary uses of genetic information to one or more separate use cases.

Some use cases are partially duplicative or overlap each other, and it is important to have consistent definitions and concepts in the different use cases. Narrowing the scope of the use cases should go along with clearer and more consistent definition of the applicability of the use case across the spectrum of health care in the US.

Legal concerns in the use cases may benefit from more resources and careful consideration by ONC instead of relying on the public comment process to the current degree.

Summary and Recommendations

In summary I will reiterate my key points and recommendations:

First, ONC is to be congratulated for its significant progress. ONC should maintain the excellent cooperation with and among SDOs that has been developed by formal SDO involvement.

Second, the scope of ONC use cases and the speed of standards development efforts should be better matched to available and funded resources.

Third, each iteration of standards development should include real world testing and more realistic implementation timing.

Fourth, keep up the pace but narrow the scope of each use case and each statement of work.

Fifth, improve coordination both across ONC programs and with other federal departments and agencies, including HITSP coordination with NHIN programs and HIPAA standards.

Sixth, the security and privacy policy requirements must be clarified for each use case, and legal concerns should be examined with more resources and careful consideration.

Finally, it is critically important to create a level playing field by applying the requirements for interoperability standards evenly and consistently to entities in different business models, different historical IT investment levels, and different geographic units.

Thank you for the opportunity to comment.