<Date>

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Dear Dr. DeSalvo,

In response to the recommendations from the Standards and Interoperability (S&I) Task Force, the Health Information Technology Standards Committee (HITSC) was asked to provide your office with recommendations around XXXXXXXXX. This transmittal offers these recommendations.

These recommendations are informed by the deliberations among the Task Force subject matter experts, and presentations from relevant stakeholders.

**Background**:

The S&I Framework is one approach adopted by ONC's Office of Standards & Interoperability to fulfill its charge of enabling harmonized interoperability specifications to support national health outcomes and healthcare priorities, including Meaningful Use and the ongoing efforts to create better care, better population health and cost reduction through delivery improvements. The S&I Framework creates a forum – enabled by integrated functions, processes, and tools – where healthcare stakeholders can focus on solving real-world interoperability challenges

At the December 10, 2014 HITSC meeting, ONC proposed the time bound interdisciplinary Task Force Model as part of the HITSC Efficiency presentation[[1]](#footnote-1). During that meeting, the HITSC recommended that a Standards and Interoperability Task Force (“Task Force”) be formed to address the specific question from ONC below:

*In what ways can ONC evolve the S & I Framework to support current industry needs and those anticipated by the 3, 6, and 10-year milestones included in the Interoperability Roadmap?*

This was revised on the recommendation of the Task Force Co-Chairs to:

*Is there a continued need for the S&I Framework (or an equivalent process) to advance standards and implementation specification development? If yes, in what ways could the current S&I Framework be improved or enhanced to better addressed identified industry needs? If no, what alternatives should be considered to addressed the identified industry needs?*

The Task Force[[2]](#footnote-2), chaired by Stan Huff and Arien Malec, convened seven meetings over a three month period to review and discuss the S&I Framework, listen to stakeholder presentations, and produce recommendations to address the Task Force Charge given by ONC. During these meetings, the Task Force heard from different stakeholder perspectives including Implementers, S&I participants, Standards Development Organizations (SDOs), and Industry Associations.[[3]](#footnote-3)

The Task Force presented its recommendations to the HITSC on March 18, 2015.[[4]](#footnote-4)

The recommendations, presented herein, respond to the Task Force Charge.

The Task Force’s highest level recommendation comes from its conclusion that the Standards and Interoperability Framework (or something like it) *does* play an important role in the advancement of standards and interoperability specification development; however, some changes are necessary to better address industry needs. Those changes are summarized in the following recommendations:

**Recommendations**:

**Areas of Focus for a Convening Function**

In our deliberation, we separated our analysis of **what** critical functions an ONC Standards and Interoperability Convening Function (e.g. S&I Framework or similar) might accomplish from the question of **how** such a Convening Function should accomplish its task.

Standards Development Organizations and similar profiling bodies perform a set of essential functions consistent with their respective vision and mission. However, we found that there are key activities SDOs do not currently fulfill as part of their missions that are critical to support the development, adoption, use and maintenance of standards, implementation guidance and certification criteria that enable a nationwide health information technology infrastructure.

We found these activities that SDOs do not currently fulfill fall in two main categories: aligning efficient development of standards and implementation guidance to identified national priorities; and ensuring that such standards and implementation guidance are informed by working implementations and production use. In addition, we found a need to more effectively engage Federal partners in standards development activities and inform infrastructure and other needs that are outside the purview of any SDO.

With respect to informing standards and implementation development by working implementation and production use, we found that effective standards development in other sectors, including Web and Internet standards, requires a tight interplay between standards development and production implementations. As examples:

* The OAuth2 specification went through 31 drafts, many of which were implementation tested by large consumer Internet companies, prior to being adopted as a Provisional Standard by IETF
* The HTTP/2 specification, which was informed by prior work with SPDY and others, was implemented in production within weeks of specification finalization

Although outside our scope, we encourage SDOs in the healthcare world to consider these lessons for effective standards development in their mission and processes.

Nonetheless, we consider it essential that standards developed for healthcare be both pilot and production tested, and that the lessons from implementation inform further refinement of standards and implementation guidance.

Therefore, we recommend that ONC support a Convening Function that focuses on the following key enabling activities:

* **Recommendation**: Support identified national priorities by coordinating across SDOs and supporting SDOs to:
  + Reduce optionality for existing standards
  + Create easy to consume consolidated artifacts (e.g., consolidated implementation guides)
* **Recommendation:** Support production use by:
  + Facilitating and funding pilots and effective production implementation
  + Feeding learnings back to SDOs (e.g., to further reduce optionality and clarify ambiguity)
  + Evaluating success of standards and implementation guidance in achieving national priorities
* **Recommendation**: Facilitate effective Federal participation in SDOs
* **Recommendation:** Identify needs for infrastructure and non-traditional SDO artifacts. For example:
  + Value sets
  + Provider directory data sources (e.g., CMS NPPES modernization)
  + Organizational identity assurance

**Prioritization of Identified National Priorities**

The workgroup deliberated on the question of what an “identified national priority” should entail in order to drive an effective Convening Function. We found that many S&I Initiatives had been prioritized on the basis of a Federal partner with an interest in solving a particular problem; we found that others had unclear paths to achieve success criteria, because of a lack of participation from provider organizations or developer organizations who would implement the outcome of the initiative.

While many initiatives may have clear clinical outcomes if successful, we found that having a large number of initiatives at one time serves to dilute talented individuals from participation, both in the Convening Function and in SDOs.

It was not in our scope to identify national priorities or even identify the process for national priorities. It was in our scope to clarify what must be true of an identified national priority in order to lead to a successful Convening Function.

**Recommendation:** A Convening Function should ensure that identified national priorities meet the following criteria:

* 1. The priority should be determined by a balanced stakeholder group representative of beneficiaries and developers of interoperability (e.g., Federal, provider, developer, patient stakeholders) and should align with a strategy that has received broad public feedback, such as the Interoperability Roadmap.[[5]](#footnote-5)
  2. If successful, projects or initiatives conducted through the Convening Function will lead to a measurable and meaningful real-world set of outcomes that will advance a given national priority (e.g., it will create healthcare value and/or equity).
  3. Projects within the Convening Function should have a high likelihood of success to achieve identified outcomes. For example:
     1. Has a reasonable path to scaled production implementation.
     2. There are key enablers (e.g., providers, vendors and developers) who seek to implement the outcomes.
     3. Takes into consideration parallel efforts, resources and ability of contributors to participate.
     4. Considered and aligned with SDO processes and timelines.

**Work Practice Recommendations**

The Task Force evaluated the work practices of the S&I Framework. We found that while the general S&I process was sound and well founded, there were several work practices that are especially necessary for success, or were not always followed. For example, establishing a clear charter and clear business requirements was mentioned many times as a key success pattern that was followed by S&I initiatives. Likewise, unclear roles for facilitators who sometimes drafted key deliverables were often mentioned as negative patterns, as were initiatives that started with engagement by business and clinical stakeholders, but where that engagement was hampered by lengthy processes or unclear timelines.

Therefore, we recommend that ONC consider the following in the work practices for a Convening Function:

1. **Recommendation:** Clear chartering driving towards real-world outcomes:
   1. Every initiative must be accompanied by a charter that lists real world outcomes and interim deliverables/outcomes that lead up to the long-term goals.
   2. The combination of both process and outcomes measures must be continually evaluated.
   3. Each initiative must have a clear plan for how the outcome could be evaluated.
2. **Recommendation:** Clear roles for facilitation:

The recognized stakeholders of the initiative should be the key, material participants in the initiative itself and should set the timeline for the initiative. ONC and other Federal agencies often use contractors to facilitate initiatives, but such facilitators must not drive outcomes or deliverables.

1. **Recommendation:** Rapid Cycle Implementation:
   1. Standards development best occurs in close coordination with implementation and rapid feedback cycles.
   2. Feedback should incorporate learning from pilots and production implementation.
   3. SDOs should consider changing work processes to accommodate rapid evolution of implementation guidance where warranted.
   4. S&I and SDOs may consider a process whereby a draft goes through rapid iteration without need for balloting (e.g., OAuth2 spec went through 31 drafts in concert with implementations prior to being formally adopted by IETF)
2. **Recommendation:** Rapid Cycle Implementation and SDOs
   1. SDOs perform a crucial role (balance of interest, copyright and IP management) and are aligned with OMB Circular A-119[[6]](#footnote-6) on the use of voluntary consensus standards.
   2. Accordingly, rapid standards development should be aligned with SDO calendars such that resulting deliverables are balloted as formal standards and implementation guides.
   3. Certification criteria should point to work that meets OMB Circular A-119.
   4. Accordingly, S&I Initiatives should work with SDOs to align rapid iteration cycles with formal balloting cycles to meet both interests.
3. **Recommendation:** Key Findings
   1. There are important stakeholders in S&I initiative who may benefit from real world outcome who may not have the capacity to participate at an ideal level to inform or progress the outcomes. This may lead to process inefficiencies or volunteer burnout.
   2. Some use cases may be defined too broadly which increases the complexity and level of effort required to achieve an outcome.
4. **Recommendation:** Specific Recommendations
   1. Consider narrowing scope of initiatives in order to target specific, achievable outcomes
   2. Set time limits , project plans and processes to expedite the narrowly defined results
5. Process should be appropriate to allow the project to move forward at the appropriate rate.
6. Phases should be time-boxed. Scope is too broad in some cases, leading to work not being completed well enough to be carried forward.
   1. Define an oversight process for S & I initiatives that includes
      1. Well-established checkpoints to evaluate the initiative against the desired real-world outcomes
      2. If and when it's determined that the outcomes are unlikely to be achieved then there should be a process to wind down the activity rather than proceed
   2. Ensure a formal consensus process is maintained to ensure balanced representation of stakeholder interests is applied to decision points on each initiative
   3. Increase input of those with expertise in development of testing tools
   4. Develop test tools in parallel of development of implementation guidance

We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/ /s/

P. Jon White John D. Halamka

Chair, Health IT Standards Committee Vice Chair, Health IT Standards Committee

1. <http://healthit.gov/facas/sites/faca/files/HITSC_Efficiencies_Final_2014-11-18.pdf> [↑](#footnote-ref-1)
2. Task Force Members : <http://www.healthit.gov/facas/FACAS/sites/faca/files/SITF_Meeting_Slides_Kickoff_Final_2015-01-23_v2_0.pptx> [↑](#footnote-ref-2)
3. Panelists: <http://www.healthit.gov/facas/FACAS/sites/faca/files/SITF_Agenda_2015-02-27_v2.docx> [↑](#footnote-ref-3)
4. <http://www.healthit.gov/facas/FACAS/calendar/2015/03/18/hit-standards-committee> [↑](#footnote-ref-4)
5. Interoperability Roadmap: <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf> [↑](#footnote-ref-5)
6. OMB Circular A-119: <http://www.whitehouse.gov/omb/circulars_a119> [↑](#footnote-ref-6)