Office of the National Coordinator for Health IT
HIT Policy Committee Certification Hearing

May 7, 2014

The following remarks were submitted by Jitin Asnaani on behalf of the CommonWell Health Alliance in connection with a hearing on ONC's EHR certification program. We thank ONC and the HIT Policy Committee for the opportunity to participate in this event and to provide testimony.

About CommonWell

The CommonWell Health Alliance is an independent, not-for-profit trade organization devoted to the simple vision that health data should be available to individuals and providers regardless of where care occurs. We believe that provider access to this data must be built into health IT at a reasonable cost for use by a broad range of healthcare providers and the people they serve. The Alliance currently consists of ten health technology vendors who collectively represent more than 40% of the acute EHR and 20% of the ambulatory EHR markets.

The Alliance plans to define and promote a national infrastructure with common standards and policies. The early core components of this infrastructure include:

- **Identity Management** services to accurately identify patients as they transition through care facilities.
- **Record Locator** services to help providers locate and access their patients' records, regardless of where the encounter occurred.
- **Consent Management** services to deliver a patient-authorized means to simplify management of data sharing consents and authorizations.
- **Trusted Data Access** to provide authentication and auditing services that facilitate trusted data sharing among member systems.

We believe that our approach will help solve the longstanding industry problem of interoperability among the fragmented health IT landscape, enabling a patient's data to be available in a secure, trusted manner to the patient and the patient's care providers regardless of where care occurs. This approach can improve care quality and foster innovation by creating an open vendor-neutral platform to break down the technological and process barriers that currently inhibit effective health care data exchange.

About Our Certification Approach

Our certification process is administered by the CommonWell Health Alliance services provider, which certifies every edge EHR system that is connected to the core services.

Our approach is to certify at the "CommonWell service" level so the services used/implemented on the edge system will drive what certification is required, as not all edge systems will use all services. We focus on certifying the actual interfaces, i.e., API calls, performance service levels, security requirements, IHE standard compliance, meta data, etc. As CommonWell services are added or significantly changed we would require an update to the edge system certification depending on the complexity of changes introduced and any new services released.

As a result of this approach, we expect updated certifications to be driven by the release of new API versions (and new services added) rather than the version of the edge system. We do not plan to certify workflows of the edge systems, but do plan to provide guidance and best practices to help drive value and usage of the CommonWell network.

Comments on ONC Certification Process

Ostensibly, the certification processes of the CommonWell Health Alliance and the ONC EHR Certification Program are both aimed at ensuring that HIT systems are built with "out of the box" interoperability that enables providers to truly focus on providing the best healthcare. However, there are some notable differences.

The most obvious difference is that our certification process is non-regulatory, which endows it with strengths that are complementary to a regulation-driven approach. For example, by being a private entity, our certification focus can be more responsive as standards evolve and market expectations change. Also, because we also provide the services that are actually used day-to-day, we are positioned to rapidly address weaknesses in the standards and certification criteria – especially when implementation guidance is poor or outdated in the first place – and can do so in an incremental and agile fashion; this is clearly a capability that is not possible with the ONC program.

Another notable difference is that the Alliance has focused on certification of interoperability only, and not on the functional behavior of individual vendor's applications. Insofar as the Alliance's scope is concerned, this seems more appropriate than certification efforts that actually delve into specific application behaviors. It is our belief that the greatest value is created by standardizing the interoperability and then letting vendors compete on how to best deliver the user's experience.

Through standing up and executing our certification process, we have discovered interoperability issues that should be on ONC's certification radar. Most notably, we have suggestions on the CCDA content standard; while comments about a particular standard may sound highly granular for this forum, we think it's critical to highlight them here because the CCDA is fast-becoming the core content "packet" for health information exchange nationwide.

- We recommend that the ONC EHR certification process should be made more rigorous so as to ensure that CCDAs are well-formed and parseable, as we have encountered several CCDAs "in the wild" that are unparseable despite the fact that the generating systems have achieved Meaningful Use Stage 2 certification. Even if the CCDA is formed correctly, the fact is that the CCDA does not define the clinical meaning of many of the core constructs. For example, it's syntactically legal to have a CCDA medication where all the values are null, so long as you express the required elements and attributes, but this is meaningless. Fixing this issue might require further tightening of the implementation guide and performing deeper testing of the CCDA.

- Further inhibiting real-world interoperability is the fact that different organizations have made different choices for CCDA implementation; for example some organizations provide every medication or problem that the patient has ever been on or experienced versus others that share only the most recent encounter. If the receiving system does not anticipate these variations, the resulting user experience can be quite poor: the horror story of today is the clinician who receives a 40-page HTML translation of the CCDA where the key information is buried across those pages. To address this, we have two recommendations:

    o At the CCDA level, we suggest that different CCDA implementations or profiles need to be specified to address different use cases, e.g., the encounter-specific summary with all the active elements at the time of that encounter, versus the complete historical record used to migrate the record, or the date-ranged on-demand record as needed for SSA disability claims.
    o While we do not recommend extending the certification process to judge how "good" the actual workflow is, we think that certification should take into account the relevance of the data. For example, systems that display all medications without the ability to filter or differentially display active meds versus discontinued medications are probably not implementing/incorporating the CCDA correctly, and are certainly not semantically interoperable.

Summary

The certification process used by the CommonWell Health Alliance has the advantage of nimbleness and the focus on real-world, actively-used services. In order to deal with regulatory and market short-comings, we can iteratively improve our ability to deal with interoperability issues so that our members can reap the benefits of our network. Through our agile approach, we can and have discovered issues that are impediments not just for us but for the entire healthcare ecosystem, and ONC's standards and certification processes can be positioned to address these issues nationwide.

Best regards,

/s/

Jitin Asnaani
Operating Committee Member, CommonWell Health Alliance
Director, Technology Standards & Policy, athenahealth