HIT Policy Committee Meeting
June 6th, 2012

Overview
The June 6th meeting of the HIT Policy Committee included: briefing from ONC on the RFI on governance for NwHIN, review and discussion of workgroup comments and recommendations on the 66 questions contained in the RFI from the Governance, Information Exchange, and Privacy & Security Tiger Team workgroups. This review was followed by a brief update from CMS on Stage 1 Meaningful Use Attestation and a presentation on the United Kingdom's proposals for shared decision-making and choice for patients from the UK State Secretary for Health Andrew Lansley.

Background
The HITECH Act, part of the American Recovery and Reinvestment Act of 2009, was passed to help promote the adoption of health information technology (HIT) and create a better health care system. HITECH established two federal advisory committees to assist the Office of the National Coordinator for Health Information Technology (ONC) in the adoption process, with one of them being the HIT Policy Committee (HITPC). This committee provides recommendations to the ONC on major HIT policy issues for consideration. HITPC is itself comprised of many workgroups covering a variety of topics including Meaningful Use (MU), quality measures (QM), the Nationwide Health Information Network (NwHIN), information exchange, enrollment, privacy & security and several others.

Summary of Meeting:

ONC Briefing on Request for Information on Governance for the Nationwide Health Information Network
Steve Posnack, ONC

The NwHIN Conditions for Trusted Exchange RFI is meant to present ONC's perspective on the progression of NwHIN. ONC has approached the CTE's with humility and admits to not knowing all of the answers or whether or not they're looking at the right end points. ONC will not govern the NwHIN, but seeks to create a "governance mechanism" meant to create a foundational structure and process in the form of technical exchange building blocks for that construct. This government mechanism is designed as the catalyst for NwHIN's acceleration of HIE. NwHIN is an integral component of the overall HIT ecosystem, and it will take time to become established.

The overall objectives of the governance mechanism include:
- Enable a more competitive, open and efficient market for HIE;
- Relieve burden on the states who have been employing disparate governance approaches;
- Establish the foundation necessary to support future Meaningful Use stages; and,
- Work with HIE marketplace to coordinate standards and interoperability activities as they evolve and mature.

The RFI seeks comment on the following areas:
- Conditions for Trusted Exchange (CTE)
    - Safeguard CTEs (10): protect individually identifiable health information (IIHI) focusing on its confidentiality, integrity, and availability and prevention of unauthorized or inappropriate access, use or disclosure.
        - [Safeguards-1]: An NVE must comply with sections 164.308, 164.310, 164.312, and 164.316 of title 45 of the Code of Federal Regulations as if it were a covered entity, and must treat all implementation specifications included within sections 164.308, 164.310, and 164.312 as "required".
        - [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.
        - [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.

        - [S-4]: An NVE must only exchange encrypted IIHI.
        - [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.
        - [S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.
        - [S-7]: An NVE must operate its services with high availability.
        - [S-8]: If an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals with electronic access to their unique set of IIHI.
        - [S-9]: If an NVE assembles or aggregates health information which results in a unique set of IIHI, then it must provide individuals with the right to request a correction and/or annotation to this unique set of IIHI.
        - [S-10]: An NVE must have the means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a treatment relationship with that individual.
    - Interoperability CTEs (3): technical standards and implementation specifications needed for exchanging electronic health information.
        - [Interoperability-1]: An NVE must be able to facilitate secure electronic health information exchange in two circumstances: 1) when the sender and receiver are known; and 2) when the exchange occurs at the patient's direction.
        - [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.
        - [I-3]: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.
    - Business Practices CTEs (3): operational and financial practices requiring adherence on the part of NVEs in support of trusted electronic HIE.
        - [Business Practice-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.
        - [BP-2]: An NVE must provide open access to the directory services it provides to enable planned electronic exchange.
        - [BP-3]: An NVE must report on users and transaction volume for validated services.
- Validation process for entities to demonstrate conformance to CTEs in order to become an NVE
    - Preconditions to apply to entities to determine eligibility to become an NVE
    - Validation through testing/certification of products or technology and accreditation of services
    - An Accreditation Body, selected by ONC, will accredit Validation Bodies, who will validate an entities compliance with CTEs
- Processes to alter CTEs as needed
    - Inclusive and transparent process
    - Classification of CTEs as "emerging", "pilot", or "national"
- Process to classify the readiness of technical standards and implementation specifications to support interoperability related CTEs
- Processes for monitoring and transparent oversight
    - Open, transparent, iterative process to set road map
    - Actors could be ONC, NwHIN accreditation and validation bodies, FTC, OCR

Discussion

Voluntary framework: The voluntary framework was designed out of a desire for NVE certification to be a value-add. It is voluntary in the same sense that Meaningful Use is voluntary. The Energy Star analogy is used often in explanation of the idea of NVE certification.

NVE criteria: ONC was wary to preclude an entity from being an NVE, as many entities could potentially qualify if they're facilitating information exchange.

Remarks
Farzad Mostashari, National Coordinator

ONC emphasized that it is important to put this RFI into perspective and consider the larger picture surrounding HIE. HIE should "just work" – providers should not have to think about exchanging information, it should just happen. For this to occur there must be a foundation of common and consistent policies, with all parties trusting the marketplace. Without a common set of rules, each will have its own – thus it is essential that a common floor exists.

Two big picture questions to consider – if ONC could adopt a common set of rules:
1) What would those common set of requirements be?
2) How should they be enforced?

Discussion
"Floor": There is concern that a floor implies that things will be piled on top of it, and people will create systems that will prevent interoperability. ONC clarified that there are two categories of "pile-ons" – those that build on existing standards and report back to a central authority, thereby breaking the trail for future developments, and those that could potentially result in back-tracking. Implementing a "floor" will provide a driving force for simplification.

Workgroup Comments on ONC Governance RFI for NwHIN
John Lumpkin, Chair, Governance Workgroup
Micky Tripathi, Chair, Information Exchange Workgroup
Deven McGraw and Paul Egerman, Co-Chairs, Privacy & Security Tiger Team

The Governance, Information Exchange, and Privacy & Security Tiger Team workgroups made extensive comments on nearly all of the 66 questions posed by ONC in the RFI on NwHIN governance. These comments are available at:
http://healthit.hhs.gov/portal/server.pt?open=512&objID=1814&parentname=CommunityPage&parentid=18&mode=2&in_hi_userid=11673&cached=true

Discussion
Discussion of the comments in response to ONC's questions was often aligned with the written responses referenced above. However, there were areas of contention that are not captured in the question responses, and certain topics that have been flagged by the Committee as requiring additional thought and discussion. There was a general remark that it's important to keep in mind that some of the CTEs only apply to an entities' function as an NVE, not to the functions of the entire entity.

Validation and Certification
Question 10: Should the validation method vary by CTE? Which methods would be most effective for ensuring compliance with the CTEs?

The Committee agrees that the type of conformance testing will vary with CTEs. There was initial disagreement over the level of oversight in the certification process – rigorous validation (including site visits) on one end of the spectrum and self-attestation on the other end. It was noted that the process can't fail many times and maintain validity. There was much discussion of crowd-sourcing as an aid to the self-attestation piece. Subsequent discussion revealed that the two sides were not conflicting, and there is general consensus that yes, validation methods should vary by CTE, and thus some will be more rigorous than others.

HIPAA Violations
Question 15: Are there other eligibility criteria that we should also consider?

The Policy Committee, especially the Governance and Information Exchange workgroups, were of the opinion that HIPAA violations should not necessarily disqualify an entity from becoming an NVE. Many organizations have policies in place for handling HIPAA violations, and eligibility should be based on assessment of these policies rather than on a single HIPAA. To prevent an entity with any HIPAA violation from certification would unfairly subject all patients to no participation in HIE.

De-Identified Data
The debate over de-identified data regarding its definition, proposed use and availability was the lengthiest and least-resolved of the meeting. Overall, the Committee decided that a follow-up discussion is needed to determine whether or not de-identified health data contained within an NVE can be used for purposes outside those of direct patient needs. There was agreement that there needs to be a clearer definition of "commercial purpose", as well as hesitancy to create a blanket policy surrounding the use of de-identified data at this time.

Question 55: What data would be most useful to be collected? How should it be made available to the public? Should NVEs be required to report on the transaction volume by end user type (e.g., provider, lab, public health, patient, etc.)?

There was general agreement among the Committee that metrics should be aggregated, but no consensus on the level of that aggregation – the Committee acknowledged that further discussion on this topic is needed.

Question 24: What is the most appropriate level of assurance that an NVE should look to achieve in directly authenticating and authorizing a party for which is facilitates electronic exchange? In reference to CTE [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.

There was much uncertainty here – the Committee liked the concept of a federal bridge but has problems with some of the federal aspects. Members noted that ONC is really "digging into the mud" here.

Question 28: Under what circumstances and in what manner should individual choices be required for other electronic exchange purposes? In reference to CTE [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.

The discussion in reference to this question involved directed queries and the locus of control in the decision to release data.

Question 32: Are there specific uses or actions about which we should consider explicitly requiring an NVE to be transparent? In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

The committee determined that yes, NVEs should have a notice about data practices. This question brought up a lengthy discussion about the use of de-identified data. There is value to using de-identified data for population and public health purposes, but also concerns about patient privacy. There could be a possibility for "re-consent" for release of data. This discussion was not resolved.

Question 37: What impact, if any, would this CTE have on various evolving business models? Would the additional trust gained from this CTE outweigh the potential impact on these models? In reference to CTE [S-6]: An NVE must not use or disclose de-identified health information to which is has access for any commercial purpose.

Again, there was much contention surrounding de-identified health information. One point made was that de-identified data is often only de-identified in reference to patient information – provider information remains viewable. There was a distinction made between "selling" data and using it for a "commercial purpose".

Patient Involvement
Question 27: In accommodating various meaningful choice approaches (e.g., opt-in, opt-out, or some combination of the two), what would be the operational challenge for each approach? What types of criteria could we use for validating meaningful choice under each approach? Considering some States have already established certain "choice" policies, how could we ensure consistency in implementing this CTE?

There was concern among the Privacy and Security Tiger Team surrounding the lack of patient involvement in the management of consent.

Question 40 and 41, referring to [S-8 and S-9], brought up the concern that requiring an NVE to provide individuals with electronic access to their unique set of IIHI would imply that the NVE is interacting directly with the patient. It's possible that patients might be taken aback as they may not be familiar with the NVE itself, and could be confused as to why their information has been shared.

Medicare & Medicaid EHR Incentive Programs: Discussion on Stage 1 Meaningful Use Attestation
Rob Anthony, CMS

This presentation by CMS was intended to provide an update on the status of the EHR incentive program as of the end of April 2012. There has been consistently high registration – approximately 71% of eligible hospitals have registered, and 50% of all eligible professionals have registered. There is an evening out on the number of payments per month, on both Medicare and Medicaid sides. As of April, thus far in 2012 payouts totaled $540 Million to over 94,000 EPs. More detailed payment information is available in the PowerPoint presentation given by CMS available at:
http://healthit.hhs.gov/portal/server.pt?open=512&objID=1814&parentname=CommunityPage&parentid=18&mode=2&in_hi_userid=11673&cached=true

The United Kingdom's Proposals on Shared Decision-Making and Choice for Patients
Andrew Lansley, UK State Secretary for Health

The UK State Secretary for Health, Andrew Lansley, shared information about the UK health system and the role of patients. The UK health system has similar goals to that of the US – greater quality, empowerment of patients, mobilization of information, among others, all surrounding the aim for excellence and equitability. The UK is in the process of re-framing its system to put the patient at the center, which has been a culture change for the National Health Service. Shared decision-making is thus essential. Surveys have revealed that patients have specific asks, including the ability to book and order prescriptions online, communicate online with providers, access test results online, find information through a single trusted source, and have confidence that data is used for both personal and population health benefit. In addition to clinical effectiveness, patients are also very concerned about the experience of their care.

Notably, there has been resistance in the UK about the use of data for population health. Many individuals do feel uncomfortable about long-term availability of de-identified data. However, the UK is coming from a very different place than the US in this respect – there has been one health scheme for the entire country, and the concept of population health is much more attractive to citizens of the UK than is the case in the US. Although there is often a demand for the reasons for data access, as long as patients are protected there is a desire for improvement of care through an understanding of population-level health.