HIT Policy Committee Meeting
April 4th, 2012

Overview
The April 4th meeting of the HIT Policy Committee included: reviews of workgroup recommendations on the Meaningful Use Stage 2 NPRM and the EHR Certification NPRM from the Meaningful Use, Information Exchange, Certification/Adoption and Quality Measures Workgroups as well as the Privacy & Security Tiger Team.

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:

Meaningful Use Workgroup Draft Recommendation on NPRM
Paul Tang & George Hripcsak, Co-Chairs

Workgroup Timeline
- April 4th: Present initial recommendations for HITPC feedback
- April: MU WG revise recommendations
- May 2nd: Revised recommendations for HITPC approval
- May 7th: Submit HITPC response to NPRM

The MU WG made extensive comments on nearly all of the Stage 2 objectives and attempted to answer several questions posed in the NPRM. These comments are available through the Workgroup's PowerPoint presentation available at:
http://healthit.hhs.gov/portal/server.pt/document/957449/application_vnd_openxmlformats-officedocument_presentationml_presentation

Discussion:
The role of scribes: Supporting teamwork and collaborative care is a favorable goal. However, it is difficult to craft a recommendation for this issue because the requirement should not be too restrictive. Should scribes be allowed as a way to encourage collaboration of care, or should the states determine the role of scribes in their jurisdiction? The real question regarding scribes is liability. If the provider's license is on the line, then a mechanism to control accountability is needed. If it is not possible to measure the person typing the orders, the focus should be on the provider workflow and encouraging the use of the technology instead of giving the responsibilities to another party.

Disparities: This topic should be addresses and is largely absent from the NPRM. Providers are collecting demographic data, but it does not seem like the information is used to address disparities. Quality measures need to be developed around disparities and applied to the requirements.

Electronic Prescribing: An opt-out may be needed for rural areas where pharmacies may not exist or accept eRx. CMS is already considering adoption of an opt-out.

Secure Messaging: May be divided into two measures. First, providers sending patient specific messaging and initiating the conversation. Second, a measure that deals with a provider's timeliness in response to patients.

There is concern over setting a percentage for secure messaging because some patients may not be digitally connected. Exclusions need to be possible because some areas and populations are known to lack broadband access.

Care Summaries: Technical capability to be incorporated into other providers' records is needed for care summaries.

Registries: The committee should expand its support of registries and do more research to determine which ones are important, as registries could have a lot of value to patients and providers. The potential for public health improvement would be large. Standards are really needed for registries. The challenge is that registries have a lot of data elements and standardizing them would be difficult. This would also require every vendor to interface with registries, so a lot of work on standards would be needed.

Following the discussion, the Workgroup will revise their recommendations based on the comments and present the final recommendation at the next HITPC meeting.

Information Exchange Workgroup Draft Recommendation on NPRM
Micky Tripathi, Chair

Workgroup Timeline
MU Stage 2 NPRM

- March 22nd: Discussed eRx, incorporate lab data, hospital send lab results, perform HIE test
- March 29th: Discussed public health (immunization, syndromic surveillance and ELR), reporting to cancer and non-cancer registries
- April 2nd: Discussed transitions of care and medication reconciliation
- April 17th: Will discuss view and download and secure messaging as well as review comments from HITPC and brainstorm on interoperability trends.
- May 1st: Review final comments for HITPC

Other Topics

- May-June: Fact-finding on State of Interoperability
- July-August: Recommendations on MU Stage 3
- TBD: Comments on NwHIN Governance ANPRM

Workgroup Recommendations:

- Hospitals Send Lab Results: Unanimous approval to restore HITPC-recommended requirement for hospitals to send structured labs. Reasoning:
    1. Would not necessarily impose a burden on hospitals; indeed, some hospitals would find it beneficial to have a standard
    2. Directly affects ability of EPs to achieve structured lab result objective
    3. Directly affects CQM capabilities
- Perform Test of HIE: Unanimous approval to remove test for Stage 1 with no replacement
    1. High market confusion about this measure
    2. Want to minimize addition of new requirements in Stage 1
    3. Only affects those attesting to Stage 1 in 2013
    4. Stage 2 requirement places enough pressure on this cohort to achieve the goal
- Public Health – Syndromic Surveillance: Support NPRM and agree with CMS that EP requirement should be Menu and EH should be Core
    1. EP requirements not mature enough to make it Core
    2. Implementation guide not expected to be published until early 2013 so can't assess the ability of technology and users to accomplish this objective
    3. Unlike hospitals, SS reporting is new to EP current practices and workflows – not simply turning paper into electronic
- Transition of Care Summaries: Remove cross-vendor requirement to meet 10% electronic exchange threshold
    1. In many markets, both rural and urban, a single vendor has high penetration

2. Want to create incentive for vendors to incorporate national standards deeply into their products
3. Don't want to force "artificial" transitions in order to meet the requirement

The Workgroup still has concerns with some topics:

- eRx
  - 65 percent threshold may be too high given geographic variation in eRX penetration and low penetration of eRX among mail order pharmacies
  - Need to refine definition of "available" formulary, and provide more specificity of what to do when no formulary is "available"
- Incorporate Lab Data
  - Workgroup is comfortable with raising threshold to 55 percent as long as hospitals are required to send structured labs
- Public Health
  - Too much discretion left to state/local public health agencies
  - No definition of "ongoing successful submission"
  - Too much optionality allowed in standards
  - Should align transport standards with EHR certification and transition-of-care requirements, but grandfather in legacy approaches that are already in production
  - On immunizations, need more specificity on scope of immunization reporting required (such as all immunizations, site-administered, most recent, etc.)
- Report to Cancer or Specialized Registry
  - Need more specificity of definition of qualifying registries
  - Lack of clarity of alignment of reporting requirements with EHR certification requirements, and possible differences with general EHRs and specialty-specific
- Transitions of Care Summary
  - Concerning the 65 percent requirement, need to specify that fulfilling requirement through electronic access should require that summary of care data elements are made available
  - Need to adjust exclusion criteria to rule out those with small numbers of qualifying transitions
  - Possible discrepancy in numerator and denominator definitions for 10 percent requirement
  - Allow queries from ED (where available) to count toward measure fulfillment?
- Medication Reconciliation
  - 65 percent may be too high for some specialties – concern because this would now be Core

The Workgroup will cover the View and Download and Secure Messaging Objectives in the future.

Discussion:
Elimination of the test of HIE requirement in Stage 1 could be a problem, as providers shifting to Stage 2 will face a huge step towards sharing information without anything in Stage 1 acting as a preliminary step. This recommendation was made because there was a desire to move away from testing the technology to actually engaging in the activity.

Transport standards were not included in Stage 1, but they could be applied in the future and clear up any market confusion.

The transmission of care summaries for the Stage 2 threshold needs to be higher than 10 percent because it should be fostering exchange to a greater degree. The workgroup believes that there is just too much market confusion right now to go above 10 percent. In the future when transport standards are more ingrained in information exchange, then this percentage can be increased.

A question was raised concerning the availability of a population health platform that could feed registries automatically from health information like summary of care documents. The consensus was that there are a variety of content requirements for each registry, and this makes it difficult to create a single

platform. The financial burden of sending data to registries needs to be taken into account if providers will be required to submit information to them.

The requirement for 10 percent of exchange with providers using different EHRs requirement should be eliminated. Instead, the focus should be on moving towards national standards and having products incorporate these standards. The interfaces to allow different vendor products to interact are very expensive. The standards should apply to all vendors regardless of where they are sending information.

Privacy & Security Tiger Team Comparison of Stage 2 Proposed Rules w/HITPC's Previous Privacy & Security Recommendations

Deven McGraw & Paul Egerman, Co-Chairs

New Guidance to State HIE Grantees

- Available at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_5545_1488_17157_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/onc_hie_pin_003_final.pdf
- Provides guidance to state grantees and requires them to submit privacy and security frameworks
- The guidance "builds from the privacy and security and governance recommendations of the Health IT Policy Committee"
- Includes adoption of policies based on ONC's articulation of fair information practices and consent

Previous Recommendations Aimed at Stage 2 Meaningful Use and Certification

- Security risk assessment & addressing encryption of data at rest
- Capability to support amendments
- Patient portals (view/download/transmit function)
- Patient matching – standard formats for demographic data fields, address normalization
- E-prescribing of controlled substances
- Digital certificates for exchange
- Certification of EHR modules for privacy & security

Status of Recommendations:

Fully Adopted:

- Security Risk Assessment, including addressing encryption of data at rest
- Amendments – provisions regarding capability to make amendments and append additional information
- Patient Portals – requirement for patient accessible audit log of portal access

Not Sure (no express adoption but may be covered by other standards such as CCDA & transport):

- Patient Portals: data provenance
- Patient Matching: standard formats for fields used for matching, missing data
- Digital Certificates: use of digital certificates (or some form of entity authentication with high degree of assurance)

Not Adopted:

- Amendments: capability to transmit amendments to other providers by Stage 3
- Patient Portals: secure download, authentication, mechanism to block programmatic or unauthorized attacks
- EHR modules
- E-prescribing of Controlled Substances (EHR capability)
- Digital certificates: testing of use
- Patient Matching and Demographics: address normalization, testing of demographic formats

Tiger Team Suggestions for Policy Committee Comments on Proposed Rules

- Comment favorably on CMS' proposal to include the security risk assessment (currently in Stage 1) and attesting to addressing encryption of data at rest in Stage 2 as privacy and security MU criteria

- With respect to amendments, comment favorably on ONC's proposal to require that Certified EHR Technology have the capability to make amendments to a patient's health data and be able to append information from the patient & any rebuttal from the entity regarding the data (per HIPAA requirements).
    - EHR Technology should be required to append patient-supplied information in both free text and scanned formats.
- Request that ONC signal in the final Stage 2 rule that by Stage 3 of MU, Certified EHR Technology must demonstrate the capability to transmit amendments (plus appended information) to other providers
- Comment favorably on ONC's proposal to require patient accessible log in Stage 2 certification

Issues Requiring Further Tiger Team Discussion

- Portals (view/download/transmit)
    - Require testing of certified EHR technology for authentication of patients (using at least single factor) and secure download
    - Proposed rule states that such technical implementations are commonplace & ubiquitous and therefore do not need to be required for certification
    - Require certified EHR technology to include requirements for data provenance that is accessible to patient/user (CCDA?)
    - Require certified EHR technology to include capability to detect and block programmatic and unauthorized user attacks (note: Standards Committee put forth different recommendation)
    - Urge ONC to more formally endorse guidance recommendations and develop and implement dissemination strategy
- EHR Modules
    - Stage 1 final certification requirements required EHR modules to be tested for all privacy and security certification requirements (except in certain circumstances)
    - Stage 2 proposed rule eliminates this requirement and instead requires the Base EHR to be certified for all privacy and security requirements.
    - HITSC adopted a different recommendation
    - Currently assessing whether proposed approach is sufficient or leaves gaps
- E-Prescribing of Controlled Substances
    - DEA rules require providers to comply with 2-factor authentication requirements when prescribing controlled substances
    - HITPC recommended that certified EHR Technology have capability to support such authentication
    - ONC declined to propose for Stage 2, noting potential policy conflicts with state law and challenges with widespread ability of products that include functionalities to support DEA requirements
    - ONC requests comment on availability point.
    - Tiger Team considering whether to push for capability in Stage 2 or strong signal from ONC for Stage 3
- Digital Certificates
    - HITPC recommended entity-level digital certificates issued with high degree of assurance
    - HITPC also recommended that certified EHR technology be tested on use of such certificates for appropriate transactions
    - Not addressed in proposed Stage 2 rule
    - Requirements for exchange for meaningful use are proposed to be increased in Stage 2. Tiger Team exploring whether additional recommendations for Stage 2 certification are needed to ensure entity-to-entity authentication (for example, are entity authentication issues addressed in proposed transport standards?).
- Patient Matching
    - Consider whether demographic data fields in CCDA (including null flavors for missing data) satisfy Policy Committee's recommendations regarding standardization of demographic data fields.

- In particular, consider reinforcing previous recommendation that certification criteria include testing that appropriate transactions are sent and received with correct data formats and data entry sequences exist to reject incorrectly entered values.
- Also consider whether to further push for USPS normalization of addresses.
- Consider ONC's request for comment on whether EHR technology should be able to perform matching between the patient in the EHR technology and the summary of care document about to be incorporated.

Discussion:
How do you know where data elements come from? Does the EHR track this?
Data provenance is important and we are just beginning to address this from the patient perspective at the moment. In the future, perhaps in stage 3, data provenance will become an important issue that is tackled with standards in place and when information exchange is more mature.

The testing of digital certificates needs to be included in the authentication process.

Quality Measures Workgroup Draft Recommendation on NPRM
David Lansky, Chair

The Workgroup had comments in three general areas:

- Alignment of measures across programs
  - MU1 was challenging for small practices; keep this in mind while increasing requirements for MU2
  - Alignment is worthy goal, but policy programs should not align to lowest common denominator – especially if it is based on pre-EHR technologies
    - For example, success with MU can satisfy PQRS, but not vice versa
  - Just as federal programs are aligning to drive payment for value, measurement alignment should facilitate new payment and policy priorities
- Vendor platform design for QM
  - If vendors can be motivated to improve QM "engine", it will increase provider capability to report measures and use them for meaningful QI
  - Vendors have hard-coded QM specifications; by moving to 125 EP measures (Option 1a), that may force them to design for more flexible calculation and reporting
  - Link between CDSS and QM selections could be powerful tool for improvement and could be reflected in "QM Engine" design
- Progress towards outcome measures
  - The QM Workgroup supports the six reporting domains
  - The QM Workgroup favors Option 1a for EPs to continue to focus attention on all six domains
  - The QM Workgroup supports linkage between QMs and clinical decision support
  - Mapping across reporting programs is desirable for alignment but must be clear and specific – need crosswalk
  - Availability of measures to satisfy reporting domains remains weak and will need substantial attention for Stage 3
  - Data elements and data types needed for Stage 3 should be captured by Stage 2 certification
  - Persistence of 'check-the-box' measures

The Measures Pipeline:
There are six categories of measures identified by CMS, each of which have several measures. However, the availability of these measures in Stage 2 is very limited. The existing measures are very specific, making them inapplicable to many providers. This needs to change in the future if any benefits are to be gained through this information.

Other Comments

- General endorsement for approach to hospital measures

- Debate between those who favor fewer measures likely to produce reliable, comparable results, and those who favor large inventory of measures to address multiple specialties, induce platform improvements
- Extended discussion of criteria for reducing length of EP measures list – many diverse perspectives
- Need for tighter specifications, implementation guides to assure measures are robust enough to use and compare
- Cautious endorsement of group reporting option – for "meaningful groups"
    - Option 1b may be an approach to consider for Group Reporting only

Discussion:
The HITPC should garner feedback from providers to determine what measures they view as the most useful and push those measures forward in development.

The focus of measures is improvement and we need to emphasize to providers how to not only record the data but also use the data to improve the care they provide. The reason for having a measure needs to be clear. Specifically, someone or something has to benefit.

Alignment of these measures is also a key factor. Tools that grant us flexibility in the future to evaluate our measures are paramount because we cannot align with measure that may not exist yet.

Update From Certification/Adoption Workgroup
Marc Probst & Larry Wolf, Co-Chairs

Workgroup Timeline for the EHR Certification NPRM
- March 29th: Review and Organize Work
- April 9th: Definition of Certified EHR Technology & Safety Enhanced Design/User Centered Design
- April 13th: Clinical Decision Support, Other Health Care Settings & Accounting of Disclosures
- April 17th: Disability Status, Data Portability & EHR Technology Price Transparency
- May 2nd: Comments to HITPC
- To Be Scheduled: Prepare Comments for Presentation to the Policy Committee

Criteria to be examined by the Workgroup:
- CPOE
- Drug-drug, drug-allergy interaction checks
- Medication list
- Medication allergy list
- Clinical decision support
- Electronic medication administration record
- Electronic prescribing
- Clinical information reconciliation

Really trying to focus on the policy side of these areas.