On June 13, 2011, Jodi Daniel, Director of the Office of Policy and Planning at the Office of the National Coordinator for Health Information Technology (ONC), provided an update on the activities of the Federal Advisory Committees and workgroups during a National eHealth Collaborative webinar event.

This HIT Policy and Standards Committees quarterly update focused on delineating the structure, nature, and function of the HIT Policy and Standards Committees.

Background and Additional Detail:

- Federal Advisory Committees were born out of the 1972 Federal Advisory Committee Act, which recognized the merit in seeking advice from the public in the policy making process. Federal Advisory Committees (FACs) are strictly advisory in nature and hold no actual policy-making power. FACs may be created either by an executive branch agency or an act of Congress.

- The Office of the National Coordinator for Health Information Technology's (ONC) FACs were created by Congress in the HITECH Act, a subtitle of the 2009 American Recovery and Reinvestment (ARRA) stimulus bill. These FACs, the HIT Policy and Standards Committees, serve in an advisory capacity to ONC.

- The role of the HIT Policy Committee (HITPC) is to advise the ONC about policy recommendations in the course of the establishment of a nationwide health information infrastructure. One key focus of the HITPC is the place of privacy and security considerations in the health data debate.

- Very specific requirements about the composition of the HITPC are outlined in the HITECH Act, including a broad range of membership from across the political and healthcare spectrum.

- The HIT Standards Committee, also created by the HITECH Act, is responsible for making recommendations to the ONC on the more technical aspects of the creation of a nationwide health data infrastructure. While membership must also reflect a wide range of interests across the political and healthcare spectrum, the rules regarding appointment to the Standards Committee are not nearly as stringent as those regarding the Policy Committee.

- The HIT Policy and Standards Committees have a variety of workgroups (WGs) that serve as the true work horses of the commission. Workgroups have the diversity and expertise to dig into the complexity at the core of issues. They are created and charged by the chair of the FACs (ONC councils the chair of the FAC in this process). Work groups

do not have to be open, but they usually are open anyway in the interest of transparency and public input, even at the draft stage. A listing of the workgroups created under the HIT Policy and Standards Committees as discussed is attached.

- Public input into the Federal Advisory Committee process is critical. Various channels for providing public input include accessing the FACA blog, the public comment period at the end of official meetings, expert testimony at meetings, formal request for comment and request for information, and more.

- The roles of the Federal Advisory Committees at the ONC include raising awareness of issues and informing discussion, putting public input into policies and standards, and providing recommendations to shape federal policies and programs (which is key in complex programs like the Electronic Health Record "Meaningful Use" Incentive program).

- Flow charts describing the functioning of the HITPC and HITSC are attached to clarify how the FACs function and interact within ONC.

The Office of the National Coordinator for Health Information Technology

Demystifying the Federal Advisory Committee Process and Recommendations

June 13, 2011

Presented by: Jodi Daniel, JD, MPH

Outline

- Federal Advisory Committee Act (FACA) 101
- Overview of the HIT Policy Committee and the HIT Standards Committee
- Role of the public in FACA work
- Role of the FACAs at ONC
- FACA recommendations process --how recommendations become rules
- Update: recent/upcoming FACA activities
- How to stay informed
- Q&A

Federal Advisory Committees (FACAs) 101

- The Federal Advisory Committee Act (FACA) of 1972 (Public Law 92-463) specifies the way in which the federal government can establish or manage committees to obtain advice or recommendations.
- Recognizes the merits of seeking advice and assistance from the public to shape programs and policies.
- Operates in public, which promotes transparency .
- Work is exclusively advisory in nature.
- Requirement that committee memberships be "fairly balanced in terms of the points of view represented and the functions to be performed."

ONC's Federal Advisory Committees (FACAs)

- The American Recovery and Reinvestment Act of 2009 (ARRA) provided for the creation of a **HIT Policy Committee** and a **HIT Standards Committee** under the auspices of the FACA.
  - Prior to ARRA (2005-2009), the American Health Information Community (AHIC) advised the Secretary on recommended actions to achieve an interoperability framework.
- Serve to advise the National Coordinator

Role of Health IT Policy Committee

- Established under section 3002(a) of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) to make ***policy recommendations*** to the National Coordinator on a policy framework for the development and adoption of a nationwide health information infrastructure, including implementation of the Strategic Plan described in section 3001(c)(3)
- Recommends areas in which standards, implementation specifications and certification criteria are needed for the HIT Standards Committee
- Initially focused on eight policy areas

Composition of the HIT Policy Committee

- 3 members appointed by the Secretary, including 1 HHS representative and 1 public health official
- 4 members appointed by the Majority and Minority Leaders of the Senate and the Speaker and Minority Leader of the House of Representatives
- Members appointed by the President as representatives of other relevant Federal agencies

- 13 members appointed by the Comptroller General of the US:
  - 3 patient advocates/consumers;
  - 2 health care providers, 1 of whom is a physician;
  - 1 labor organization representative of health care workers;
  - 1 expert in health information privacy and security;
  - 1 expert in improving the health of vulnerable populations;
  - 1 representative from the research community;
  - 1 health plan/3rd party payer representative
  - 1 representative of IT vendors;
  - 1 representative of purchasers or employers; and
  - 1 expert in health care quality measurement and reporting.

Role of HIT Standards Committee

- Established under section 3003(a) of the HITECH Act
- Makes recommendations to the National Coordinator on ***standards, implementation specifications, and certification criteria*** for the electronic exchange and use of health information for purposes of adoption under section 3004 of the HITECH Act
- Receives recommendations originally developed by the Health IT Policy Committee

Composition of the HIT Standards Committee

- The membership shall at least reflect:
  - Providers
  - Ancillary healthcare workers
  - Consumers
  - Purchasers
  - Health plans
  - Technology vendors
  - Researchers
  - Relevant Federal agencies
  - Individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

Formation of FACA Work Groups

- Work Groups (WGs) are created to provide expert input to the full committees on specific topics
- In consultation with ONC, FACA Committee Chairs are responsible for commissioning new WGs, setting their charge, and designating who will serve on the various WGs
- ONC provides staff support for each of the WGs

FACA Work Groups

HIT Policy Committee

- Adoption/Certification
- Governance
- Information Exchange
- Meaningful Use
- Privacy & Security "Tiger Team"
- Quality Measures
- Enrollment
- *PCAST*

HIT Standards Committee

- Clinical Operations
- Implementation
- Clinical Quality
- Vocabulary Task Force
- Privacy & Security Standards
- "Summer Camp" Power Teams

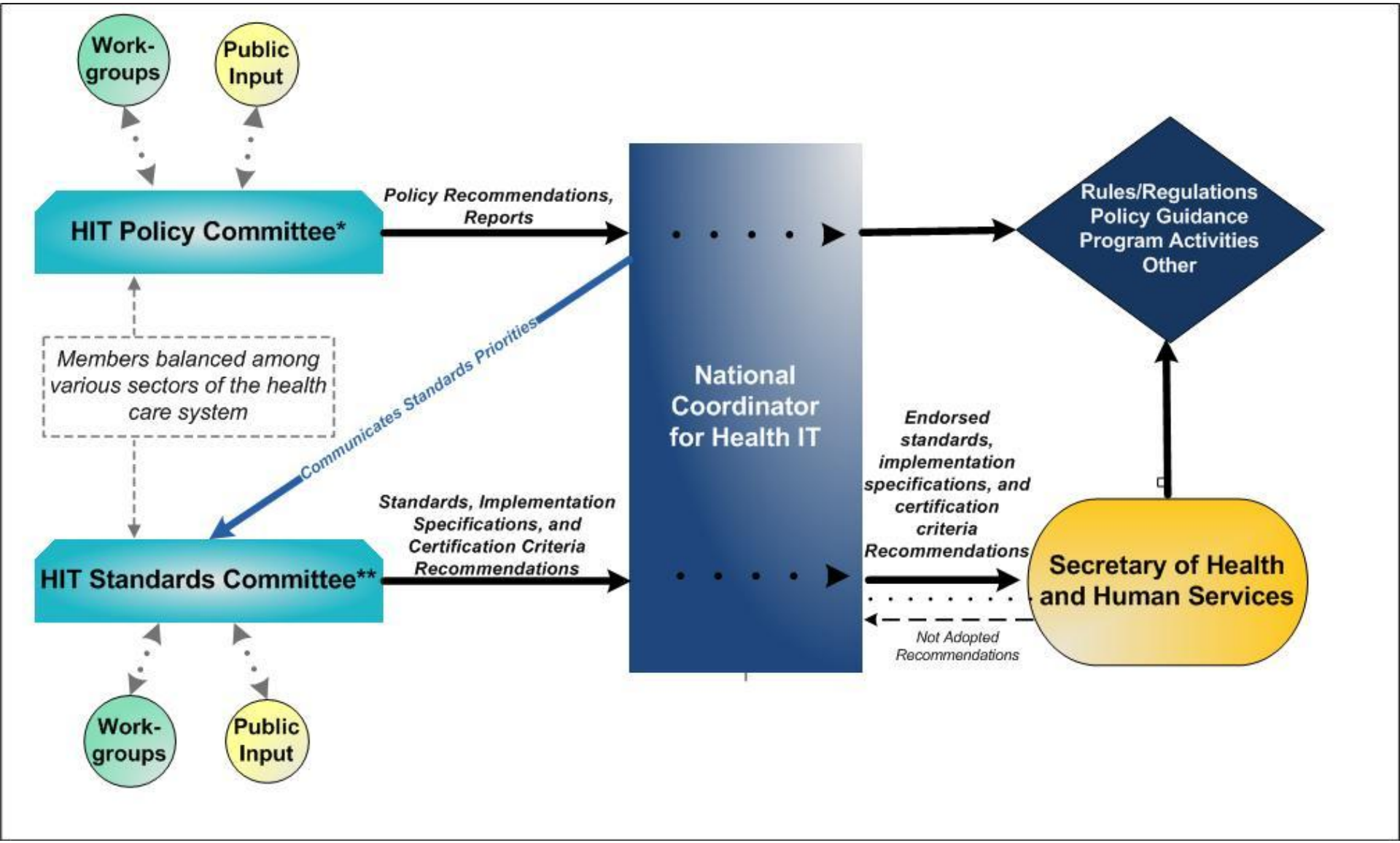
Public Input into FACA Process

- Foundational for the FACAs
- Various channels to provide input, including:
  - FACA Blog (http://healthit.hhs.gov/blog/faca/)
  - Public comment period at the end of meetings
  - Testimony at hearings
  - Formal Request for Comment / Request for Information
  - Other

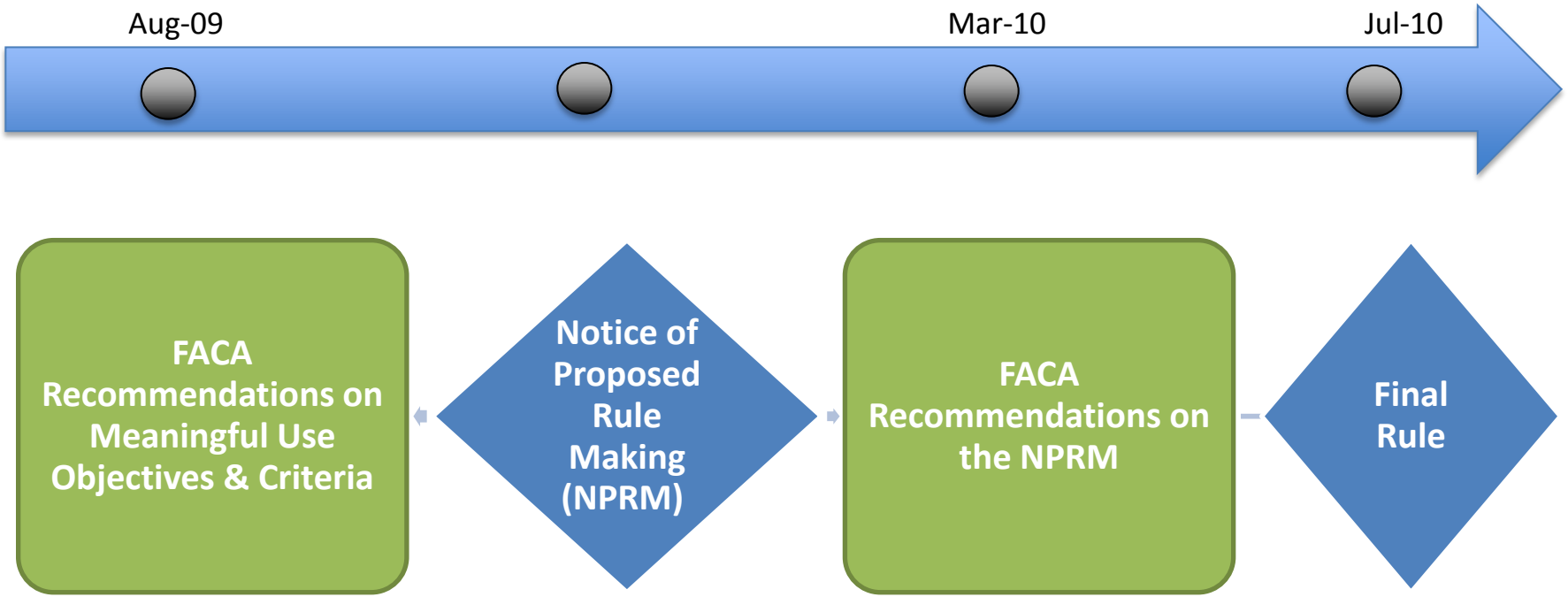
Role of the FACAs at ONC

Raise Awareness/Inform the Discussion	• Hearings: Specialists (5/13), Usability (4/21), Medical Device Interoperability (3/28), Experience with Stage One Meaningful Use (1/10-1/11)
Public Input Into Policies/Standards	• Recommendation on Patient Safety to commission a study with the Institute of Medicine (IOM) on patient safety concerns ➔IOM study • Testimony during a Workgroup meeting ➔The DIRECT Project
Recommendations to Shape Federal Policies and Programs	• Recommendations from Committees shape the development of the Meaningful Use NPRM • Recommendations from Committees shape the development of the Standards and Certification Criteria Regulation

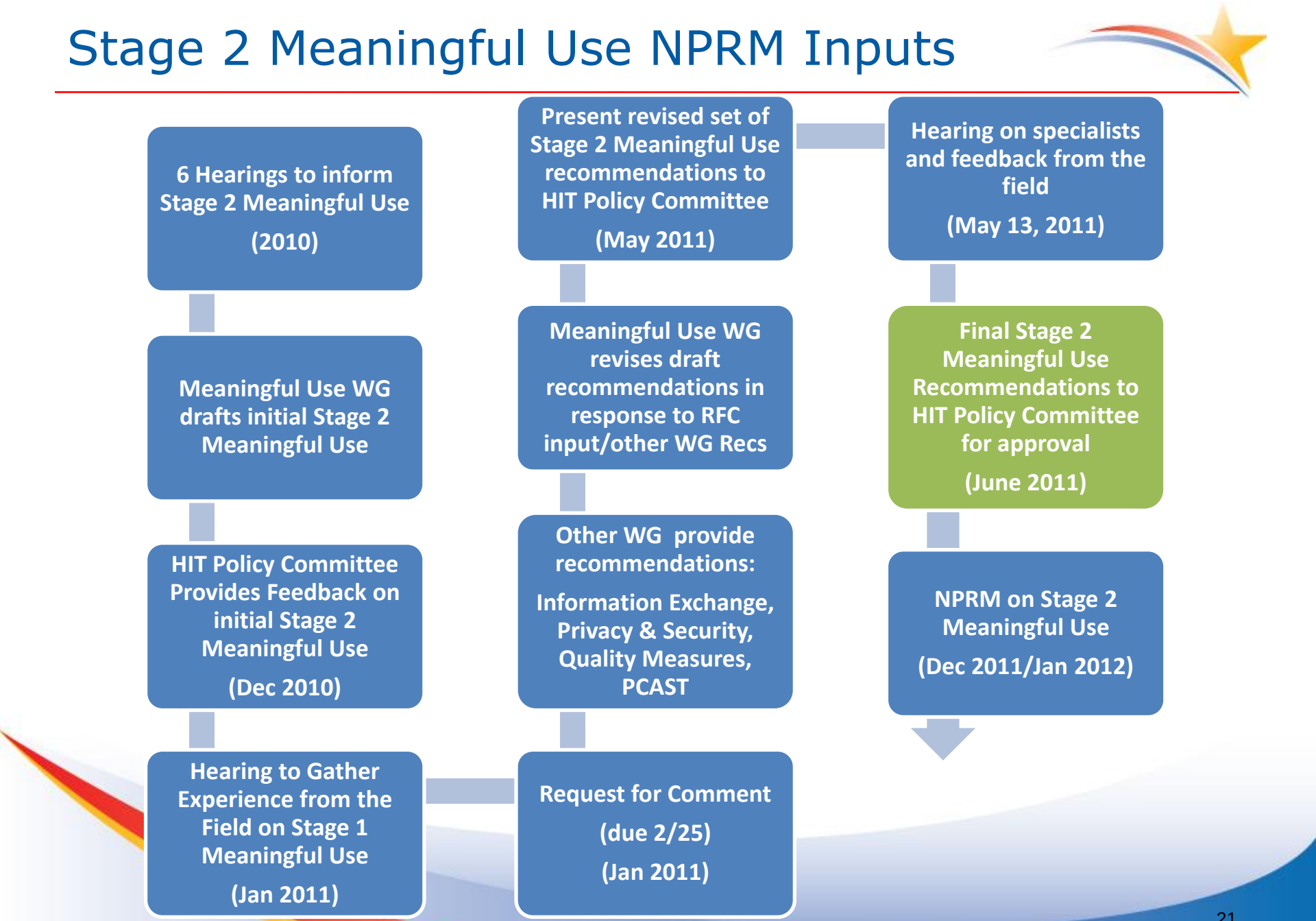
HIT Policy and Standards Committees Information Flow



FACA Recommendations: Stage 1 Meaningful Use



Stage 2 Meaningful Use NPRM Inputs



HIT Policy Committee Plan

FACA Workgroup	2011												2012
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Meaningful Use				5/13: Specialists	▲	★	Stage 2 Meaningful Use			Review NPRM on Stage 2 Meaningful Use			●
Quality Measures					▲ 5/19: Stakeholder Experience w/ Clinical QMs ★ Stage 2&3 Concepts/Measures								
Certification /Adoption	▲	1/10-1/11: Real World Experience with Meaningful Use		▲	4/21: Usability								
Information Exchange		★	Entity-Level Provider Directories		★	Individual-Level Provider Directory							
Governance										Review NPRM on NWHIN Governance			●
Enrollment				★	Streamline eligibility & enrollment in HHS programs								
PCAST		▲	2/15-16: PCAST	★	PCAST Report: Impact on Health IT Policies & Programs								
Privacy & Security Tiger Team		★	Patient Matching	★	Authentication	★	Certificate Authority-Provider Authentication						

▲ Public Hearing

★ Recommendations

● Review NPRM

HIT Standards Committee Plan

FACA Workgroup	2011												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
Clinical Operations			3/28: Medical Devices						Stage 2 Standards & Certification Criteria (CC)				
Implementation	1/10-11: Real World Experience with Stage One of Meaningful Use										Review NPRM on Stds & CC		
Clinical Quality						5/19: Stakeholder Experience with Clinical QMs			Quality Measures Standards & CC				
Vocabulary TF								Vocabulary standards to support Stage 2 Standards & CC					
Privacy & Security Standards		Digital Certificate Standards					Entity-level and Individual-level Provider Directory Standards						
"Summer Camp " Power Teams								Report out through HIT Standards Committee on various standards development activities					

Public Hearing

Recommendations

Review NPRM

Stay Informed

- Health IT Buzz Blog: http://www.healthit.gov/buzz-blog/
- FACA Meetings Calendar

  http://healthit.hhs.gov/FACAs
- Attend a monthly FACA Meeting—either in person or via the web
  - 6/22: HIT Standards Committee
  - 7/6: HIT Policy Committee
- Follow us on Twitter (#ONC, #HealthIT, #HITPol) http://www.twitter.com/ONC_HealthIT