The Office of the National Coordinator for Health Information Technology

ONC Update

NCVHS Meeting
September 22, 2014

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ONC

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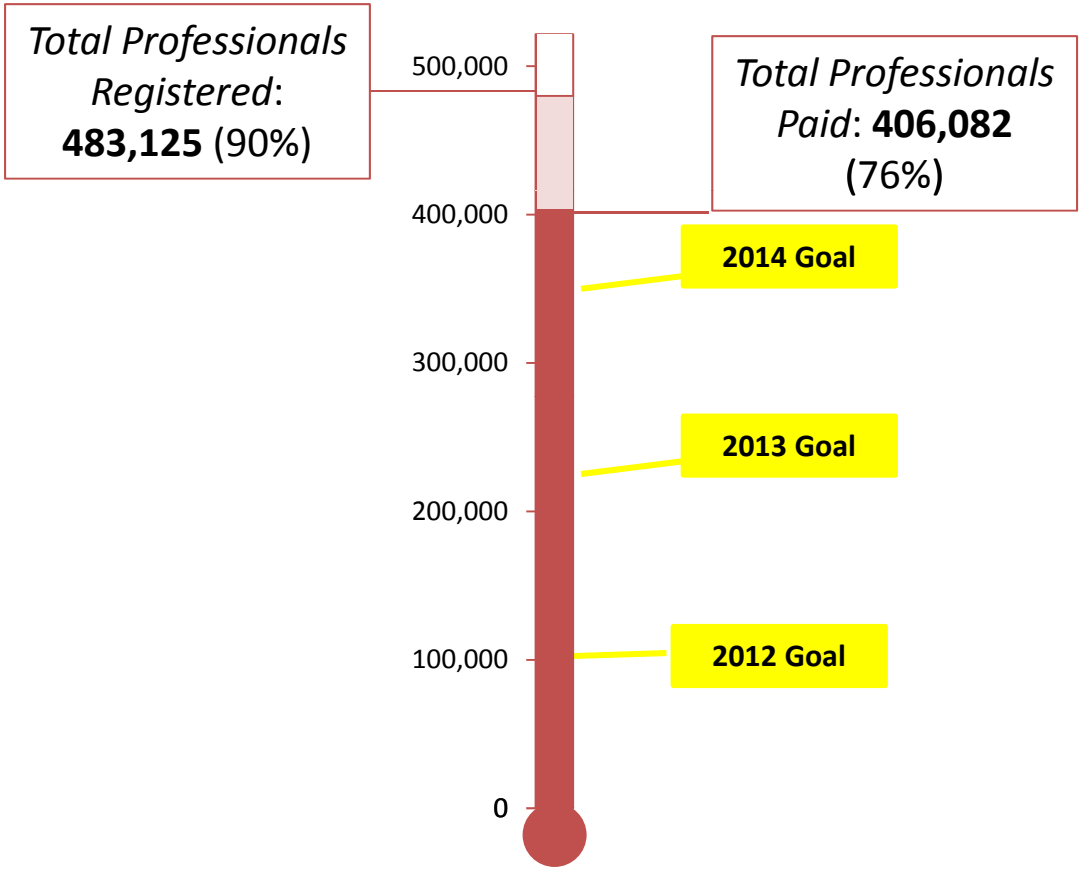
ONC Update Items

1. EHR Adoption Statistics
   - 2014 Attestation
2. Meaningful Use CEHRT Flexibility – Final Rule published
3. Meaningful Use 2014 Edition Release 2 – Final Rule published
   - Naming Convention
   - What's Next
4. Re-aligned FACA Workgroups
5. 2014 FACA Workplan

Eligible Professionals *Thermometer*

Progress toward Achievement of Meaningful Use

537,600
Total Eligible Professionals



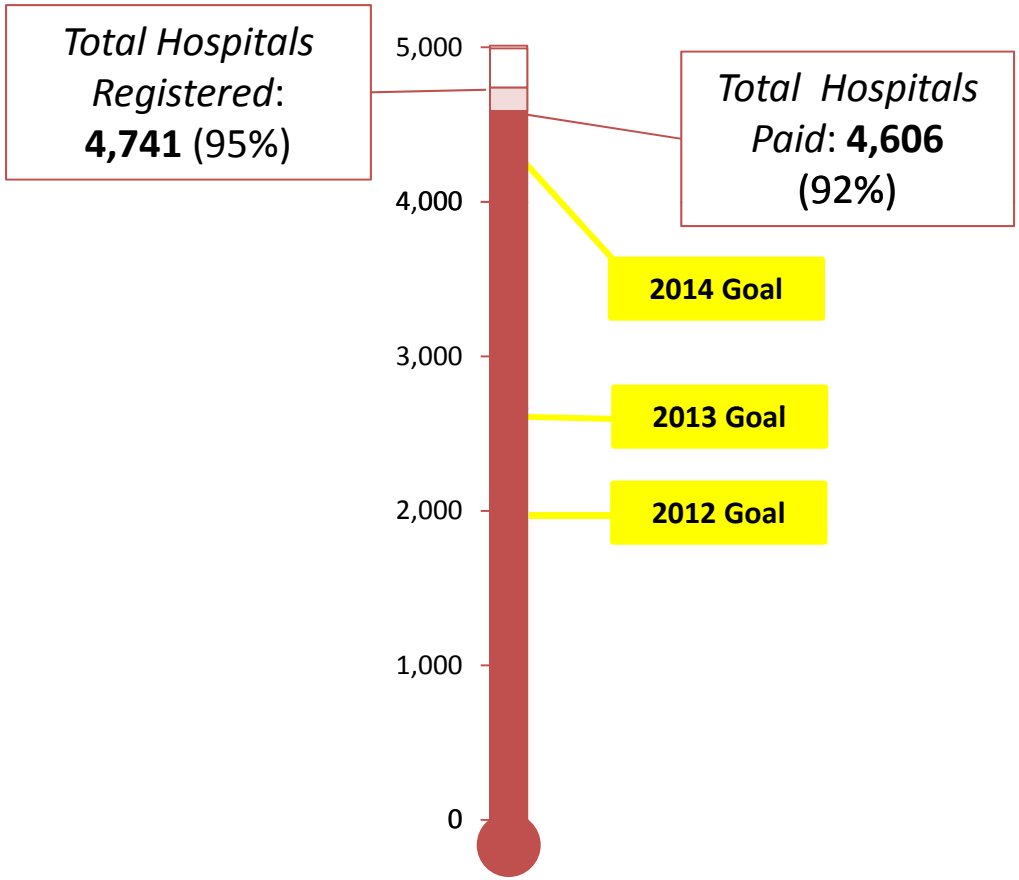
Source: *CMS EHR Incentive Program Data as of 07/31/2014*

Eligible Hospitals *Thermometer*

Progress toward Achievement of Meaningful Use

4,993

Total Eligible Hospitals



Source: *CMS EHR Incentive Program Data as of 07/31/2014*

Total EHR Incentive Payments to All Eligible Providers and Hospitals by Month

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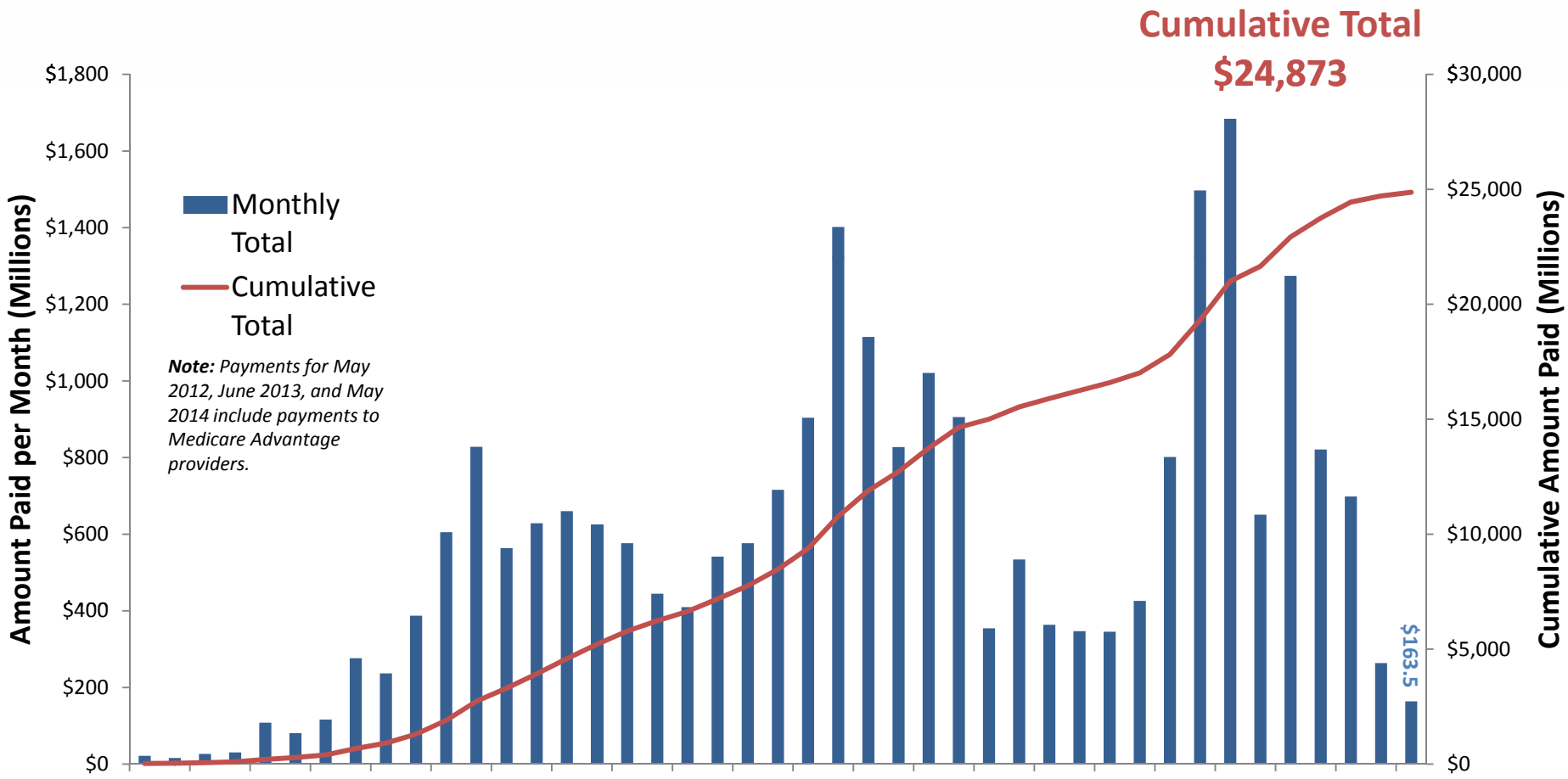

Source: *CMS EHR Incentive Program*
Data as of 07/31/2014

2014 Attestations thru August 25, 2014

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- 8,024 Eligible Professionals attested for the 2014 Reporting Year
  - 1,479 are new participants
  - **3,152 attested to Stage 2**

- 436 Eligible Hospitals have attested for the 2014 Reporting Year
  - 136 are new participants
  - **143 attested to Stage 2**

Meaningful Use CEHRT Flexibility

- CMS and ONC NPRM published on May 20 proposing 2014 CEHRT flexibility and extension of Stage 2

- The Final Rule was published on Sept 4th:

  - Allow providers to meet meaningful use with EHRs certified to the 2011 or the Edition criteria, or a combination of both Editions in 2014

  - Require providers to report using 2014 Edition CEHRT for 2015 EHR Reporting Period

  - Extend Stage 2 through 2016

Proposed Options: Stage 1

Proposed options for providers scheduled to meet Stage 1 in 2014

2011 CEHRT	2011 & 2014 CEHRT	2014 CEHRT
• 2013 Definition Stage 1 objectives and 2013 CQMs	• 2013 Definition Stage 1 objectives and 2013 CQMs; **or** • 2014 Definition Stage 1 objectives and 2014 CQMs	• 2014 Definition Stage 1 objectives and 2014 CQMs

Proposed Options: Stage 2

Proposed options for providers scheduled to meet Stage 2 in 2014

2011 CEHRT	2011 & 2014 CEHRT	2014 CEHRT
• 2013 Definition Stage 1 objectives and 2013 CQMs	• 2013 Definition Stage 1 objectives and 2013 CQMs; **or** • 2014 Definition Stage 1 objectives and 2014 CQMs; **or** • 2014 Definition Stage 2 objectives and 2014 CQMs	• 2014 Definition Stage 2 objectives and 2014 CQMs; **or** • 2014 Definition Stage 1 objectives and 2014 CQMs

2014 Edition Release 2 Background

- ONC proposed a Voluntary Proposed Edition of certification criteria on February 26, 2014.
- Our goals with the Voluntary Proposed Edition were to provide regulatory flexibilities, clarify our policy, improve interoperability, and make administrative changes to the ONC HIT Certification Program.
- Stakeholders stated that the full set of proposals in the Voluntary Proposed Edition was too expansive.
- Support for incremental rule making was mixed.
- Final Rule was published on Sept 11th.

2014 Edition Release 2 Overview

- In consideration of stakeholder feedback, we adopt a small subset of the proposals as optional and revised 2014 Edition Release 2 certification criteria and make only a few changes to the ONC Health IT Certification Program that make our program more effective and less burdensome.

- The 2014 Edition Release 2 includes:
  - 10 optional and 2 revised certification criteria
  - A small number of changes to the ONC Health IT Certification Program
  - Administrative updates

Edition Naming Approach

- Our previous editions of EHR certification criteria were named for the first year when we would expect compliance to support the EHR Incentive Programs.
  - e.g., 2011 and 2014 Editions.

- Stakeholder feedback on our most recent February NPRM stated that this naming approach creates unrealistic expectations that certified products will be available by the edition year.

- We determined that Editions should not have any additional implied meaning and will therefore name editions of certification criteria by the year in which the final rule is released.

- Other rulemakings like the 2014 Edition Release 2 final rule would be added to the most current edition of certification criteria (e.g., 201X Edition Release 2).

Edition Naming Visual
Past vs Future (Illustrative Only)

Past

2010 CY Final Rule
"Initial Set"

2012 CY Final Rule
"2014 Edition" &
Initial Set now "2011 Edition"

2014 CY Final Rule
Proposed Voluntary Edition
"2015 Edition"

2015 CY Final Rule
"2017 Edition"

MU S1
2011 Ed = 2011
1st Year Compliance

MU S1 & S2
2014 Ed (was) = 2014
1st Year Compliance

MU S1 & S2 Supportive
No Compliance Year

MU and beyond supportive

MU and beyond supportive

Future

2010 CY Final Rule
"Initial Set"

2012 CY Final Rule
"2014 Edition" &
Initial Set now "2011 Edition"

2014 CY Final Rule
"2014 Edition Release 2"

2015 CY Final Rule
"2015 Edition"

201X?|201X? CY Final Rule
"2015 Edition Release 2"

2014 Edition Release 2
EHR Certification Criteria

Optional Certification Criteria		Revised Certification Criteria	
Regulation Section	Title of Regulation Paragraph	Regulation Section	Title of Regulation Paragraph
§ 170.314(a)(18)	Optional – computerized provider order entry – medications	§ 170.314(e)(1)	View, download, and transmit to 3rd party
§ 170.314(a)(19)	Optional – computerized provider order entry – laboratory	§ 170.314(g)(3)	Safety-enhanced design
§ 170.314(a)(20)	Optional – computerized provider order entry – diagnostic imaging		
§ 170.314(b)(8)	Optional – transitions of care		
§ 170.314(b)(9)	Optional – clinical information reconciliation and incorporation		
§ 170.314(f)(7)	Optional – ambulatory setting only – Transmission to public health agencies – syndromic surveillance		
§ 170.314(g)(1)	Optional – automated numerator recording		
§ 170.314(h)(1)	Optional – Applicability Statement for Secure Health Transport		
§ 170.314(h)(2)	Optional – Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging		
§ 170.314(h)(3)	Optional – SOAP Transport and Security Specification and XDR/XDM for Direct Messaging		

What's Next?

- ONC will be publishing a proposed rule for the next edition of EHR certification criteria jointly with the next CMS EHR Incentive Programs proposed rule. We expect these rules to be published by the end of 2014.
- We anticipate that the next edition of EHR certification criteria will contain functionalities that will be required for the next stage of the EHR Incentive Programs.
- The public comment we received on the Proposed Voluntary Edition will help inform our proposals for the next certification edition.

HITPC Workgroups and Chairs

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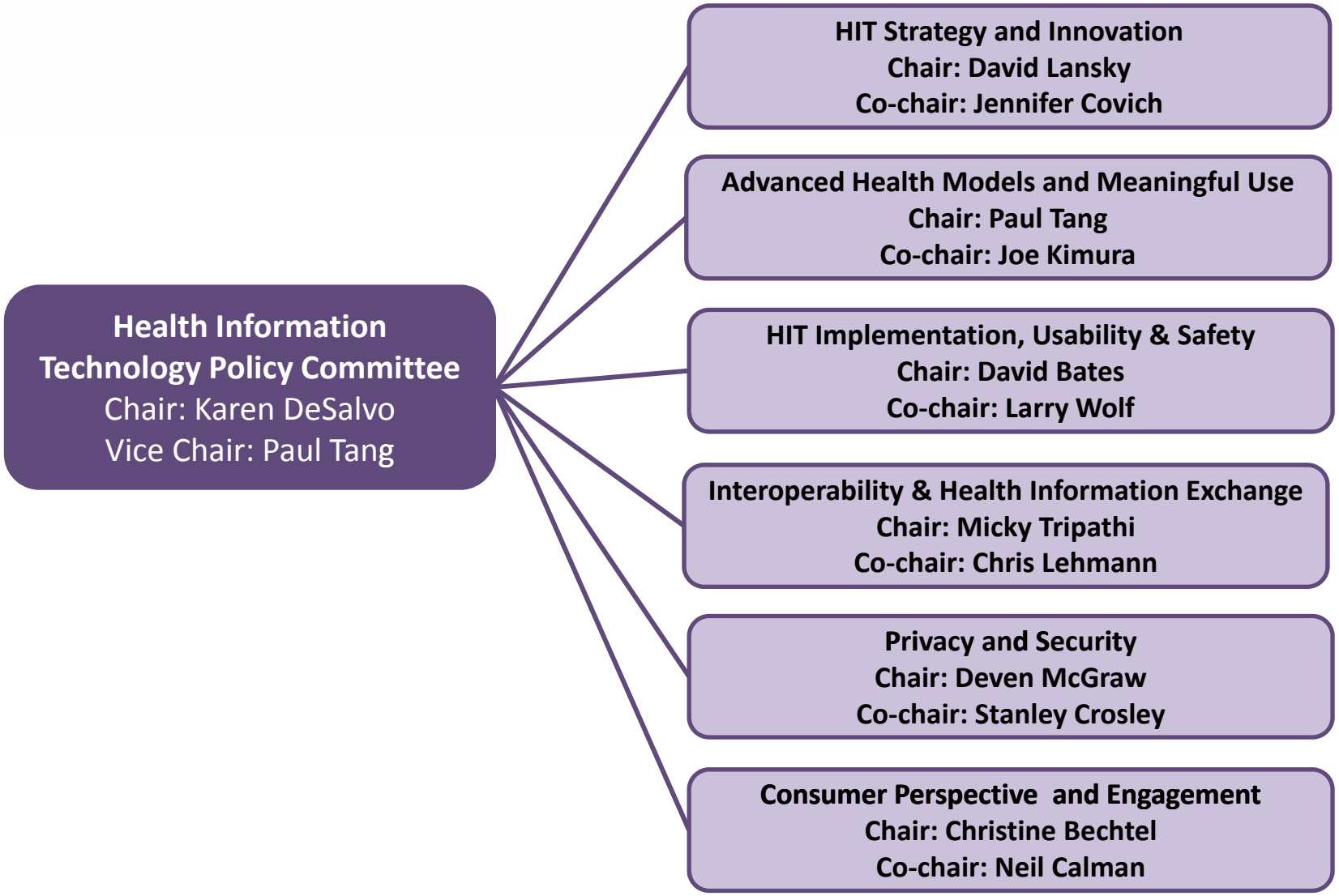

*Task Forces may be needed for specific work assignments

HITSC Workgroups and Chairs

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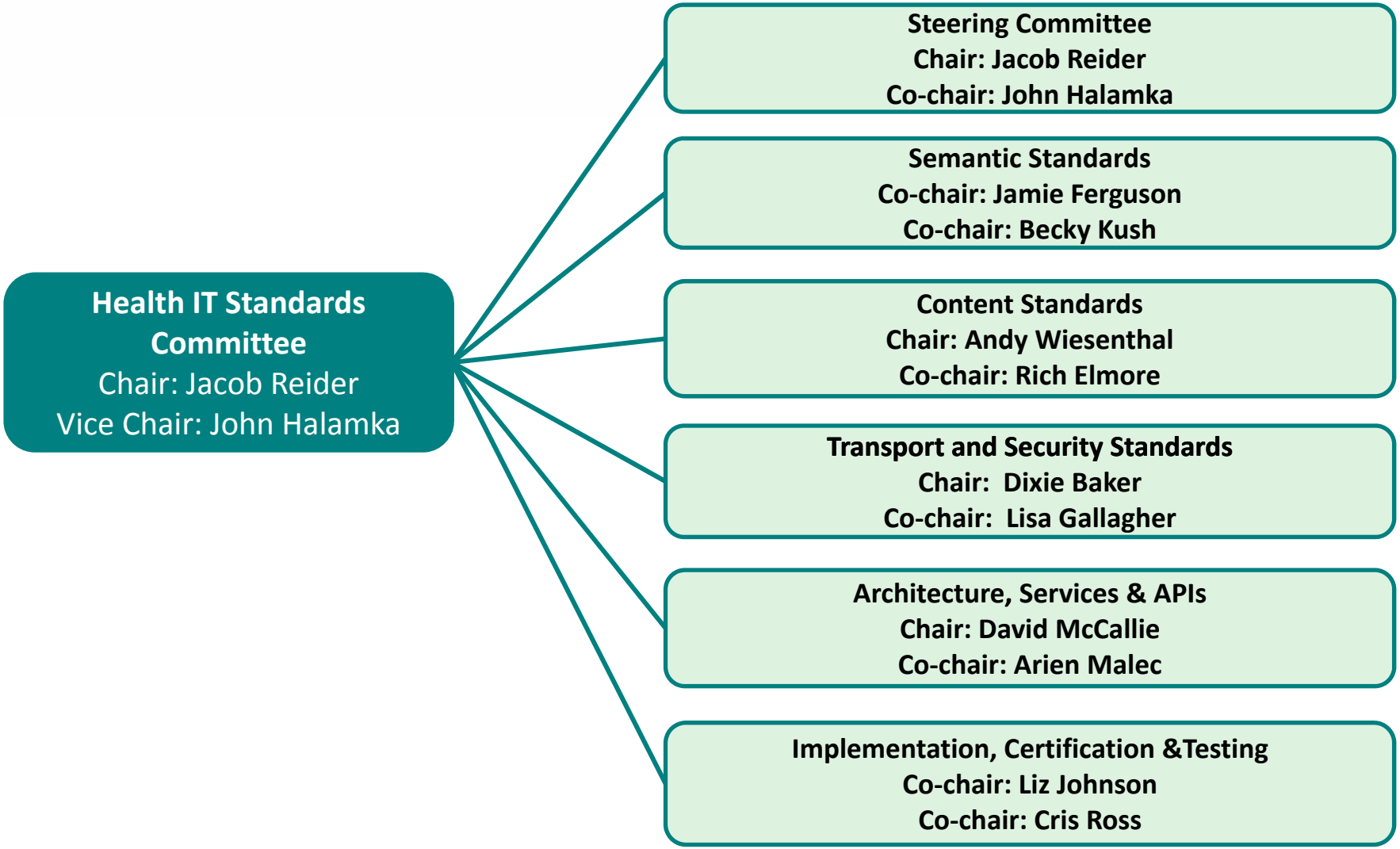

*Task Forces may be needed for specific work assignments

FACA Workplan

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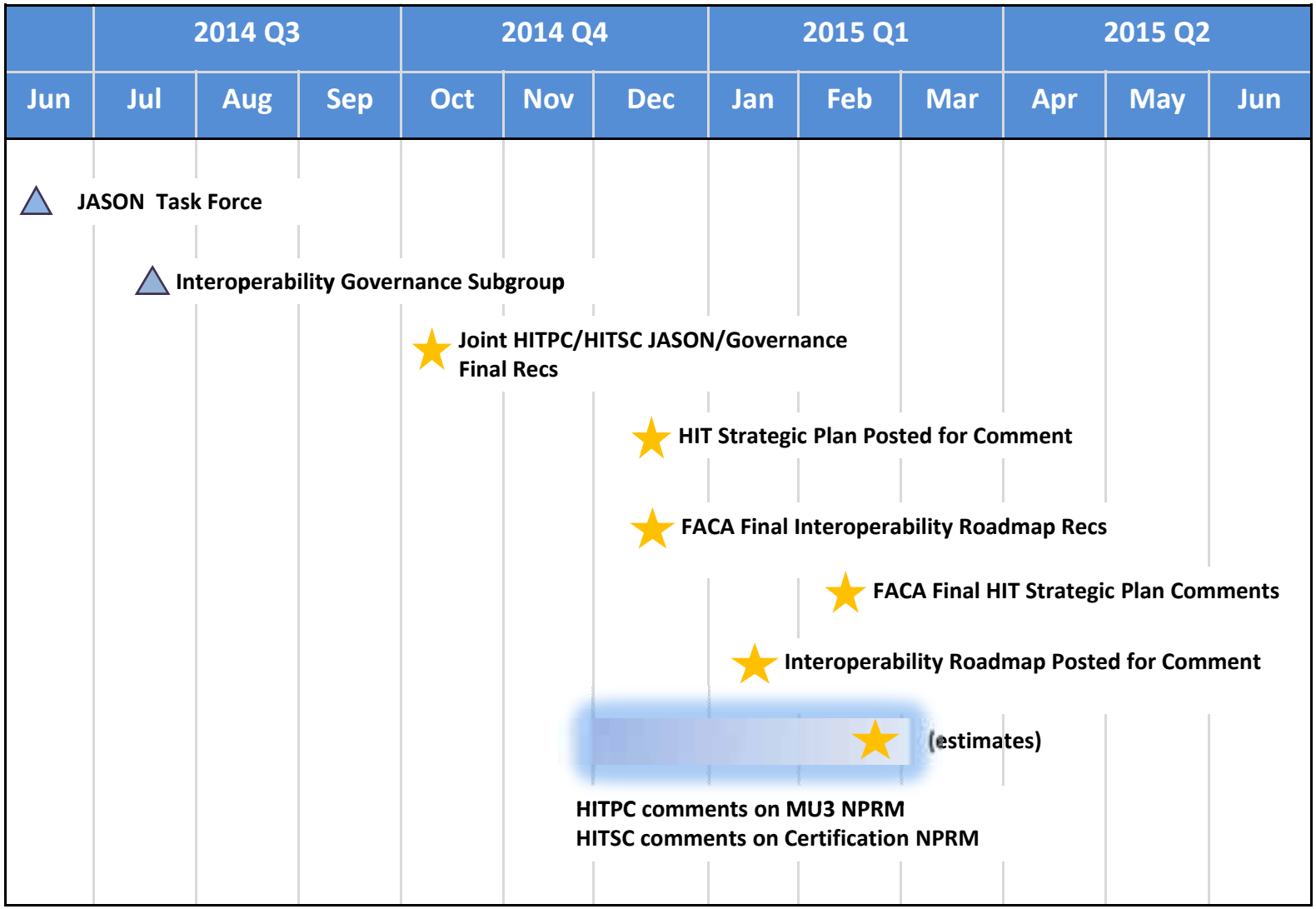

FACA Workplan

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Tasks	Start Date	Due Date	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15
HITPC/HITSC JASON TF charged	6/10/14	6/10/14										
HITPC Governance Subgroup (GS) charged	7/8/14	7/8/14										
HITPC Governance strawman – Draft	7/8/14	9/3/14										
JASON TF recommendations - Draft	6/10/14	9/10/14										
HITPC Governance recommendations - Final	9/3/14	10/15/14										
JASON TF recommendations - Final	9/3/14	10/15/14										
Interoperability Roadmap charge	10/15/14	10/15/14										
Interoperability Roadmap recommendations – Draft	10/15/15	11/4/14										
Health IT Strategic Plan Posted	CY Q4 2014	CY Q4 2014										
HITPC - Health IT Strategic Plan charge	CY Q4 2014	CY Q4 2014										
JASON/GS Interoperability Recommendations – Final	11/4/14	12/2/14										
HITPC Health IT strategic plan comments	12/2/14	2/2015										
Interoperability Roadmap Posted	CY Q1 2015	CY Q1 2015										
HITPC and HITSC Interoperability Roadmap Comments	CY Q1 2015	CY Q1 2015										
HITPC and HITSC MU/Certification NPRM Comments	CY Q1 2015	CY Q1 2015										

Extra Refrence Slides

Adopted Optional and Revised Certification Criteria in 2014 Edition Release 2

Computerized Provider Order Entry

- We split the 2014 Edition "computerized provider order entry" criterion into three optional certification criteria based on capabilities (medications, laboratory, and diagnostic imaging).
- These three option criteria would allow an EHR to provide adaptations, such as mobile apps, for a specific capability (e.g., medications) and not have to be certified to the other two capabilities.
- Reason for Release 2 policy change: added flexibility

Transitions of Care
View, Download, and Transmit to 3rd Party

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- We decouple the "content" portion of the 2014 Edition "transitions of care" (ToC) criterion from the "transport" capabilities, and adopted a new set of optional transport criteria (discussed on the next slide).
- This decoupling would allow health information service providers (HISPs) and other health IT developers to provide either content or transport capabilities without having to be certified to both.
- We also adopt the Edge Protocols Implementation Guide (IG) v1.1 for the optional ToC criterion to promote an EHR's ability to reliably connect to a HISP.
- We adopt a revised "view, download, and transmit to 3rd party" (VDT) criterion that offers the same revisions made to the optional ToC criterion as optional for testing and certification (e.g., Edge Protocols IG v1.1)
- Reasons for Release 2 policy changes: added flexibility and improved interoperability

Transmission Method Certification Criteria

- As part of decoupling “content” and “transport” for ToC and VDT, we adopt three optional certification criteria for transmission methods:

1. Direct
2. Direct and XDR/XDM for Direct Messaging
3. SOAP RTM and XDR/XDM for Direct Messaging

- Reason for Release 2 policy change: added flexibility

Clinical Information Reconciliation and Incorporation

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- We adopt an optional "clinical information reconciliation and incorporation certification" (CIRI) certification criterion that moves "incorporation" from the ToC certification criterion.
- Commenters stated that this was a better fit for the capabilities and more appropriate for clinical workflow.
- Reason for Release 2 policy change: added regulatory clarity

Syndromic Surveillance

- Note: this policy change affects only non-urgent care ambulatory settings.
- We adopt an optional certification criterion that permits any electronic method of creating syndromic surveillance information for exchange in non-urgent care ambulatory settings.
- In the 2014 Edition criterion, we only permitted the use of the HL7 2.5.1 standard. At the time, we expected the industry to develop an HL7 2.5.1 IG for ambulatory (and non-urgent care) syndromic surveillance.
- The industry has not developed an HL7 2.5.1 IG.
- We are aware of providers that are sending syndromic surveillance data to public health using alternate standards (such as CDA and QRDA III), but also without developed, consensus IGs for syndromic surveillance.
- To promote providers' ability to achieve the MU syndromic surveillance objective for Stage 2, we are permitting EHR technology to certify to this optional criterion that allows any electronic method of transmission.
- Reason for Release 2 policy change: added flexibility

Utilization Certification Criteria

- Safety-enhanced design (SED): We revise the SED criterion to include the optional three CPOE criteria and optional CIRI criterion.
  - Reason for Release 2 policy change: added regulatory clarity
- Automated numerator calculation: We change this criterion to designate it as “optional” for the purposes of excluding it from the 2014 Edition Complete EHR definition.
  - Reason for Release 2 policy change: added regulatory clarity

Gap Certification Eligibility

- Our gap certification policy allows the use of test results from a previous certification for certification to functionalities that have not changed, subject to the ONC-Accredited Certification Body's (ONC-ACB) discretion.
- Seven Release 2 criteria are eligible for gap certification if EHRs were certified to the 2014 Edition versions of these functionalities:
  - Three optional CPOE criteria
  - Optional syndromic surveillance criterion
  - Three optional transmission criteria

Certification Program Changes

- We finalize our proposal to discontinue the "Complete EHR" definition and Complete EHR certification beginning with the next adopted edition of certification criteria. **This does not affect prior or future 2014 Edition certification.**
  - Reason for Release 2 policy change: added regulatory clarity and flexibility
- We adopt the "ONC Certified HIT" certification and design mark for required use by ONC-ACBs.
  - Reason for Release 2 policy change: provide clarity for the market as it relates to health IT certified under the program
- We adopt an updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs.
  - Reason for Release 2 policy change: maintains alignment with industry practices

Other Administrative Changes

- We finalize a proposal to remove 2011 Edition-specific EHR certification criteria and related standards, terms, and requirements from the Code of Federal Regulations (CFR) effective March 1, 2015.
  - Reason for Release 2 policy change: EHR technology certified to 2011 Edition will no longer meet the Certified EHR Technology definition starting in 2015
  - Keeping criteria editions current for the purposes of Stark/Anti-Kickback EHR donation rules
- We finalize a proposal to remove the temporary certification program regulations from the CFR on the effective date of this final rule.
  - Reason for Release 2 policy change: The temporary certification program sunset on October 4, 2012, and is no longer in existence