Health IT Policy Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Certification and Adoption Workgroup Update:

1. An Analysis Framework for New Certification Proposals Under Consideration by ONC

2. Application of the Framework to Ineligible Providers: Long-Term/Post-Acute Care (LTPAC) and Behavioral Health (BH)

Marc Probst, Co-Chair
Larry Wolf, Co-Chair

December 4, 2013

Certification and Adoption Workgroup

Member	Organization
Marc Probst, Co-Chair	**Intermountain Healthcare**
Larry Wolf, Co-Chair	**Kindred Healthcare**
Joan Ash	Oregon Health & Science University
John Derr	Golden Living, LLC
Carl Dvorak	Epic Systems Corporation
Paul Egerman	Businessman/Entrepreneur
Joseph Heyman	Whittier IPA
George Hripcsak	Columbia University
Stanley Huff	Intermountain Healthcare
Elizabeth Johnson	Tenet Healthcare Corporation
Charles Kennedy	Aetna
Michael Lardiere	National Council for Community Behavioral Healthcare
Donald Rucker	Siemens Corp.
Paul Tang	Palo Alto Medical Foundation
Micky Tripathi	MA eHealth Collaborative
Maureen Boyle, ex officio	Substance Abuse and Mental Health Services Administration (SAMHSA)
Jennie Harvell, ex officio	Office of the Assistant Secretary for Planning and Evaluation (ASPE)

History of ONC Certification Programs

- Pre-HITECH: Began in 2006
  - EHR safe harbor under the anti-kickback statute and the EHR exception under the physician self-referral (Stark) law
  - ONC issued a Certification Guidance Document
  - Established CCHIT as the Recognized Certification Body

- HITECH/Meaningful Use: Began in 2009
  - 2009: Recommendations from the HITPC Certification and Adoptions Workgroup
  - 2010 – 2012: ONC Temporary Certification Program (ONC-ATCBs) (includes Safe Harbor/Self-Referral Exception Certification)
  - 2012 – present: ONC Certification Program (ONC-ACBs)

- Broad Authority beyond "Meaningful Use"
  - *… programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted [by the Secretary]…*

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- *HHS intends to rely on all applicable and appropriate statutory authorities, regulations, policies, and programs to accelerate rapid adoption of health information exchange across the care continuum in support of delivery and payment reform.*

- RFI Issued: March 7, 2013

- Comments Due: April 22, 2013

- Principles and Strategy: August 7, 2013

- Charge to Certification & Adoption WG: October 2013

HITPC Charge to the C/A Workgroup

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- Recommend a process for prioritizing health IT capabilities for EHR certification that would improve interoperability across a greater number of care settings

- Recommendations shall take into account previously adopted ONC certification criteria and standards and identify the key heath IT capabilities needed in care settings by providers who are ineligible to receive EHR incentive payments under the HITECH Act

Workgroup Timeline

Date	Event
10/25/2013	Overview of new charge
11/4/2013, 11/18/2013	Develop a framework for certification
12/2/2013, *12/12/2013 1/10/2014, TBD*	LTPAC expert presentations and virtual hearing
1/21/2013, 1/28/2014, 2/7/2014, TBD	BH expert presentations
2/21/2014, TBD	Workgroup review of recommendations
3/11/2014	Recommendations to HITPC
3/26/2014	Recommendations to HITSC

1. Focus certification on Meaningful Use.

2. Leverage the certification process to improve progress on privacy, security and interoperability.

3. Improve the objectivity and transparency of the certification process.

4. Expand certification to include a range of software sources, e.g., open source, self-developed, etc.

5. Develop a short-term certification transition plan.

http://www.healthit.gov/FACAS/sites/faca/files/hit_pc_transmittal_ltr_8-14-09.pdf

The Scope of Work for the Charge

Complete ✓

Step 1: Draft a process that could be used to identify and prioritize certification criteria for health IT that is used by providers outside of the Meaningful Use Program and for which an ONC certification program would be helpful.

Began on 12/2/13

Step 2: Recommend a specific application of this process for EHRs used in long-term/post-acute care (LTPAC) and behavioral health (BH) settings.

By 3/2014

Step 3: Revise Step 1 recommendations, if needed, based on experience applying them during Step 2.

When evaluating whether to establish a new certification program, ONC should consider whether the proposed certification program would:

- **Advance a National Priority or Legislative Mandate:** Is there a compelling reason, such as a National Quality Strategy Priority, that the proposed ONC certification program would advance?

- **Align with Existing Federal/State Programs:** Would the proposed ONC certification program align with federal/state programs?

- **Utilize the existing technology pipeline:** Are there industry-developed health IT standards and/or functionalities in existence that would support the proposed ONC certification program?

- **Build on existing stakeholder support:** Does stakeholder buy-in exist to support the proposed ONC certification program?

- **Appropriately balance the costs and benefits of a certification program:** Is certification the best available option? Considerations should include financial and non-financial costs and benefits.

Application of the Five Factor Framework (Examples) Factor 1 of Framework

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Advances National Priority

- **Advance a National Priority or Legislative Mandate:** Is there a compelling reason, such as a National Quality Strategy Priority, that the proposed ONC certification program would advance?

Sample questions for ONC to ask as part of an analysis:

- Care Coordination (NQS Priority):
  - Would information exchange among more providers occur as a result of the certification program?
  - Would care coordination be improved with broader EHR adoption and interoperability?
  - Would emerging payment models, that rely on care coordination, be advanced?

- Safety (NQS Priority):
  - Would the new certification program improve the use of clinical decision support?
  - Would systems and software be more reliable?

Factor 2 of Framework

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Align Fed/State Programs

- **Align with Existing Federal/State Programs:** Would the proposed ONC certification program align with federal/state programs?

Sample questions for ONC to ask as part of an analysis:

- Would existing federal/state programs be advanced?
  - Mandated assessments (MDS, OASIS, IRF-PAI, CARE sub-set)
  - Consider: Patient -Centered Medical Home (PCMH), Patient-Centered Health Homes (HCHH), State Innovation Models (SIM), Accountable Care Organizations (ACO), Hospital Readmission Reduction Program
  - Consider: Quality reporting (e.g., eCQM efforts)
  - Consider: Provider Reporting (e.g., SAMHSA requirements)
  - Consider: Provider Survey and Certification (e.g., CMS requirements)
- Would regulatory burden decrease?
  - Collect once, re-use of data for multiple reporting requirements (report once)

Utilize Pipeline

- **Utilize the existing technology pipeline:** Are there industry-developed health IT standards and/or functionalities in existence that would support the proposed ONC certification program?

Sample questions for ONC to ask as part of an analysis:

- Are existing standards/functionalities mature?

- Has there been adoption of existing certification options or similar certification "alternatives?"

- Is there new health IT in development (even if not mature) that could benefit the setting/functionality under consideration?

- Does the right standard exist, but lack broad adoption by stakeholder EHRs?

Factor 4 of Framework

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Stakeholder Support

- **Build on existing stakeholder support:** Does stakeholder buy-in exist to support the proposed ONC certification program?

Sample questions for ONC to ask as part of an analysis:

- Does stakeholder support exist for a more robust health IT framework in the setting/functional area and for the proposed ONC certification program?
- Do the stakeholders need different functionality than what is addressed by existing certification programs?
- Would certification address key misperceptions about the availability of EHRs and HIT standards for the setting/functionality?
- Do stakeholders want a certification program that supports functionality (i)within an organization / (ii) across organizations?

Cost/Benefit

- **Appropriately balance the costs and benefits of a certification program:** Is certification the best available option? Considerations should include financial and non-financial costs and benefits.

Sample questions for ONC to ask as part of an analysis:

- What are the costs and benefits of certification? Considerations include: impact on innovation, cost of development and testing, varying functional needs of specialists and settings, changes in workflow and surrounding processes, changes in usability, effect on patient care.

- What are the risks from software being used that is not certified?

- Would alternate approaches achieve similar ends with less burden?

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Next Steps for the Workgroup: Step 2

- 12/2/13 – Presentation on LTPAC HIT landscape by Jennie Harvell (HHS/ASPE) and Sue Mitchell (LTPAC Expert)

- **12/12/13 – Extended Hearing on LTPAC HIT (testimony from diverse stakeholders, including testimony from presenters providing the patient, provider, clinical & vendor perspective)**

- Dec. to Jan. 2014 – Workgroup meets to develop a recommendation on the criteria necessary for a successful LTPAC certification program (recommendation will consider the 5 Factor Framework)

- Late January 2014 – Workgroup meets to begin consideration on the existing behavioral health HIT landscape and to develop associated recommendations for a successful BH certification program (recommendation will consider the 5 Factor Framework)

Supporting Material

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National Quality Strategy

Aims:

- **Better Care:** Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- **Healthy People/Healthy Communities:** Improve the health of the U.S. population by supporting proven interventions to address behavioral, social and, environmental determinants of health in addition to delivering higher-quality care.
- **Affordable Care:** Reduce the cost of quality health care for individuals, families, employers, and government.

Six Priorities:

- Making care safer by reducing harm caused in the delivery of care.
- Ensuring that each person and family is engaged as partners in their care.
- Promoting effective communication and coordination of care.
- Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
- Working with communities to promote wide use of best practices to enable healthy living.
- Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

http://www.ahrq.gov/workingforquality/about.htm

Supporting Material Continued

- Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf

- EHR Payment Incentives for Providers Ineligible for Payment Incentives and Other Funding Study: http://aspe.hhs.gov/daltcp/reports/2013/ehrpi.shtml