ONC 2015 Edition EHR Certification Criteria
Notice of Proposed Rulemaking

HIT Standards Committee

Steve Posnack
By the end:

• Why a 2015 Edition?
  – 30,000ft and 10ft

• Certification Policy Perspective
  – Past
  – Present
  – Future

• Highlights:
  – 2015 Edition Proposals
  – 2017 Edition topics under consideration
• Why certification?
  – For meaningful use incentives it’s required by law (HITECH)
  – In general, certification provides assurance and accountability
  – Creates a “gold baseline” in a sense

• ONC’s role as a coordinator, convener, & enabler
  – Certification program policy as a service to others
    – “Policy API” for convergence – a method through which industry and other Federal policy and program needs can be met with mutually beneficial outcomes.
    • Means to reduce overall regulatory burden (“compliance fast-track”)

The future: 3-year ONC Rulemaking Roadmap (milestones reflect best guestimates)
Major Certification Rulemakings Timeline by Proposed Rule/IFR Release

2011 Edition
Published January 2010

2014 Edition
Published March 2012

2015 Edition
Published February 2014

Permanent Certification Program Final Rule January 2011
What does more incremental rulemaking accomplish?

• Makes rulemaking more nimble, better able to keep up with industry updates.

• Less change between editions of certification criteria.

• Provides ample opportunity for public comment and earlier visibility into potential policy directions.
• Included the concept of “gap certification”

• *Gap certification* means the certification of a previously certified Complete EHR or EHR Module(s) to:
  1. All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and
  2. All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).
Chronological Composition (New/Revised/Unchanged) of Certification Criteria Editions by Year

<table>
<thead>
<tr>
<th>Edition</th>
<th>Ambulatory</th>
<th></th>
<th></th>
<th>Inpatient</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 Edition</td>
<td>100% N (baseline)</td>
<td>n = 33</td>
<td></td>
<td>100% N (baseline)</td>
<td>n = 32</td>
<td></td>
</tr>
<tr>
<td>2014 Edition</td>
<td>20% U, 50% R, 30% N</td>
<td>n = 9, 22, 13</td>
<td></td>
<td>22% U, 51% R, 27% N</td>
<td>n = 10, 23, 12</td>
<td></td>
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<tr>
<td>2015 Edition</td>
<td>64% U, 28% R, 8% N</td>
<td>n = 34, 15, 4</td>
<td></td>
<td>66% U, 26% R, 8% N</td>
<td>n = 35, 14, 4</td>
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</tbody>
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- Over 60% of the 2015 Edition certification criteria are eligible for gap certification
- Possible for an HIT developer to get a 2015 Edition certification without retesting
Resource Allocation Comparison: Rulemaking vs HIT Developer (no incremental rules)
Resource Allocation Comparison: Rulemaking vs HIT Developer (with incremental rules)
2015 Edition highlights

• Lab orders & CLIA compliance
  – Computerized Provider Order Entry (CPOE) for lab order IG
  – Incorporate lab test results updated IG

• Clinical Decision Support (CDS)
  – Propose the adoption of the Health eDecisions work.
    • Requirements for computable CDS as well as interface requirements needed to request CDS guidance from a CDS supplier.

• Implantable device list
  – Record and display the unique device identifiers (UDIs) associated with a patient’s implanted devices
2015 Edition highlights (2)

• Transitions of Care
  – Propose to separately test and certify:
    • “Content” capabilities (i.e., Consolidate CDA); and
    • “Transport” capabilities (i.e., Direct Project specification).
  – Propose to require testing to an “edge protocol” implementation guide
  – Propose a new “performance standard” that would require EHR technology to successfully receive Consolidated CDA’s no less than 95% of the time.
  – Data quality constraints to improve patient matching
2015 Edition highlights (3)

• Patient Population Filtering for CQMs
  – Ability to create different patient population groupings by, for example:
    • practice site
    • primary and secondary insurance

• Syndromic Surveillance
  – Propose to revise the 2014 Edition version as well as adopt a 2015 Edition that mirrors those revisions
    • Add certification alternatives for CDA and QRDA III standards
2015 Edition highlights (4)

- Non-Percentage-Based Measures
  - Re-proposed in response to OIG recommendation

- Transmission
  - Four separate certification criteria for transmission
  - Newest includes Direct + Delivery Notification
ONC HIT Certification Program/Definitions

• “Complete EHR” certification
  – Propose to discontinue
    • Outlived original intent
    • Misnomer
      – Only applies to scope of all certification criteria not entire product
    • Exceeds the flexibility now provided in the Certified EHR Technology definition
    • Not necessarily “complete”
      – No guarantee that it will included all CQM capabilities
      – May not include capabilities designated as “optional” certification criteria
Non-MU EHR Technology Certification

- Propose to remove existing regulatory burden that would require EHR technology designed for non-MU purposes to include MU measure calculation capabilities in order to get certified.
- Propose to permit “MU EHR Modules” and “non-MU EHR Modules” to be certified. The latter would not need to include the MU-specific measure calculation capabilities to get certified.
2017 Edition Topics Under Consideration

1. Additional Patient Data Collection
   – Disability information
   – US Military Service
   – Work Information Industry/Occupation
2. Medication Allergy Coding
3. Certification Policy for EHR Modules and Privacy and Security
4. Provider Directories
5. Oral Liquid Medication Dosing
6. Medication History
7. Blue Button +
8. 2D Barcoding
9. Duplicate Patient Records
10. Disaster Preparedness
11. Certification of Other Types of HIT and for Specific Types of Health Care Settings
   – Best way to distinguish beyond “EHR technology”
   – Specific types of health care settings
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