Implementation, Certification, and Testing (ICT) Workgroup

2015 Edition Certification NPRM
HITSC Report Out

May 20, 2015

Liz Johnson, co-chair
Cris Ross, co-chair

Current Membership

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

Name	Organization
Cris Ross, co-chair	**Mayo**
Liz Johnson, co-chair	**Tenet Healthcare Corporation**
Sarah Corley	QSI NextGen Healthcare
David Kates	The Advisory Board Company
Udayan Mandavia	iPatientCare
Kyle Meadors	Drummond Group Inc.
Rick Moore	National Committee for Quality Assurance
Andrey Ostrovsky	Care at Hand
Danny Rosenthal	Inova Health System
John Travis	Cerner Corp.
Steve Waldren	American Academy of Family Physicians
Zabrina Gonzaga	Lantana
Kevin Brady, Federal Ex officio	National Institute of Standards and Technology
Brett Andriesen, staff lead	Office of the National Coordinator for Health IT

Implementation, Certification & Testing NPRM Assignments

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

Group 1 – David Kates (lead), Rick Moore, Kevin Brady	**Group 2 – John Travis** (lead), Steve Waldren, Udayan Mandavia	**Group 3 – Sarah Corley** (lead), Danny Rosenthal, Zabrina Gonzaga, Andrey Ostrovsky, Kyle Meadors
• Costs and Benefits , p.14 • Applicability, p.28 • Gap Certification Eligibility Table, p.234 • Common Clinical Data Set Definition, p.245 • Consolidated CDA Creation Performance, p.202 • Open Data Certified Health IT Product List (CHPL), p.288 • "Removal" of Meaningful Use Measurement Certification Requirements, p.253 • The ONC Health IT Certification Program and Health IT Module, p.12	• Base EHR Definitions, p.240 • Retesting and Certification, p.197 • Safety-enhanced design, p.190 • Web Content Accessibility Guidelines, p.164 • Design and Performance, p.261 • Request for Comment on Summative Testing, p.196	• Encounter Diagnoses, p.105 • Medication Dosing, p.118 • Implantable Device List, p.73 • Pharmacogenomics Data – Request for Comment, p.236 • There are certification approaches that could enhance the end-user's (provider's) adoption and continued use of health IT implementations that guide prescribing through CDS using pharmacogenomic data • Data Portability, p.124 • Automated Numerator Recording/Calculation, p.190

Overarching Comments

- Intent and spirit of changes proposed is directionally great, but there may be unintended consequences.
- Balance is needed between benefits received from lofty goals proposed compared to the cost and time commitments required from implementation.
- Be cognizant of time and bandwidth required by developers to support proposed criteria, particularly when criteria are not required by Meaningful Use or other programs.
- ONC and ANS should ensure ACBs and ATLs behave consistently to reduce variability and ensure all developers are held to the same level of requirements.

Costs and Benefits

- Estimates related to cost ($100M) are significantly low
  - Does not include additional direct and indirect costs incurred by providers and vendors to analyze and prepare for regulatory requirements including development, training, etc.
- Await further feedback from industry for realistic evaluation of time/effort required for development.

Applicability

- While it's a positive development to recognize other care settings (e.g. long term care) may benefit from use of certified health IT, need to ensure appropriateness based on current baseline and feasibility for implementation.
- Be cautious that changes proposed are specific to needs of specific domain and avoid inappropriately including requirements from other care settings.

Gap Certification Eligibility Table

- Regardless of whether a product was certified via gap certification or via traditional testing, end users should have the same level of confidence in all certified products.
- ONC and ANSI should minimize variability across ACBs and ATLs, and ensure they are behaving consistently in what requires re-testing or certification vs gap certification.
  - ONC should consider a form of standardization or defined set of criteria for how an ACB assesses vendor products for gap certification.

Common Clinical Data Set Definition

- Generally supportive of semantic change to CCDS .
- Inclusion of Unique Device Identifier (UDI) is problematic for a number of reasons particularly for ambulatory practices.
- Inclusion of immunizations mapped to NDC codes may be problematic as most providers do not include NDC codes when documenting immunizations, these may be missing from historical immunizations, and because immunizations are often received outside of the practice setting.

Consolidated CDA Creation Performance

- Further constraint of optionality C-CDA standard is needed before additional testing at certification will provide assurance that in-field C-CDAs map appropriately.
- A “gold standard” C-CDA is a good concept, but more clarity is needed around who will develop and maintain for reference.
- Consider ongoing, non-mandatory test frames to allow for developers and end users to test C-CDAs against to ensure interoperability.
  - Look to HIPAA X12 for lessons learned.
- ONC should provide further details to ACBs as to what specific aspects that C-CDA testing should focus on.

Open Data Certified Health IT Product List (CHPL)

- Generally supportive of proposals here.

"Removal" of Meaningful Use Measurement Certification Requirements

- Supportive of this proposal, as provides additional optionality for industry.

The ONC Health IT Certification Program and Health IT Module

- ONC should clearly articulate what "field surveillance of a deployed system" would entail.
- WG supports recognition that deployed versions of a lab-tested system vary in performance from site to site, though variations are often a result of site-specific user training, configuration or usage issues.
- Alterations to the "standard" or "lab tested" implementation should only require documentation if alterations affect the achievement of MU or other programs.
- ONC should limit with specificity what is meant by the audit and/or the requirement to document and report changes to the "standard" deployment of the "lab-tested" system to prevent undue burden on developers and sites.

Base EHR Definitions

- ONC should consolidate redundant criteria (b)(6) and (g)(7) relative to the full CCDS as both criteria amount to production of a full C-CDA upon request.
- ONC should explicitly include security criteria 170.315(d)(1)-(8) in the base EHR scope as removal could cause confusion among developers and users.
- It is premature to include implantable device list and UDI in the Base EHR definition.
- Support the inclusion of application access to the CCDS for the provider to provider use case
- Consumer access to the CCDS should be optional as the criterion as proposed may result in an emphasis on enabling data requests rather than simply making data available to consumers
- Include 170.315(a)(4) – Drug-Drug/Drug-Allergy interaction checking for CPOE in the definition
- Support for 170.315(h)(2) as an equivalent alternative means to 170.315(h)(1)

Retesting & Certification

- Support this proposal
- ONC should adopt guidance for ONC-ACBs to use in evaluating if user interface changes have been made in “an apparent significant” change
- ONC should not fix a monthly update cycle but instead gear this requirement to match to a given vendor’s typical release cycle for major and minor updates
- ONC should normalize how major and minor updates appear on the ONC CHPL

Safety Enhanced Design

- Do not require recruitment of clinical end users for testing for "administrative" criteria (e.g. configuring drug-drug alert settings, or CDS rules)
- Consider reducing testing burden, especially for smaller vendors and practices
- Focus on summary descriptor information that demonstrates participants have relevant perspective (e.g., occupation/role , professional experience) rather than descriptive factors (e.g., sex, age, education) as they are not evidence of correct use of UCD procedures.
- Recommend using industry standard, literature recognized satisfaction measures rather than proposed User Satisfaction Rating
- Urge that all the ACBs include the full usability test report in the public test report

Web Content Accessibility Guidelines

- Recommend ONC postpone raising WCAG level to 2.0 Level AA due to lack of quality compliance test tools and a need for clearer guidance on mobile accessibility.
- ONC should:
  - Support improvement of tools (or at least better consolidate existing viable tools)
  - Help develop guidance for mobile accessibility
  - Then revisit decision on moving to 2.0 Level AA

Design and Performance

- Generally supportive of this proposal
- Recommend pattern requirement after the 2014 Edition “Quality System Management” which permits a response that “no health IT accessibility centered design standard or law was applied to all applicable capabilities” as an acceptable means of satisfy this proposed certification criterion
- Recommend requirement related to, “identification of user-centered design standard(s) or laws for accessibility that were applied,” be in form of a global statement of what accessibility criteria are supported.

Request for Comment on Summative Testing

- Formative testing should not be a required form of testing, but at most it may be an alternative / option to summative testing
- Issues related to formative testing in certification:
  - Occurs during the product development lifecycle and hence may not correctly represent the product which is being certified
  - Difficult to achieve standardization as approaches vary widely and are context-specific, results may be deployment-specific

Encounter Diagnoses

- Recommend ONC clarify that this is meant to be the “billing diagnoses” and whether necessary to include all billing diagnoses for encounters or simply the primary one.
  - If required to include a single one, please clarify how the primary billing diagnosis should be determined (e.g., use the first code entered, provide functionality so end users can sort/rank diagnoses, etc).
- Encourage discussion about solutions to problem of requiring double coding with full stakeholder participation.

Medication Dosing

- Non-metric units are allowed in the NCPDP and C-CDA R2 standards. These should be updated to exclude non-metric units if they are expected to be removed from EHRs.
- This requirement is reasonable for *structured* fields, but vendors must continue to support option for including free text fields, where end users may choose to use non-metric measurements.

Implantable Device List

- Full functionality of this requirement should not be required for all products and domains of care as most devices are not inserted in an ambulatory environment and requiring additional functionality for all end-users increases costs without direct benefit.
- It is reasonable to require fields to store/display device identifier and description, but not reasonable to expect software will support retrieval of the device description from the global UDI from the database.
  - This increases complexity of the products, often leading to increased costs to end-users if it must be in all products regardless of market segment need.
  - Many vendors will be forced to use a third party provider as data changes frequently, further adding to costs.

Pharmacogenomic Data – Request for Comment

- The standards for representation of pharmacogenomic data are not mature, the evidence for improved outcomes with widespread use of genomic data is not available, and the costs are high.
  - Before mandating all developers support this functionality, evidence is needed that significant costs will have ROI.
- While this holds promise for providing more personalized "precision" medicine, this is not ready for incorporation into EHRs as structured data. Further consensus is needed in representation of these genetic variations.
- While there is movement towards use of Reference SNP (rs) ID#s, this has not been standardized. Much work remains to better understand other factors affecting the health of an individual with a given SNP, as mutations alone do not tell whole story.

Data Portability

- More appropriate name for this requirement would be “Bulk Export of CCDAs” as more data needed for transfer/conversion to a new system (e.g. financial data/ accts receivable)
  - As written, requirement does not meet expectation of broad universe of HIT consumers who expect data portability means entire chart, not just a subset.
- Adding data elements required for a few specialties to all certified products increases costs, development effort, and complexity, so there should be a clear business case with solid ROI for all data elements. For base certification vendor certification requirements should be limited to what’s needed to support specific care domains:
- Vital signs are not part of base EHR definition or part of MU requirements, but are listed as part of CCDS. They should be made part of base EHR requirement or removed.

Data Portability (Continued)

- Provide realistic use cases for these new timeline/event requirements as one would likely not need to export all information for all patients on the first of every month. (e.g. send updates to an HIE rather than entire C-CDA at time of change/finalization of encounter)
- Time frame and event requirements for generation are overly prescriptive and do not seem to meet “data portability” functional requirements (e.g. more likely HIE or for ToC than for moving to a new practice or product).

Automated Numerator Recording

- There should be no requirement for automated numerator recording for any measure where to do so would require additional clinical documentation that's not necessary for patient care. (Biggest factor in creating inefficiencies in EHR use)
- Measures for both 170.315(g)(1) and (2) that are unchanged from Stage 2 should be eligible for gap certification where the measure definition is the same
- Unless there is a proven business need to document numerator performance , and that it can be done without requiring development work or data entry not necessary for care provision, it should be eliminated from this requirement.
- Measures that require complicated set up in order to accurately calculate these should be eliminated.

Automated Numerator Calculation

- Similar issues as automated numerator calculation. Need to calculate measures has required vendors add buttons/check boxes/other methods so systems can calculate measure performance.
- There should be no requirement for automated measure calculations for any measure where doing so would require additional documentation, and measures that require complicated set up in order to accurately calculate should be eliminated.
- Unless there is a solid, proven business need to document measure performance and it can be done without requiring development work / data entry that is not necessary for care provision, it should be eliminated from this requirement.