Implementation Workgroup

Summary of Comments on the
ONC Voluntary 2015 Edition Proposed Rule

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April 24, 2014

The Subject Matter and Deadline

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

What the Implementation Workgroup commented on:

Notice of proposed rulemaking: ***Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements*** (79 FR 10880).

Comments due:

ONC is accepting comments through April 28, 2014

How we are commenting:

- **PowerPoint Presentation**

- **Submission:** By ONC on our behalf through regulations.gov

Focus Areas

ONC's New Approach, Overall Policies & the 2015 Edition Proposals

- Incremental rulemaking (not tied to Meaningful Use)
- Policy/program alignment & leveraging the ONC HIT Certification Program
- 2015 Edition proposals

If there was time, the Implementation Workgroup would respond to the 2017 Edition request for comments - THERE WASN'T TIME ☺

- Note - HITSC can provide *recommendations* for the 2017 Edition NPRM and the workgroup plans to undertake this as part of its next charge.

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Meeting Date	Comment Items	Status
March 13, 2014	§ 170.315(a)(1) CPOE - Meds	General Agreement
	§ 170.315(a)(2) CPOE - Labs	Discussion Item
	§ 170.315(a)(3) CPOE - Rads/Imaging	General Agreement
	§ 170.315(b)(4) Incorporate tests and values/results.	Discussion Item
	§ 170.315(b)(5) Inpatient only— lab tests & values/results to ambulatory.	Discussion Item
March 21, 2014	§ 170.315(b)(1) Transitions of care.	Discussion Item
	§ 170.315(b)(2) Clinical information reconciliation and incorporation.	General Agreement
	§ 170.315(b)(6) Data portability.	General Agreement
	§ 170.315(e)(1) View, download, and transmit to a third party.	Discussion Item
April 4, 2014	§ 170.315(e)(2) Ambulatory setting only– clinical summary.	Discussion Item
	§ 170.315(h)(1) Transmit— Applicability Statement for Secure Health Transport. (Direct)	General Agreement
	§ 170.315(h)(2) Transmit— Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging.	Discussion Item
	§ 170.315(h)(3) Transmit— SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.	Discussion Item
	§ 170.315(h)(4) Transmit— Applicability Statement for Secure Health Transport and Delivery Notification.	General Agreement
	§ 170.315(a)(11) Electronic notes.	Did not Discuss
	§ 170.315(a)(15) Family health history.	Discussion Item

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Meeting Date	Comment Items	Status
April 17, 2014	§ 170.315(f)(2) Transmission to immunization registries.	Discussion Item
	§ 170.315(f)(3) Transmission to public health agencies – syndromic surveillance.	Discussion Item
	§ 170.315(f)(4) Transmission of reportable laboratory tests and values/results.	General Agreement
	§ 170.315(f)(6) Transmission to cancer registries.	General Agreement
	§ 170.315(a)(5) Demographics.	General Agreement
	§ 170.315(a)(10) Clinical decision support. (not Health eDecisions Proposal)	General Agreement
	§ 170.315(a)(16) Patient list creation.	General Agreement
	§ 170.315(a)(17) Patient-specific education resources.	General Agreement
	§ 170.315(a)(20) Implantable device list.	Discussion Item
	§ 170.315(g)(3) Safety-enhanced design.	Discussion Item
	§ 170.315(g)(5) Non-percentage-based measure report.	Discussion Item
April 23, 2014	Discontinuation of the Complete EHR definition	Did not Discuss
	Non-MU EHR Technology Certification	Did not Discuss
	"Certification Packages" for EHR Modules	Did not Discuss
	Regulatory Impact Analysis	Did not Discuss

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Comments

Comments on Incremental Rulemaking and the Voluntary 2015 Edition

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- No guarantee that the items contained in 2015 Edition will be part of 2017 Edition/MU Stage 3
- Unclear benefits to provider community related to implementing an incremental update while continuing to gather data for attestation period in any fiscal year on 2014 Edition
- Would prefer vendors focus on optimizing current code releases and begin preparation for MU Stage 3
- Cost burden to both vendors and providers

- **EHRs will not be able to distinguish between a 2014 and 2015 CCDA – although 2015 Edition EHR technology must be able to receive both types**
- **EHR technology certified to the 2014 Edition will not be able to receive/process a ToC using CCDA 2.0**
- **Should be asynchronous bilateral upgrades**
- <u>**Direct Edge Protocol Implementation Guide (IG)**</u>
  - o **Too ambiguous. Not constrained enough.**
  - o **Define how the non-email aspects of secure use of the protocol are handled, such as registering of new providers, managing of org-specific secret keys, etc.**
- <u>**Performance Standard**</u> **- Difficult to understand how it could be tested for certification**
  - o **It would seem minimally that a library of derivative CCDAs would have to be available or a testing tool capable of generating same would need to be available for vendors to prepare with.**
- <u>**Patient Matching**</u> **- Requiring month, day and year is an unnecessary constraint. Instead, use just the year.**

Transmission Certification Criteria

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- How would testing and certification ensure that a CCDA could be exchanged using transport standards besides Direct? Would this not require multiple Edge protocols and an EHR to be certified against all of them to ensure widespread exchange?
  - § 170.315(b)(1) requires Direct Edge Protocol certification and send/receive capability related to the CCDA.
  - § 170.315(b)(1) and the Direct Transport standard are part of the Base EHR definition requirements

View, Download, and Transmit

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- **It is good to push Direct Edge Protocol requirement (once constraint issues are resolved), but this is a small part towards getting to HISP neutrality (will not make it happen alone)**
- **Should not be required to send or receive health information from *any* Direct address without an established trust relationship.**
- **Certification should follow the approach used for 2014 certification of ToC summary transmission. Prove the capability to establish a trust relationship during testing for the purpose of testing and certification.**

Implantable Device List

- **Capture in EHR and parsing to allow user to view the ''device identifier'' and ''production identifier'' portions of the Unique Device Identifier (UDI) – Support (focus on capture for the 2015 Edition before moving to interoperable exchange in 2017 Edition)**

- **Not Ready for Interoperability/Electronic Exchange – HL7 product instance template (for CCDA) does not fully align with FDA UDI requirements**

  o **This comment applies to the inclusion of UDI in 170.315(b)(1), (b)(6),(e)(1), and (e)(2).**

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- **Ok with using CDX codes for immunizations/vaccinations**
- **LOINC**
  - **Clinician orders are not precise, particularly for future scheduled tests**
  - **LOINC doesn't cover all orders**
    - **Should not be "all" – should be "whenever available or when possible"**
  - **Issue about the specificity of LOINC codes versus indefinite nature of future orders that needs to be resolved in final rule**
- **Situational Dependency**
  - **Concern about how to define the encounter for testing purposes – How it should be limited/customized** (expectation is that it would be consistent with MU requirements for defining an office visit)

- **ONC does not offer evidence that HL7 Pedigree and the new Implementation Guide (IG) are in wide use (IG is fairly new)**

- **Converging to just HL7 Pedigree (from SNOMED CT) will be complicated and very burdensome**

Safety-Enhanced Design (SED) Request for Comment (RFC)

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Source: In light of feedback that ONC received during the HITPC "Implementation and Usability'' hearing on July 23, 2013, ONC asked the following questions:

- **RFC 1:** Should the scope of ''Safety-enhanced design'' should be expanded to include additional certification criteria?

- **RFC 2:** Should formative usability tests should be explicitly required, or used as substitutes for summative testing?

- **RFC 3:** Should there are explicit usability tests that should be required in addition to summative testing?

- **RFC 4:** Should there should be a minimum number of test subjects explicitly required for usability testing?

Safety-Enhanced Design (SED) Feedback

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- **RFC 1-3 Response: Don't expand SED criteria or testing processes.**
  - o Certification only represents a point in time and not the vendors' evolution of addressing usability concerns
  - o MU created a difficult environment in terms of development (rush to meet requirements and little time for anything else)
  - o Worry about regulations becoming too prescriptive in design of HIT, although acknowledged that current certification requirements are only to show that SED was incorporated into development, which can be done in multiple ways including adherence to consensus-based usability standards
- **RFC 4 Response:** ONC has not provided guidance on types or number of test subjects for comment.

Non-Percentage-Based Measure Report

- **Support the concept of capturing this data for MU audit purposes**

- It should not be overly prescriptive in what methods are used for capturing the information (e.g., not just in the audit log when it was turned on or off).

- Rather, ONC should provide examples that illustrate compliance with the certification criterion.

Syndromic Surveillance

§ 170.314(f)(3) and § 170.315(f)(3) Transmission to public health agencies – syndromic surveillance.

- **Certification to Alternative Standards (CDA, QRDA III, or HL7 2.5.1)**
    - **Support allowing additional flexibility**
    - <u>Clarification</u>: An EHR technology developer can be certified to any one of the 3 standards under this criterion and be considered certified, but providers must used technology that is certified (e.g., to use QRDA III, the EHR technology must be certified to that standard).

- <u>**Inpatient Setting Updated Implementation Guide (IG)**</u> - PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, and Inpatient Settings, Release 1.9 (April 2013) / Prior adopted version was Release 1.1
    - **Permit 1.9 for <u>voluntary</u> certification (for those who see benefit in it), but we emphasize the importance of v2.0 for the 2017 Edition as the likely <u>mandatory</u> standard for certification. 2.0 is significantly different that 1.9 and stakeholders are moving in the direction of 2.0. Our feedback is that 1.9 needs revised per state and association feedback.**

CPOE and Lab Exchange Certification Criteria

- CPOE – **support for splitting the criterion into 3 criteria**

- Inclusion of LOI standard/implementation guide (IG) in CPOE-Labs (§ 170.315(a)(2)) and LRI standard/IG in provider laboratory test results exchange criteria (§ 170.315(b)(4) and (5))

  - Concern expressed that stakeholders aren't using LOI and LRI standards/IGs (**newer standards/IGs**)

  - Workgroup questioned whether certification should push adoption of standards or let the market determine what's best (to note, lab standards were developed by broad stakeholder group and have gone/are going through HL7 balloting)

  - Workgroup questioned whether these standards and capabilities should be included in separate criteria for "voluntary" certification and not be required for MU certification purposes

General Agreement Certification Criteria

§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation
- **No objections to shifting incorporation from ToC certification criterion into this criterion**
- **Agreed it made sense from a workflow standpoint**

§ 170.315(b)(6) Data Portability
- **Recommend calling the certification criterion "core clinical data migration"**
- Support the idea of use of the CCDA as a basis for porting a specific patient's record say for the use case of a patient changing their provider and wanting an electronic basis of their record to help support that transition
- Do not think it a feasible basis for supporting a provider migrating their EHR from one vendor to another

General Agreement Certification Criteria

§ 170.315(a)(5) Demographics.

- Date of Death Capture – **Agree to include it**
- Preferred Language Standard (OPTIONS: ISO 639-2 in full; ISO 639-3; or RFC 5646) – **Recommend RFC 5646**

§ 170.315(a)(10) Clinical decision support. (not Health eDecisions Proposal)

- **Agree with clarifications for use of demographics data categories and Infobutton standard (not for vital signs, medication allergies, and "laboratory values/results" data).**
- **Support updated SOA Implementation Guide**

§ 170.315(a)(16) Patient list creation.

- **Agree with clarifications for use of demographics data categories**

§ 170.315(a)(17) Patient-specific education resources.

- **Agree with clarifications for 2-method certification requirement (using Infobutton and an alternative method that does not rely on Infobutton) and Infobutton standard (not for "laboratory values/results" data).**
- **Support updated SOA Implementation Guide**

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§ 170.315(f)(4) Inpatient setting only – transmission of reportable laboratory tests and values/results.

- **Updated IG:** CDC has issued an updated IG (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, DSTU, Release 2 (US Realm), 2013) that address technical corrections and clarifications for interoperability with laboratory orders and other laboratory domain implementation guides.
  - **Support Updated Implementation Guide**

§ 170.315(f)(6) Ambulatory setting only – transmission to cancer registries.

- **Updated IG:** CDC has issued an updated IG Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.1, March 2014) to address technical corrections and clarifications for interoperability with EHRs and cancer registries.
  - **Support Updated Implementation Guide**

General Agreement Certification Criteria

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§ 170.315(f)(2) Transmission to immunization registries.

- **Updated Implementation Guide (IG):** CDC has issued an updated IG (HL7 Version 2.5.1 Implementation Guide: Implementation Guide for Immunization Messaging, Release 1.5) that promotes greater interoperability between immunization registries and EHR technologies.
  - **Support Updated Implementation Guide (non-controversial – clarifies ambiguity and improves interoperability through removing state variability)**

- **Vocab Codes for immunizations/vaccines:**
  - **Prefer CVX to NDC with robust mapping to RxNorm.**
  - NDC is more geared toward packaging and manufacturing labeling. Lose granular level of coding by switching to NDC.
  - For consistency and alignment, should move to RxNorm for all/most drugs and biologics.

- **Bidirectional Exchange Request for Comment (RFC)**
  - **Bidirectional exchange should not be an MU requirement, but the workgroup endorses an IG for bidirectional exchange (for those who *want* to use it)**

Electronic Notes
Not Discussed in the Workgroup

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<u>***New Requirement***</u>: Search for information across separate notes within the EHR technology rather than just within one particular note.

- <u>Rationale</u>: Intended to reduce provider time spent looking for specific patient information.
- Search requirement is **not** limited to a specific method

<u>***Request for Comment (RFC)***</u>

- **RFC 1:** Should the functionality extend to all patient electronic notes stored in the EHR or just to a specific patient's electronic notes or specific types of patient notes?
- **RFC 2:** Should ONC require this functionality in the 2015 Edition or wait to include it in a potential 2017 Edition ''electronic notes'' certification criterion?
- **RFC 3:** <u>*Health care providers*</u> opinions on whether the availability of such functionality (either searching across a specific patient's electronic notes stored in the EHR or all patients' electronic notes stored in an EHR) is so widespread that it would be unnecessary to require it as a condition of certification. Note that the ''electronic notes'' objective and measure for MU Stage 2 requires that notes be text searchable, but does not require searching across electronic notes.
- **RFC 4:** Should additional metadata be required as part of electronic notes (such as the HL7 R2 header) to assist in both searching of notes, but also to make exporting electronic notes for patient data portability easier?

Electronic Notes Feedback
Not Discussed in the Workgroup

- The types of notes would certainly need to be specified. For example, does it include scanned notes (which would require OCR tools)? Does it require searching of PDFs? What about proprietary formats like MS Word? HTML? What about the source of the notes – internal vs. external from dictation services? Some notes may be linked to from within the EHR, but may not actually be contained by the EHR — would those linked notes be included?
- **RFC 1 Response:** One-patient-at-a-time searching makes sense as a potential requirement, but that searching across-all-patients-at-once does not. The latter requires considerably greater complexity as it has to deal with complex security issues such as which patients the provider has rights to access, etc. and does not strike me as a core capability that merits an EHR certification test.
- **RFC 2 Response:** Suspect that many vendors are not prepared. Sounds like a 2017 consideration.
- **RFC 3 Response:** In general, if the market is working, there need not be a certification test, particularity one that does not deal with interoperability.
- **RFC 4 Response:** No, the metadata is typically stored in EHR data tables that are associated with the note, and it would be redundant to put the same data into the note header as well. if the note is exported out of the EHR, then the metadata can be added via a standard CDA header, wrapped around the note.

Discontinuation of the Complete EHR
Not Discussed in the Workgroup

- Commend ONC's proposal but acknowledge/recognize that because Complete EHR will remain a desired option for vendors/providers who do want to seek it, it should remain in play. To do away with it likely increases vendors' burden and cost.

- ONC should not do anything in their policies and rulemaking that serve to favor Complete EHR over a modular approach in the development of certification criteria, test procedures, or conformance testing tools that would serve to mandate it as a certification approach.

- Consider labeling requirements or test report requirements for a product to be listed on the ONC CHPL to provide more disclosure and description related to the certified product architecture to allow for buyers to be more aware of how it came to be put together.

- ONC should consider requiring more disclosure as to the technical/architectural approach/schema/compilation of the CEHRT no matter if it is an EHR Module or Complete EHR.

- Create help for the provider/ buyer/user to understand if the product suite is truly integrated….composed of interfaced components….composed of separate technical platforms….etc.

Discontinuation of the Complete EHR
Not Discussed in the Workgroup

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- Complete EHR certification does not ensure integration of capabilities or commonality of architecture

- An EHR Module can be certified to everything a Complete EHR is certified to – it's just not *called* a Complete EHR
  o Possibly include a required Base EHR definition label for those products that meet it

- Complete EHR becomes too big as currently defined considering that the criteria set continues to become larger and more diverse as it factors in more public policy considerations.

- Vendor Discretion: It's up to the vendor to get certified to what the customer/provider needs. To meet the Certified EHR Technology definition, providers have to have EHR technology that is certified to the Base EHR definition requirements and whatever else they need for the MU stage they are attempting to achieve and to report CQMs.

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- Support other program requirements that serve to enfranchise other types of providers beyond EPs and Hospitals to have access to CEHRT appropriate to their venues of care, and to support use requirements that make sense for public policy for their venue of care.

- Every care setting does not need a meaningful use program of its own.

- Other venues of care and federal health programs can determine their own interest and public policy motivations for adoption of CEHRT without having to try to fit square pegs into round holes.

- An MU-like incentive program may make little sense for another venue of care but maybe it makes entire sense for attaching to value-based purchasing concepts or to conditions of participation that do serve to motivate provider adoption of EHR technology in those venues.

- **The challenge that is still unmet is our external partners are not held to the standards which support interoperability.**

Certification Packages
Not Discussed in the Workgroup

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- Vendor does not have to do anything beyond certification to claim it

- Workgroup members questioned whether it really would add to buyer or user understanding of the certification label

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- Consider using HIMSS EHRA comments on RIA