

# Health IT Standards Committee

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



## Content Standards Workgroup

2015 Edition Certification NPRM

May 20, 2015

Andy Wiesenthal, chair

Rich Elmore, co-chair

# Workgroup Members



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

Name	Organization
<b>Andy Wiesenthal, Chair</b>	Deloitte
<b>Rich Elmore, Co-Chair</b>	Allscripts
<b>Kelly Aldrich</b>	HCA Healthcare
<b>Calvin Beebe</b>	Mayo Clinic
<b>David Dinhofer</b>	Infotek Solutions and Services, Medical Society of the State of NY
<b>Floyd Eisenberg</b>	iParsimony, LLC
<b>Grahame Grieve</b>	National eHealth Transition Authority
<b>Susan Hull</b>	Wellspring Consulting
<b>Charles Jaffe</b>	Health Level 7 International
<b>Kevin Kirr</b>	Dignity Health
<b>John Klimek</b>	National Council for Prescription Drug Programs
<b>Kim Nolen</b>	Pfizer, Inc.
<b>Marjorie Rallins</b>	American Medical Association
<b>Joyce Sensmeier</b>	Integrating the Healthcare Enterprise (IHE USA), HIMSS
<b><i>James Ferguson, liaison member</i></b>	Kaiser Permanente
<b><i>Rebecca Kush, liaison member</i></b>	Clinical Data Interchange Standards Consortium (CDISC)
<b><i>Kin Wah Fung, Ex Officio</i></b>	National Library of Medicine
<b><i>Clem McDonald, Ex Officio</i></b>	National Library of Medicine
<b><i>Dianne Reeves, Ex Officio</i></b>	National Cancer Institute, National Institutes of Health
<b><i>Matthew Rahn</i></b>	Office of the National Coordinator for Health IT



- Getting to interoperability on a national scale requires focus
  - Focus exclusively on Consolidated CDA 2.0
  - Limit set of templates to CDA, discharge, referrals
  - Do not require CCDA 1.0 <->2.0 exchange
    - 1 year overlap provides limited value
    - Vocabulary and value set changes not conducive to asymmetric upgrades
  - Globally require existing transport standards (Direct Project)
- Ensure that the API requirement is consistently implemented
  - Despite maturity issues, specify FHIR as the API standard if successfully balloted before the final rule
  - Because of maturity issues, specify a lower bar for this certification round
- Re-think several standards in light of API/FHIR evolution including clinical decision support, care planning



- Certification NPRM includes many standards requirements that will have significant beneficial impact on the health care system:
  - Including clinical quality measures, common clinical data set, updated SNOMED, quality reporting and the API requirement (For evolutionary standards, use latest versions – not a maturity issue)
  - Correctly identifies the need for some standards, but refinement needed including identification of food/substance-reactions/intolerances, lab and med order entry
- Standards not ready for prime time:
  - Immature: clinical decision support, Data Segmentation for Privacy, Electronic Sending of Medical Document requests, virtual Medical Record, Quality Improvement and Clinical Knowledge data model, electronic Delivery of Service
  - Should be reconsidered: NCPDP Formulary and Benefit Standard (prefer Real Time Prescription benefit), CCDA Care Plan Template (prefer HL7 Coordination of Care Services Functional Model for dynamic care planning)
- Deliver testing requirements and “gold standards” prior to, or with, the final rule

# Content Standards NPRM Assignments



Health IT Standards Committee  
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## Group 1 Assignments

- Medication Allergy List, p.57
- Computerized Provider Order Entry – Medications, p.38
- Computerized Provider Order Entry – Laboratory, p.38
- Computerized Provider Order Entry – Diagnostic imaging, p.41
- Drug-drug, Drug-allergy Interaction Checks for CPOE, p.41
- Drug Formulary and Preferred Drug List Checks, p.63
- Electronic Prescribing, p.113
- Structured and Codified “Sig”, p.115
- Incorporate Laboratory Tests and Values/Results, p.120
- Transmission of Laboratory Test Reports, p.123
- Pharmacogenomics Data – Request for Comment, p.236 (first 4 bullets)

## Group 1 Members

- **Kim Nolen**
- Andy Wiesenthal
- John Klimek
- Kevin Kirr
- Kin Wah Fung
- Dianne Reeves
- Clem McDonald



## § 170.315(a)(9) Medication allergy list Page #57

- We do feel it is important to develop vocabularies for environmental and food allergens to facilitate achieving interoperability
- We do not recommend putting food allergies in the medication allergy list. There should be a discrete field for this information. Since the standards are not mature ONC should allow users to enter information as free text
- Clinical decision support systems today currently do not support this functionality therefore industry may not be ready for this criterion
- Should consider starting with a requirement that identifies a set of the most critical allergens be represented in an appropriate vocabulary. For example, FDA has stated, “1. (A) eight major foods or food groups--milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans-- account for 90 percent of food allergies.” See Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II): <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>
- Of note, the ingredients of food substances are not adequately identified or listed individually making it difficult to use for higher level functionalities such as CDS, getting pushed into patient portals, or being named as standard at this time

# Group 1 - NPRM Assignments, con't



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## § 170.315(a)(1) Computerized provider order entry – medications Page #38

- Additional elements are more relevant for diagnostic image ordering and less so for medication ordering
- There is no message standard specified for drugs collected by CPOE in inpatient care
- Should consider specifying use of HL7 v2

## § 170.315(a)(2) Computerized provider order entry – laboratory Page #38

- LOI defines the requirements for lab order entry, whether or not there's an eDOS available
- It is unclear regarding whose cardinality is being referred to. The LOI should hold sway if there are any conflicts between eDOS and LOI standard
- We support the LOI and the use of LOINC to promote interoperability
- There should be some consideration given to the differences and impact of implementation between the two versions of LRI
  - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm, July 2012
  - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) May 2014
- We are in agreement with the incorporation of laboratory test results compliant with CLIA as it relates to the incorporation and display of test results in a receiving system
- There needs to be more clarity around the vocabulary used for medications in the CCD 1.1 and 2.0 Implementation Guide
  - RxNorm should be used when referencing any medication or medication allergy
  - LOINC should only be used at a higher level to describe how the medication was used or for an observation from a medication use and should not be used in reference to a medication name or medication allergy



## § 170.315(a)(3) Computerized provider order entry – diagnostic imaging Page #41

- We are in agreement with the addition of certain data elements to be included in a transmitted order
- The examples (especially the reason for ordering) of additional data elements are more relevant for diagnostic image ordering and less so for medication ordering (e.g., secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider) and are usually required for billing

## § 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE Page #41

- The user should not be required to enter additional information beyond the normal workflow to satisfy this requirement
- Organization should be able to choose the level of severity associated with trigger of alerts
- We are concerned about the level of alerts that would be generated and how effective the alerts might be
- Some thought needs to go into decision support strategy to avoid alert fatigue
- We think it is the right approach to track actions for DD/DAI however we also feel that it should be a non-interruptive process that factors in consideration for end-user needs / usability to minimize disruption to workflow
- There should be consideration around specificity of alerts, or built in logic (e.g., if a patient has been on a drug for a length of time without consequences, then an allergy alert to that drug should not pop-up / alert





## § 170.315(a)(11) Drug-formulary and preferred drug list checks Page #63

- Drug information the EP or EH receives needs to be consistent with information received in other care settings, such as the pharmacy, and as specified this may lead to inconsistencies
- Should consider excluding the NCPDP Formulary and Benefit Standard and instead wait for the NCPDP Real Time Prescription Benefit Inquiry standard to be completed
- Should explore the Telecom Standard (NCPDP) which provides patient out of pocket costs and formulary information to the pharmacist
- HealthIT Module should have the functionality to capture data in discrete, structured fields to accurately match the patient to their prescription benefit plan similar to the pharmacies
  - CMS mandated pharmacies include the 4Rx data elements when adjudicating a prescription: 1) RxBIN; 2) RxGRP; 3) RxPCN; 4) Rx-ID
  - Same 4 data elements could be used to accurately match the patient to their prescription benefit plan if they were included in structured fields in the HealthIT module which would lead to better information at the point of care and promote consistency of data between the Healthcare settings within the patient journey
  - These data elements could be captured in the eligibility transaction (270/271) and pulled into the HealthIT module
- Prescription Benefit Information should be made available not only to eligible providers, but also to other healthcare participants in the care continuum including pharmacies, pharmacists, and patients. Each should be considered an actor in the use cases and standards developed around prescription benefit inquiries.



## § 170.315(b)(3) Electronic prescribing Page #113

**In order to improve the ability to capture and represent medication history consider prioritizing the additional transactions or segments, namely Change Prescription, Refill Prescription, Cancel Prescription, Fill Status, and Medication to address needed functionalities in both the pharmacy software systems and the prescriber's software systems / health IT modules.**

- Agreement with adding Cancel Prescription (CANRX, CANRES) and Refill Prescription (REFREQ, REFRES) as transactions or segments from NCPDP SCRIPT v10.6 in order to better facilitate prescriber-pharmacist communication
- RXCHG: we are aware that several pharmacy software vendors have this functionality to be developed by the end of 2015 and in 2016, so this would be a criterion that could be rapidly adopted if both prescribers and dispensers have the functionality
- Fill Status (RXFILL) notifications should occur in the electronic health record and not outside (e.g., email or other means of communication)
- However, we feel we need healthcare professional input (e.g., from those engaged in prescribing and dispensing prescriptions) on what the appropriate triggers should be for notifications to ensure criterion does not generate excessive messaging. This specifically applies to Fill Status (RXFILL)

### **Medication Dosing**

- Should be prescribed first in dose strength, then in volume for oral liquid medications. We are in agreement with the volume being expressed in the metric unit standard only and not utilizing the imperial standard (e.g., teaspoons)
- We are in agreement with dosing numbers (i.e., including both dose strength and dose quantity) having leading zeros before the decimal point for amounts less than one (e.g., 0.5 mg) and should not use trailing/terminal zeros after the decimal point (e.g., 5.0 mg)
- Consider greater specificity in RXNORM implementation guides



## Structured and Codified “Sig” Page #115

- We are in agreement with having a structured “Sig,” however we would like consideration of the structured Sig that is already in use in the inpatient setting over NCPDP SCRIPT v10.6
- We are in agreement with continuing to enable users to enter free text, in addition to structured Sig elements

## § 170.315(b)(4) Incorporate laboratory tests and values/results Page #120

- Functional requirements should not supersede implementation guides where there are inconsistencies between the two
- We are in agreement with adding the certification criteria to the inpatient setting, also it should utilize the same message standards HL7 v 2.5.1
- Laboratory NPRM already specifies what LOINC Codes should be used, value sets have answer lists but they are not formally enumerated
- Today value sets are largely determined by the measure developers/stewards, and this would need to be broadened to be more comprehensive for populations and values outside the measure



## § 170.315(b)(5) Transmission of laboratory test reports Page #123

- We are in agreement with adopting and including HL7 Version 2.5.1 Implementation Guide
- The S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (“LRI Release 2”) is currently under ballot and should not be named in The Final Rule until the balloting process is complete, assuming it passes the ballot process
- There should be some consideration given to the differences and impact of implementation between the two versions of LRI
  - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm, July 2012 and
  - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) May 2014
- We are in agreement with the incorporation of laboratory test results compliant with CLIA as it relates to the incorporation and display of test results in a receiving system
- We are in agreement with the designation of LOINC as the vocabulary standard
- We do not feel that eDOS is ready for implementation



## Pharmacogenomics Data – Request for Comment Page #236 (Comment on first 4 Bullets Only page #239)

- We do believe that genotype-based drug metabolizer rate information is important, however, it is not the same as a medication drug allergy and therefore should not be included in the medication allergy list. It should have its own category or concept
- The maturity level relative to being able to capture pharmacogenomics data in the CDS may be low such that it would not be of benefit to include as a certification criterion at this time.
  - ONC should encourage the development of standards around pharmacogenomics
  - In some cases the market may advance more quickly than standards
  - Capturing the data, regardless of standards, in settings where used (e.g., retail care, clinical trials) may be a valuable first step
  - Establishing a vocabulary would be another good starting point
  - Value in giving the market direction regarding what standards should be used so that they when implementers are ready they can invest in technologies and minimize re-work

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## Pharmacogenomics Data – Request for Comment Page #236 (Comment on first 4 Bullets Only page #239)

### (Continued from Previous Slide)

- In the NPRM there is repeated mention of pharmacogenomics information in the CPOE system but should also consider how this would be influenced in the ambulatory e-prescribing module as two different standards are used
- Similar to food allergies, a good first step might be to enter the information as text in a discrete, unstructured field.
- Consideration should be given to an appropriate vocabulary that can represent pharmacogenomic data or take a subset of highly used values, such as the Cytochrome P450 enzymes which are the most prevalent drug-metabolism enzymes, to represent first in a vocabulary to pilot.
- Because there is a lack of standardized vocabularies it will be challenging to represent / capture pharmacogenomics data in a structured fashion.
- Another potential starting point, or opportunity, might be to capture genotype-based drug metabolizer rate information
- Clarification may be needed regarding the correlation between pharmacokinetic and pharmacogenomics information
  - Drug labels typically feature pharmacokinetic information but not pharmacogenomics

# Content Standards NPRM Assignments



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## Group 2 Assignments

- Decision Support – Knowledge Artifact, p.94
- Decision Support – Service, p.96
- Clinical Quality Measures (all sections), p.138
- Electronic Submission of Medical Documentation, p.222

## Group 2 Members

- **Floyd Eisenberg**
- Marjorie Rallins
- Susan Hull
- Kelly Aldrich
- David Dinhofer



## § 170.315(a)(22) Decision support – knowledge artifact Page #94

- Support the use of CDS knowledge
- Promote the use of standards expressed in clinical quality measures
- Encourage the use of structured data to support the CQM and CDS process.
- The HL7 standard resulting from the S&I Framework activities (Health eDecisions) is HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 (DSTU). It specifically references the virtual medical record (vMR) that is references in the following HL7 standards:
  - HL7 Version 3 Standard: Clinical Decision Support; Virtual Medical Record (vMR) Templates, Release 1 (DSTU)
  - HL7 Version 3 Standards: Virtual Medical Record for Clinical Decision Support (vMR-CDS) XML Specification, Release 1 (DSTU)
  - HL7 Version 2 Implementation Guide: Implementing the Virtual Medical Record for Clinical Decision Support (vMR-CDS), Release 1
- EHRs have not adopted HeD
  - HeD artifact requires vMR which no commercial EHRs support
  - No compilation engine available to configure the artifact into an EHR-specific format for implementation. No current automated method to author HeD artifacts and the ecosystem of CDS Knowledge Artifact Suppliers and CDS Knowledge Artifact Integrators is also insufficiently mature.

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## § 170.315(a)(22) Decision support – knowledge artifact Page #94

### (Continued from Previous Slide)

- Ecosystem adoption is still early, evolution in progress and not at all mature.
- Highly premature for any rule to address standards that are somewhat outdated (HeD referencing vMR) or not yet developed or tested.
- Standards are also in the midst of significant evolutionary change.
  - The HL7 Clinical Quality Information (CQI) Workgroup plan to move quality-related artifacts to
    - Metadata
    - Data Model
    - Expression Language.
- Supported by the S&I Clinical Quality Framework activities, the HL7 CQI and Clinical Decision Support (CDS) Workgroups have balloted metadata (informational), and expression language (Clinical Quality Language) and is still evolving a new data model to incorporate both the vMR and the Quality Data Model currently used for eCQMs in the US.
- New data model (i.e., QUICK) remains in evolution and was withdrawn from the ballot in May 2015.
- Will not be balloted again until September 2015
- New FHIR quality profile is in development (and is included in the HL7 May 2015 ballot) and the FHIR profile will inform the QUICK model for later ballot.
  - FHIR standard remains in draft; final FHIR standards are expected in Summer 2015.
  - It will take vendors time to integrate FHIR into their next versions and to begin to use FHIR to support new development

### (Continued on Next Slide)



## § 170.315(a)(22) Decision support – knowledge artifact **Page #94**

### **(Continued from Previous Slide)**

- Support the effort to harmonize the standards process for all of quality (measurement and clinical decision support) in concert with standards used for routine data capture and interoperability
- Encourage adopting a framework that moves standards at the forefront while we move ahead.
- CDS standards are insufficiently mature and insufficiently tested to include in this round of rule making
- NPRM discussion presumes clinicians as the focus for clinical decision support. We suggest expanding the focus to include patients and consumers



## § 170.315(a)(23) Decision support – service Page #96

- Support the concept of a decision support – service
- Reiterate the need to use standards to build cross platform capabilities (interoperability) which will aid in the development of tools to make it easier to share and standardize quality measures
- Support identification of process improvements through standard CQI techniques to help evolve the standards and decision support services
- The standards are in the midst of significant evolutionary change, previous comments
  - FHIR should be considered as a good place to set structural standards and content standards but needs a dictionary like SNOMED or RADLEX
  - The Structured Data Capture effort is working on setting its own standards. They should be included in setting vocabulary standards
- Requirement assumes maturing of CDS as a service and maturity of standards
  - Including the ecosystem maturity of CDS Knowledge Artifact Suppliers and CDS Knowledge Artifact Integrators
- Time the requirement appropriately rather than require use of vMR-based standards when they are not currently implemented and the current path is to subsume vMR with QUICK and/or FHIR Quality Profiles



## § 170.315(c)(1) Clinical quality measures – record and export Page #138

- Support the direction to use standards with recording and exporting CQM data
  - Requiring this functionality and including it in a rule may be premature
  - Recommend adopt a phased approach
- “We propose to require that a system user be able to export CQM data at any time the user chooses and without subsequent developer assistance to operate”
  - This statement is laudable but it is the execution that will judge its value
  - A user should be able to export the data for analysis whenever the user chooses
  - Exporting the QRDA as expected for transmitting data to CMS is a different use case and addresses a complete data set for a quality measure
  - Exporting more often, i.e., whenever the user decides, is a different use case and QRDA may not represent the right solution
  - Exporting may include sending all data to another analysis engine to determine the extent to which a EP or EH complies as of the current date (i.e., an aggregate analysis based on existing data. Requiring each analysis engine to import QRDA may be excessive)
- NPRM refers to the S&I Framework CQF initiative as a standard (based on the National Technology Transfer Act)
  - Standards addressed in MU have been developed by international standards organizations
    - HL7 standards address these requirements – some are US domain only (QRDA) and others international (HQMF)
  - The NPRM should use a true standard – and one that has been tested and in place in real world settings to assure it is acceptable and usable
  - The most recent QRDA should be adopted, not earlier versions (i.e., the ballot update from January 2015 HL7 ballot cycle) to ensure incorporating lessons learned from recent implementations
  - Newly balloted version for mid-May 2015

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## § 170.315(c)(1) Clinical quality measures – record and export Page #138

### (Continued from previous slide)

- Import CQM data: Standards are still in the process of stabilization. HQMF is an evolving standard and the newest version is just being balloted now, add date in the May 2015 balloting cycle (incorporating the Clinical Quality Language and maintaining QDM)
- Assuming the current HL7 ballot succeeds, the resolved and published version should be the subject of the Final Rule
  - However, expecting clinical software to import and calculate a measure is excessive
  - EHRs are developed to capture information – analytic engines are developed to analyze
- An analytic engine might be expected to import a CQM *if that CQM is based on feasible and valid and reliable data that might normally be found within clinical settings based on normal workflow*
- Many CQMs expect excessive and non-feasible data
- Since HQMF is still evolving, it is premature to expect that EHRs or any analytic engine can automatically import an HQMF measure
  - More testing and work is required



## § 170.315(c)(2) Clinical quality measures – import and calculate Page #141

- QRDA Category 1 should be updated to the new version including errata
- HQMF should be named with the newest version that has been balloted so that it is easier to understand and has a better chance of being imported successfully

### User ability to import CMDCQM data

- Description for CQM import data needs clarification
  - Data will be imported into what and where?
  - Is it an import of the specification into the health IT system?
  - Is it an import of quality measure results?
  - Recommend incorporating a definition of CQM data, IT systems demonstrating ability to import data is a good start
  - Statement should go further to say “import and understand” CQM data.
- Expecting that all data required by CQMs and CDS will be present in the EHR may be a misperception.
- Not all data points coming from other sources are appropriate for the EHR.
- If NPRM is referring to ability to include data documented elsewhere into the EHR so it can be used to calculate a quality measure, then any structured information coming from a C-CDA should be “in play” here and not just information needed to calculate a quality measure
  - If the information is captured elsewhere and not generally available, then measure is not feasible and thus a faulty measure
- Vendors should not be expected to support any and all amount of data concepts and classifications that measure developers determine important to evaluate quality.
- Measures often require the original source of data elements to include them in the measure. Provenance at the data level is not currently feasible when importing from C-CDA

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## § 170.315(c)(2) Clinical quality measures – import and calculate Page #141

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#### Testing of Import and Calculate Functionalities

- Ability to test a larger number of cases is likely useful
- Should not be a fixed number but derived based on the complexity of the CQM and the minimum number required for adequate “coverage” of the measure.
- ONC should devise a formula to determine the minimum number of test cases required
- Additional clarification needed to determine count of test cases and approach to CQM calculation

#### Technology must be able to calculate each and every clinical quality measure for which it is presented for certification

- Some eQMs still include data that are not captured routinely in EHRs or require information captured elsewhere but for which provenance is not maintained with interoperability
- eCQM feasibility remains a significant concern and the statement "each and every" is too far reaching.
- “Technology” should address analytic engines and not require that an EHR perform calculation

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## § 170.315(c)(2) Clinical quality measures – import and calculate Page #141

### Continued from Previous Slide

- We support the concept of clinicians importing data on request without requesting support from the system developer
- As data are structured they should be accessible as published by the 2015 Interoperability Standards Advisory (<http://www.healthit.gov/standards-advisory>) and made available without requiring system developer assistance
  - To make this work, all data sources (e.g., devices, monitors, EHRs, etc.) need to support the same standards for data sharing and structured content
- Final rule should address what data and standards are required
- Evaluating longitudinal data over time requires standards on expressing and maintaining provenance
- We define independence from a small practice perspective as the ability to upload “apps” that automatically connect data from different sources
- ONC should support development of such capability
- In the meantime, system developers will still need to support a significant amount of connectivity for small practices or consumers





## Reserved for § 170.315(c)(3) Clinical quality measures – report & export Page #138

- Support the direction to use standards with recording and exporting CQM data; however, requiring this functionality and including it in a rule may be premature, recommend a phased approach

### Standards for Clinical Quality Measures

- Public has an opportunity to provide input and vote on HL7 standards
  - ONC should increase awareness of opportunities to vote on various standards
- When such standards successfully update based on balloting and comments (e.g., QRDA Category 1 and 3), the update is based on public user input that provides an opportunity to fix issues inherent in earlier versions
- Requiring the CMS version of these standards puts MU at risk for falling behind the DSTU updates in HL7
  - CMS systems are not ready to accommodate updates that might benefit EPs, EHs, and vendors.
  - Risk that the HL7 process is slow and CMS guidance can circumvent less responsive HL7 processes
  - Risk for delay incurred by CMS systems that are slow to update is greater.
- Updates should be based on the most recent HL7 balloted standards and vendors and CMS should equally need to accommodate to the more recent standards
- SDOs and other quality measures decision-making bodies should continue to collaborate and coordinate to promote alignment of quality measures

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Reserved for § 170.315(c)(3) Clinical quality measures – report & export Page #138

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## **User Ability to Import CQM Data**

- Not all data points coming from other sources are appropriate for the EHR, per previous comments
  - Emerging efforts address adherence (to measures and CDS) reported through Patient Generated Health Data (PGHD), including mobile devices
  - PGHD may or may not be included in EHR, but rather to remote monitoring, care coordination, or population management systems
  - Account for innovation in PGHD without restricting available data elements to those in an EHR.
- The Final Rule should constrain requirements to known and tested data classes such as those existing in EHRs

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Reserved for § 170.315(c)(3) Clinical quality measures – report & export Page #138

## (Continued from Previous Slide)

- Support the concept of clinicians importing data on request without requesting support from the system developer
- As data are structured they should be accessible as published by the 2015 Interoperability Standards Advisory (<http://www.healthit.gov/standards-advisory>) and made available without requiring system developer assistance
- This will require all data sources (e.g., devices, monitors, EHRs, etc.) to support the same standards for data sharing and structured content
- Final rule should address, in detail, what data and standards are required
- Evaluating longitudinal data over time also requires standards on expressing and maintaining provenance of the data
- We define independence from a small practice perspective as the ability to upload “apps” that automatically connect data from different sources, and ONC should support development of such capability
  - In the meantime, system developers will still need to support a significant amount of connectivity for small practices or consumers



## § 170.315(c)(4) Clinical quality measures – filter Page #145

- Support the ability to report at practice and organizational levels and the ability to stratify data
- Balance population health with privacy and security
- Clinical data points should be added but the relevance of data points needs to be determined

## § 170.315(i)(1) Electronic submission of medical documentation

- This section seems out of scope for the Clinical Content Workgroup
- General comments:
  - The information is helpful. However, for CDS and eQMs, the scope for structured data to evaluate clinical care is potentially everything. Requiring structure for all data is excessive and unrealistic
  - Further, the CDS and eQMs often need provenance at the data level that is not included in the C-CDA.
  - Ten minutes for time out may be too short

# Content Standards NPRM Assignments



Health IT Standards Committee  
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Group 3 Assignments	Group 3 Members
<ul style="list-style-type: none"><li>• Transitions of Care, p.98</li><li>• Updated C-CDA Standard, p.99</li><li>• Valid/Invalid C-CDA System Performance , p. 102</li><li>• C-CDA Data Provenance, p.110</li><li>• Consolidated CDA Creation Performance, p. 202</li><li>• Clinical Information Reconciliation and Incorporation, p.111</li><li>• Incorporation System Performance, p.111</li><li>• Care Plan, p.136</li><li>• Common Clinical Data Set, Updated C-CDA, and Diagnostic Image Reports, p.160</li><li>• Application Access to Common Clinical Data Set, p. 205</li></ul>	<ul style="list-style-type: none"><li>• <b>Calvin Beebe</b></li><li>• Charles Jaffe</li><li>• Rich Elmore</li><li>• Graham Grieve</li><li>• Joyce Sensmeier</li></ul>



## § 170.315(g)(6) Consolidated CDA Creation Performance Page #201

### **For (6) (i) – Reference C-CDA match.**

- Any Gold standard C-CDA document(s) established will need to be made publicly available as early as possible to encourage vendor use
- Need means to allow for public / technical review / feedback

### **For (6) (ii) (A) - Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.**

- It may be worth providing the ability for a system to prove, in a structured format, that the use cases it supports do not involve producing one or more documents, document sections, or specific data points
- Examples of such systems are medical transcription systems and natural language processing systems

### **For (6) (ii) (B) - Inpatient setting only. Discharge Summary.**

- Well executed implementation of a limited set of templates, at national scale will accomplish more than requiring the capability to address every single kind of document template
- Limit templates to CDA, discharge and referral
- Unclear if the rule is intending that Health IT solutions provide wider support for C-CDA document types
  - If so, then language supporting the possibility of having data requirements supported via multiple document types need to be provided
- Can a transition of care be supported with a set of Consultation Notes, H&P and other notes, along with a CCD?
  - If not, can only one document be utilized? We would like to encourage flexibility
- Clarification needed: It does not seem to serve any useful purpose to require that all Common Clinical Data Set elements be present in every clinical document



## § 170.315(b)(2) Clinical information reconciliation and incorporation Page #111

### For (2)(iii) Reconciliation

- Incorporation of a patient's active medication list, medication allergy list, and problem list would enable a user to reconcile the data needed to improve overall clinical communications for improved patient care.
- We are in agreement with the incorporation of problems, medication, and medication allergies into the CCDA for exchange but we feel automated reconciliation will be a challenge at this time due to inconsistencies in vocabulary implementations.
- There should be consideration around greater specificity in RxNorm implementations to better define how term types should be created & consumed in the HealthIT module.
- For each list type: Medication reconciliation may not apply to a lot of situations outside medical referrals, for example, referrals involving ancillary services such as physical therapy (see comment above)
- Recommend that use cases and system roles be taken into consideration in determining when this rule applies

## Incorporation System Performance Page #111-112

- For core EHR system to EHR system C-CDA exchange we agree with the recommendation, as long as human readability is also verified for all C-CDA documents incorporated into Health IT solutions. Specific test requirements should be referenced in the regulation (not after) or this requirement should be deferred
- EMR to EMR or provider to provider exchanges functions like medication reconciliation make sense for EMR but changing the scope from EMR to health IT may change the applicability of some the use cases driving certification criterion
  - Example: some medication scheduling patterns are excessively complex and go beyond templates built into many systems, and therefore reconciliation cannot be automated
- Only require C-CDA 2.0 to 2.0 based exchange. Too complicated for too little a time period and too little value to solve for C-CDA 1.1 handling as the standards differ in the vocabulary and value sets for the same concepts. For example, problem type changes from SNOMED to LOINC



## Common Clinical Data Set, Updated C-CDA, and Diagnostic Image Reports Page #160

- For core EHR system to EHR system C-CDA exchange we agree with the recommendation, however, transcription and NLP (Natural Language Processing) systems working with early stage IT systems have questioned this. However we note that “Unstructured Document IG”
- The preclusion of using the “Unstructured Document IG” found in C-CDA needs to be amended to assert that for the purposes of supporting reuse of clinical information (medications, problems, allergies, etc.) that the Unstructured Document IG cannot be used for obvious reasons. However, practices may use the Unstructured Document IG, when providing reports with images or scanned forms as long as they are included in exchange packages with the Continuity of Care Document, Discharge Summary Documents, Referral Summary document, etc. There is a need to support imaging both within and alongside of C-CDA documents used for MU 3. There needs to be some clarifying language about this in the certification requirements.
- Use case for the structured representation of the care plan may be unclear. Regardless Care Plan template is immature and should not be included in Cert requirements
- ONC should engage professional societies to get feedback on care plan and/or what would make it more valuable or what other document would more valuable, less a tech question more a practice question

**(Continued on Next Slide)**





## Common Clinical Data Set, Updated C-CDA, and Diagnostic Image Reports Page #160

### (Continued from Previous Slide)

- Ability to process care plans dynamically across settings of care and systems is going to take more work and refinement. Look to HL7's Coordination of Care Services Functional Model as a longer term framework/goal.
- Optional sections should not become required, e.g., Health Status Evaluation, Outcomes, Interventions (V2) - - EPs / EHS want systems reflecting content, for example "no known...", when sections are required but there is no such data for a patient
- Practices may use the Unstructured Document IG, when providing reports with images or scanned forms as long as they are included in exchange packages with the Continuity of Care Document, Discharge Summary Documents, Referral Summary document, etc.



## § 170.315(g)(7) Application access to Common Clinical Data Set

### For (7)(iii)(A) Data-category request.

- The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data in either XML or JSON

### (7)(iii) (B) All-request

- The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data in a summary record formatted according to the standard adopted at § 170.205(a)(4).
- What is meant by a, “full set of data”? May not always be appropriate.

### For (7)(iv) Documentation. The API must include accompanying documentation that contains, at a minimum:

- API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns
- Software components and configurations necessary for APIs
- Rather than leaving it open for vendors and implementers to select any API needs and document how it works FHIR should be specified as the required standard, but a relatively low bar should be established since it is new
  - Too much freedom to select various APIs may result in proliferation of a variety of standards
- “All” requests should not be tied to C-CDA. FHIR composition resource should fulfil the requirement
- Need to seek practice guidance on a reasonable set of criteria that can be used to support the automatic selection of content to be included in C-CDA summary documents



# DISCUSSION