

Health IT Standards Committee

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



Semantic Standards Workgroup

2015 Edition Certification NPRM

May 20, 2015

Becky Kush, co-chair

Jamie Ferguson, co-chair

Membership



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

Members	Organization
Co-Chairs	
Jamie Ferguson	Kaiser Permanente
Rebecca Kush	Clinical Data Interchange Standards Consortium (CDISC)
Members	
John Carter	Apelon, Inc.
Todd Cooper	Breakthrough Solutions Foundry, Inc. , Center for Medical Interoperability
Stan Huff	Intermountain Healthcare
Rosemary Kennedy	eCare Informatics, LLC, Thomas Jefferson University
Harry Rhodes	AHIMA
Eric Rose	Intelligent Medical Optics (IMO)
John Speakman	New York University Langone Medical Center
Asif Syed	American Medical Association (AMA)
Andy Wiesenthal - liaison member	Deloitte Consulting, LLP
Ex Officio Members	
Steve Brown	Veterans Administration (VA)
Margaret Haber	Enterprise Vocabulary Services, National Cancer Institute (NCI)
Betsy Humphreys	National Library of Medicine (NLM)
Mitra Rocca	Food and Drug Administration (FDA)
ONC Staff Lead	
Patricia Greim	Office of the National Coordinator for Health IT



- More attention should be paid to the broader range of standards and requirements essential to learning health system objectives.
 - Many HIT systems that support research and many clinical activities currently use other standards that might not transition or interoperate well.
- The Certification Program should allow for versioning of standardized terminologies without changes in regulation.
 - It is preferable to specify the floor, rather than the ceiling
 - Specific codes should not be identified in regulation
- The NPRM should support methods for combining use of LOINC and SNOMED that are consistent with current published cooperation agreements
 - Cooperation Agreement July 2013 Between The International Health Terminology Standards Development Organisation (IHTSDO) and The Regenstrief Institute, Incorporated (RII).
 - In general use LOINC for the question and SNOMED CT for the answers unless there is a good reason not to.
- The Common Clinical Data Set needs further vetting.
 - The Common data set items should align with Clinical Data Acquisition Standards Harmonization (CDASH) as closely as possible.
- NPRM should avoid regulation that depend on action by entities outside the regulator’s control such as specifying “pending” codes.



Group 1	Members
<ul style="list-style-type: none">• Pharmacogenetics Data – Standards Question, p.239<ul style="list-style-type: none">• There are existing or developing standards applicable to the capture, storage, display, and exchange of potentially clinically relevant genomic data, including the pharmacogenomic subset• Common Clinical Data Set Definition - vocabulary standards p.246• National Drug Codes for Administered Vaccinations, p.170• Transmission to Public Health Agencies – all sections, p.176• Immunization History and Forecast, p.174	<ul style="list-style-type: none">• John Carter (lead)• Todd Cooper• Jamie Ferguson (co-chair)• Margaret Haber• Stan Huff• Mitra Rocca• John Speakman



Pharmacogenomics Data – Standards p. 239

- The pharmacogenomics domain in the CDISC Study Data Tabulation Model (SDTM) standard should be considered.
- P. 237: Pharmacogenomics data is being included in an increasing number of FDA-approved drug labels. Recommend leveraging HL7 Structured Product Labeling (SPL) standard for inclusion of pharmacogenomics data.
- A natural area of focus for needed standards development should be in future versions of SPL
- Pharmacogenomics standards developed through CDISC for research and the Life Sciences Domain Analysis of the NCI should be considered as sources.

Common Clinical Data Set Definition - Vocabulary Standards p. 246

- The Common Clinical Data Set needs further vetting and harmonization, especially among federal agencies.
- The Common data set items should align with Clinical Data Acquisition Standards Harmonization (CDASH) as closely as possible.
- Specific versions of vocabulary standards specified may become obsolete or superseded and systems that are able to use later versions should be allowed to do so.
- Workgroup members would like to see source of truth on each item in the common clinical data set and its associated vocabulary (e.g., a table)
- An effort should be made to align the Common Clinical Data Set with the Core Common Dataset (~ 200 elements) that is recommended by FDA and paves the way to standards required by FDA and a learning health system



[National Drug Codes for Administered Vaccinations](#) p. 170

1. Disagree with replacing CVX with NDC because CVX is specifically useful for coding instances when the and recommend augmenting records to include NDC with CVX for specific use cases. CVX is used for times when the precise manufacturer and package are not known and not needed as in shot records.
2. Support the use of NDCs to augment CVX. CVX should not be replaced by NDC

[§ 170.315\(f\)\(2\) \(Transmission to public health agencies – syndromic surveillance\)](#) p. 176

- Assuming that UCUM is not precluded based on our reading of the implementation guide we believe the proposed rule is acceptable

[§ 170.315\(f\)\(3\) \(Transmission to public health agencies – reportable laboratory tests and values/results\)](#) p. 179

- Agree, as long as Unified Code for Units of Measures (UCUM) is not precluded.

[Immunization History and Forecast](#) p. 174

- CVX codes exist to support documentation of immunization when manufacturer, package, and lot number are not known or needed, such as in a shot record. We disagree with replacing CVX with NDC and support the ability to augment the CVX with the NDC when information is available and needed.



Group 2

- Family health history, p.16
- “Minimum Standards” Code Sets , p.32
- Object Identifiers (OIDs) for Certain Code Systems, p.32
- Demographics , p.44
- Vital Signs, Body Mass Index (BMI), and Growth Charts, p.49
- Smoking status, p.67
- Social, Psychological, and Behavioral Data, p.81
- Work Information – Industry/Occupation Data, p.89
- U.S. Uniformed/Military Service Data, p.92
- Encounter Diagnoses, p.105
- Medication Dosing, p.118

Members

- Eric Rose (lead)
- Steven Brown
- Betsy Humphreys
- Rosemary Kennedy
- Becky Kush (co-chair)
- Harry Rhodes
- Asif Syed

**The Common Dataset
should be aligned and
harmonized across
Federal Agencies**



§ 170.315(a)(14) Family health history p. 68

- 1) §170.207(a)(4): The NPRM text should indicate that both SCT-International plus the US Extension are included in the US Edition of SNOMED CT distributed by the National Library of Medicine.
- 2) The phrase “in accordance with” is ambiguous and should be clarified. In particular, it would be advisable to clarify that use of an interface terminology mapped to the referenced standard for recording data constitutes recording of the data “in accordance with” the standard.

“Minimum Standards” Code Sets p. 32

“If adopted, a newer version of a minimum standards code set would serve as the baseline for certification. As with all adopted minimum standards code sets, health IT can be certified to newer versions of the adopted baseline version minimum standards code sets for purposes of certification, unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and [77 FR 54268](#)).”

- Agree the Certification Program should allow for versioning of standards without requiring changes in regulation.



[Object Identifiers \(OIDs\) for Certain Code Systems](#) p. 32

The Object Identifiers (OIDs) p.32 are consistent with the OIDS identified in the National Library of Medicine Value Set Authority Center (VSAC).

[§ 170.315\(a\)\(5\) Demographics](#) p. 44

It would be valuable if there was harmonization of demographic data across federal agencies.

Since the prior requirement for CEHRT was to use the simpler OMB standard, adopting the CDC standard would require re-collection of data from all patients.

The CDC race list* is long, and may be confusing in use.

*<http://www.cdc.gov/nchs/data/dvs/RaceCodeList.pdf>

- Preamble proposes, “health IT developers and health care providers would work together to establish the appropriate implementation given the care setting.” This could result in user interfaces with poor usability, which in turn could affect the accuracy of data collection.

Requirement that CEHRT be “able to aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity”

- If the CDC race code list is adopted, then transformation of the CDC-encoded race data to the OMB standard would more suitable for downstream analytical systems.



§ 170.315(a)(6) Vital signs, body mass index, and growth charts p. 49

Re: vital signs measurements that may be calculated based on other vital signs measurements

- Should explicitly state that if a CEHRT provides the capability to calculate these values, it need not provide the ability to directly enter them (superfluous and introduce the possibility of error).

Re: The stipulation of specific LOINC codes

- Avoid identifying specific LOINC codes for storage of vital signs (or any data).
- LOINC codes may be updated or deprecated by the publishers of LOINC
- Specific LOINC codes listed are unduly restrictive since other, more specific, LOINC codes exist that are pre-coordinated with relevant details
- Restricting specific LOINC codes to a more granular level could potentially discard critical clinical information
- Measurements are not semantically identical, and to promote admixture of instance data as if they are (which would be the effect of the regulation as written) would potentially be detrimental to patient care

Re: The requirement to record date of birth and sex along with BMI percentile, weight for length, and occipital-frontal circumference.

- Seems redundant, as recording of sex and DOB would be part of the demographic recording function of the EHR and would generally be performed one time only for every patient.
- It seems to imply that this data should be captured separately for each instance where BMI percentile is calculated, which would be unnecessary and superfluous.
- Re: Weight for length-It seems that this is likely to reflect weight for length percentile.
- Re: “measuring- or authoring-type source of the vital sign measurement”-Should ideally be standardized (SNOMED has some codes that would be applicable, e.g. for type of sphygmomanometer; Might need to be built out in some areas e.g. source of information).



§ 170.315(a)(12) Smoking status p.67

- Laudable to liberalize the use of SNOMED CT codes to represent smoking status beyond the 8 codes used for 2014 edition certification criteria
- Problem that only those 8 codes are permissible for representing smoking status in the Common Clinical Data Set and for electronic transmission in a summary care record.
- The premise that any other smoking status code could be mapped to one of those 8 (as stated in the preamble) is erroneous.
 - Example: For instance, SNOMED 266920004, “trivial cigarette smoker (less than one cigarette/day)” is not a child, in the SNOMED hierarchy, of any of the 8 smoking-related codes required in the 2014 edition certification rule.
- Clarify that this refers to tobacco smoking status, rather than information on the smoking of other substances, since the intent of this criterion appears to be tobacco-specific.
- The Committee recommended a different and shorter (2 questions) measure for tobacco use and exposure than the one previously established as the standard for EHR certification.
- Shorter seems better, even if it requires making a change



§ 170.315(a)(21) Social, psychological, and behavioral data p.81

- Valuable to be able to capture psychosocial and behavioral data in EHRs in structured and coded form.
- The proposal to encode “answer” data should be rethought, generally not in the semantic scope of LOINC
 - SNOMED “qualifier value” hierarchy does cover this semantic area
 - Commonly used in other similar use cases
 - For the “questions”, however, e.g. “highest level of education completed”, LOINC would certainly be appropriate
- Regulation should not be based on any premises of action by entities outside the regulator’s control
 - If NRPM refers to a “pending” code, should have publicly available assurances from the SDO that the code will be release
- The ability to record gender identity separate from biological sex is important and its inclusion is laudable.
- Regarding sexual orientation - allow any SNOMED code describing sexual orientation to be used instead of limiting to 3 specific SNOMED coded
- The list of specific data required probably exceeds what is needed (e.g. increasing knowledge of, and reducing, health and health care disparities based on psychosocial parameters)
 - Example: capture how many times a week someone talks by phone with family, friends, and neighbors
- Add
 - Dietary habits
 - Use of psychoactive substances other than alcohol and nicotine



Work Information – Industry/Occupation Data pp. 90-92

- Use of SNOMED CT for encoding occupation should be given strong consideration
 - Contains 3,750 distinct codes for occupation
 - Already well-established as a health care terminology for use in CEHRT
 - May be less overhead in its adoption for encoding occupation data.
 - Its hierarchical structure facilitates its use for reporting, decision support, and other uses that rely on logic that groups together similar concepts.
 - SNOMED would facilitate easily identifying all patients who are healthcare professionals, (e.g. to make sure they have been vaccinated for hepatitis B or get annual screening for tuberculosis)
- Options
 - Analyze SNOMED CT for gaps vis-à-vis other preferred lists like the CDC occupation list and propose addition of any cap concepts to SNOMED CT US Extension
 - Cross-map SNOMED occupation codes with the CDC's occupation codes to allow analysis that combines data encoded in both



[U.S. Uniformed/Military Service Data](#) p. 92

- SNOMED CT contains
 - A sub-hierarchy “military personnel” within the “occupation” hierarchy
 - Codes to represent particular characteristics of uniformed service that may be relevant to future health risks, e.g. “exposure to combat” (SNOMED 224356007).

[Encounter Diagnoses](#) p. 105

- No comment

[Medication Dosing](#) p. 118

- The NPRM proposes to require that CEHRT “be capable of limiting a user's ability to electronically prescribe all medications in only the metric standard”.
- Metric units do not apply to all medication dosage forms.
 - Topical medications are often by necessity imprecise (e.g., apply lightly to affected areas twice daily),
 - By necessity use non-metric units (e.g. eye drops, where the dosage will be in terms of number of drops, or inhalers, will the dosage will be in puffs)
- Per the preamble, the intent of this criterion is to apply to oral liquids, so revising the text to indicate that would address this issue.

Semantic Standards – Certification Rule Workplan



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

	Meetings	Task
✓	March 27, 2015 2:30pm-3:30pm ET HITSC Administrative Meeting	<ul style="list-style-type: none"> • Charged by HITSC with commenting on the Certification NPRM
✓	April 1, 2015, 12:00pm-1:30pm	<ul style="list-style-type: none"> • Certification NPRM Introduction and process for commenting on NPRM
✓	<i>April 22, 2015 – HITSC meeting</i>	<ul style="list-style-type: none"> • Interoperability Roadmap V.1 comments to the HITSC
✓	April 24, 2015 1:00pm ET	<ul style="list-style-type: none"> • Group 2 - Small Group Discussion #1
✓	April 30, 2015 2:00pm ET	<ul style="list-style-type: none"> • Group 2 - Small Group Discussion #2
✓	May 4, 2015, 11:30 -1:00pm	<ul style="list-style-type: none"> • Group 2 to report out to full workgroup
✓	May 15, 2015, 10:30 -11:30am	<ul style="list-style-type: none"> • Group 1 to report out to full workgroup
✓	May 18, 2015, 10:00am-11:30am	<ul style="list-style-type: none"> • Finalize Comments for both groups 1 & 2
➔	<i>May 20, 2015 – HITSC Meeting</i>	<ul style="list-style-type: none"> • <i>Present Certification NPRM Comments to the HITSC</i>