

**Semantic Standards (SS) Workgroup**

**Certification NPRM Comment Template (Group #2)**

| [**§ 170.315(a)(14) Family health history**](http://www.federalregister.gov/a/2015-06612/p-310)  **p. 68** | |
| --- | --- |
| **Included in 2015 Edition Base EHR Definition?**  No, but proposed for the EHR Incentive Programs CEHRT definition | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (14) Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4). | |
| **Preamble FR Citation:** 80 FR 16822 | **Specific questions in preamble?** *No* |
| **Public Comment Field:**  ER:   1. To clarify, does §170.207(a)(4) both SCT-International plus the US Extension? 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.   What about (15) (pedigree)-Seems like overreach, and also has the HL7 Pedigree standard had any real-world use? | |

| [**“Minimum Standards” Code Sets**](http://www.federalregister.gov/a/2015-06612/p-161)  **p. 32** |
| --- |
| We propose to adopt newer versions of four previously adopted minimum standards code sets in this proposed rule for the 2015 Edition. These code sets are the September 2014 Release of the U.S. Edition of SNOMED CT®, LOINC® version 2.50, the February 2, 2015 monthly version of RxNorm, and the February 2, 2015 version of the CVX code set. We also propose to  adopt two new minimum standards code sets (the National Drug Codes (NDC) – Vaccine Codes, updates through January 15, 2015 and the “Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System (VADS) Release 3.3.9 (June 17, 2011)). As we have previously articulated (77 FR 54170), the adoption of newer versions improve interoperability and health IT implementation, while creating little additional burden through the inclusion of new codes. (Continued on page #32) |
| **Public Comment Field:** |

| [**Object Identifiers (OIDs) for Certain Code Systems**](http://www.federalregister.gov/a/2015-06612/p-162)  **p. 32** |
| --- |
| We are providing the following table of OIDs for certain code systems to assist health IT developers in the proper identification and exchange of health information coded to the vocabulary standards proposed in this proposed rule. (Continued on page #33) |
| **Public Comment Field:**  ER/SB/AS: Re: the proposal to require NDC vaccine codes   * The stated advantages, pertaining to pharmacy inventory management and barcode scanning, are potentially valid but would depend on extensive links between HER systems and pharmacy inventory management systems that are not widely available. * Existing patient data, per prior certification requirements, are largely coded in CVX, and to move to NDC codes would require either extensive code mapping (which may not be possible in all cases) or invalidation of existing patient data. * Organizations have made significant investments in building reporting, decision support, and other logic around CVX codes to represent vaccination data, and moving to NDC codes would invalidate this * NDC codes are not centrally controlled, change frequently, and known frequently to have data quality issues, e.g. re-use and duplication for different products, etc. * The statement that NDC codes “Can improve patient safety with better specificity of vaccine formulation” may not be plausible. For issues with specific lots of vaccine, lot #’s are needed, and as noted in the preamble, specific product formulations should be derivable from the combination of CVX code, MVX code, and if necessary, lot #. |
| BH: According to NLM's Value Set Authority Center, the Object Identifiers (OIDs) for Certain Code Systems, p.32 are correct for the systems listed. |

| [**§ 170.315(a)(5) Demographics**](http://www.federalregister.gov/a/2015-06612/p-204)  **p. 44** | |
| --- | --- |
| **Included in 2015 Edition Base EHR Definition?**  Yes | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (5) Demographics**.**  (i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.  (A) Race and ethnicity. (1) Enable each one of a patient’s races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.  (2) Enable each one of a patient’s ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.  (3) Aggregate each one of the patient’s races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).  (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.  (C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).  (ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of a mortality. | |
| **Preamble FR Citation:** 80 FR 16816 | **Specific questions in preamble?** *No* |
| **Public Comment Field:**  ER:   * Re: race, it is understood that the purpose of collecting this data is to allow for analysis of race-based disparities in health care or health outcomes. However, the CDC list (<http://www.cdc.gov/nchs/data/dvs/RaceCodeList.pdf>) is extraordinarily long, unwieldy, and in many cases quite confusing. The preamble proposes that “health IT developers and health care providers would work together to establish the appropriate implementation given the care setting”, but it seems likely that this would result in poorly-usable user interfaces in many instances, which in turn would affect the accuracy of data collection. It is hard to envision the use of this standard leading to data that can be used for reliable or valid analysis of race-based disparities. Regarding the 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”, it seems unnecessary and excessive to put this data transformation requirement on CEHRT. Instead, if the CDC list is indeed adopted, then transformation of the CDC-encoded race data to the OMB standard would more appropriately be performed in the system doing that analysis. Lastly, since the prior requirement for CEHRT was to use the simpler OMB standard, and to adopt the CDC standard would require re-collecting data from all patients, this would pose an unreasonable data collection burden on EPs and EHs. | |

| [**§ 170.315(a)(6) Vital signs, body mass index, and growth charts**](http://www.federalregister.gov/a/2015-06612/p-225)  **p. 49** | |
| --- | --- |
| **Included in 2015 Edition Base EHR Definition?**  No | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (6) Vital signs, body mass index, and growth charts.  (i) Vital signs. Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient’s height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.):  (A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1);  (B) Metadata. For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following:  (1) Date and time of vital sign measurement or end time of vital sign measurement;  (2) The measuring- or authoring-type source of the vital sign measurement; and  (3) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and  (C) Metadata for oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient’s inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478-0.  (ii) Optional – Body mass index percentile per age and sex. Enable a user to record, change, and access a patient’s body mass index [percentile] per age and sex for patients two to twenty years of age in accordance with the following (The patient’s body mass index [percentile] per age and sex must be recorded in numerical values only.):  (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 59576-9 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and  (B) Metadata. The technology must also record the following:  (1) Date and time of vital sign measurement or end time of vital sign measurement;  (2) The measuring- or authoring-type source of the vital sign measurement;  (3) The patient’s date of birth;  (4) The patient’s sex in accordance with the standard specified in § 170.207(n)(1); and  (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).  (iii) Optional – Weight for length per age and sex. Enable a user to record, change, and access a patient’s weight for length per age and sex for patients less than three years of age in accordance with the following (The patient’s weight for length per age and sex must be recorded in numerical values only.):  (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with the LOINC® code and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and  (B) Metadata. The technology must record the following:  (1) Date and time of vital sign measurement or end time of vital sign measurement;  (2) The measuring- or authoring-type source of the vital sign measurement;  (3) The patient’s date of birth;  (4) The patient’s sex in accordance with the standard specified in § 170.207(n)(1); and  (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).  (iv) Optional – Head occipital-frontal circumference. Enable a user to record, change, and access a patient’s head occipital-frontal circumference for patients less than three years of age in accordance with the following (The patient’s head occipital-frontal circumference must be recorded in numerical values only.):  (A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8287-5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and  (B) Metadata. The technology must also record the following:  (1) Date and time of vital sign measurement or end time vital sign measurement;  (2) The measuring or authoring-type source of the vital sign measurement;  (3) The patient’s date of birth;  (4) The patient’s age in accordance with the standard specified in § 170.207(n)(1); and  (5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).  (v) Optional – Calculate body mass index. Automatically calculate and display body mass index based on a patient's height and weight.  (vi) Optional – Plot and display growth charts. Plot and display, upon request, growth charts for patients. | |
| **Preamble FR Citation:** 80 FR 16817 | **Specific questions in preamble?** *Yes* |
| **Public Comment Field:**   * Re: vital signs measurements that may be calculated based on other vital signs measurements (e.g. BMI, BMI percentile, mean blood pressure): The regulation should explicitly state that if a CEHRT provides the capability to calculate these values, it need not provide the ability to directly enter them (which would be superfluous and introduce the possibility of error). * Re: The stipulation of specific LOINCs. For several reasons, it would be advisable to avoid identifying specific LOINC codes for storage of vital signs (or any data). For one thing, LOINC codes may be updated or deprecated by the publishers of LOINC, and if this were to occur for these stated LOINCs, the regulation would be impossible to comply with. More to the point, the specific LOINCs listed are unduly restrictive since other, more specific, LOINCs exist that are pre-coordinated with relevant details, e.g. the route by which temperature was measured (e.g. oral, tympanic, rectal, etc.) or the patient position in which body height was measured. These 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. In brief, if LOINC allows for metadata to be precoordinated, use of such precoordinated codes should be allowed. * Re: The requirement to record date of birth and sex along with BMI percentile, weight for length, and occipital-frontal circumference. This 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. The mention here 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**](http://www.federalregister.gov/a/2015-06612/p-301)  **p.67** | |
| --- | --- |
| **Included in 2015 Edition Base EHR Definition?**  Yes | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (12) Smoking status. Enable a user to record, change, and access the smoking status of a patient in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4). | |
| **Preamble FR Citation:** 80 FR 16822 | **Specific questions in preamble?** *No* |
| **Public Comment Field:**  ER: It is laudable that ONC proposes to liberalize the use of SNOMED CT codes to represent smoking status beyond the 8 codes that were required under the 2014 edition certification criteria. However, it is still a 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. 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. Lastly, it would be helpful to 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.  BH: NLM admires the work done by the IOM committee that looked at social and behavioral domains and measures (see summary at <http://www.iom.edu/~/media/Files/Report%20Files/2014/EHR-phase-2/EHRfindingsrecs.pdf>). 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. In other cases, the NPRM follows the recommendations in the IOM report. Shorter seems better, even if it requires making a change. I understand that this is matter on which intelligent and well-meaning people can disagree. | |

| [**§ 170.315(a)(21) Social, psychological, and behavioral data**](http://www.federalregister.gov/a/2015-06612/p-364)  **p.81** | |
| --- | --- |
| **Included in 2015 Edition Base EHR Definition?**  No | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (21) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.  (i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.  (ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.  (iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.  (iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.  (v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.  (vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.  (vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.  (viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.  (ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.  (x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence). | |
| **Preamble FR Citation:** 80 FR 16826 | **Specific questions in preamble?** *Yes, and also see requests for comment on work information (industry/occupation) data and U.S. uniformed/military service data* |
| **Public Comment Field:**  ER:   * It will be valuable to be able to capture psychosocial and behavioral data in EHRs in structured and coded form. The proposal to encode “answer” data (e.g. for financial resource strain, the responses “very hard”, “somewhat hard”, etc.) should be rethought, as this is generally not in the semantic scope of LOINC. The SNOMED “qualifier value” hierarchy ***does*** cover this semantic area, and is commonly used in other similar use cases, e.g. to record categorical or ordinal results for laboratory data (e.g. “mild”, “moderate”, etc.). 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, such as addition of new codes to a standardized terminology. In cases where the NRPM refers to a “pending” code, if there are assurances from the SDO that the code will be released, those should be made publicly available. Otherwise, regulation should not require use of not-yet-existing codes. * The ability to record gender identity separate from biological sex is important and its inclusion is laudable. * Regarding sexual orientation, rather than limit recording of data to 3 specific SNOMED codes, it would be advisable to allow any SNOMED code describing sexual orientation to be used. * The list of specific data required to be captured is quite extensive, and probably exceeds what is needed to fulfill the basic requirements for expected use of this data, e.g. increasing knowledge of, and reducing, health and health care disparities based on psychosocial parameters. For instance, requiring the ability to capture how many times a week someone talks by phone with family, friends, and neighbors seems excessive. * Use of psychoactive substances other than alcohol and nicotine should be added, as well as dietary habits | |

| [**Work Information – Industry/Occupation Data**](http://www.federalregister.gov/a/2015-06612/p-388)  **pp. 90-92** |
| --- |
| The Institute of Medicine identified patients’ work information as valuable data that could be recorded by health IT and used by both health care providers and public health agencies.65 Similarly, the 2012 HHS Environmental Justice Strategy and Implementation Plan echoed the potential benefits of having work information in EHR technology. 66 The combination of industry and occupation (I/O) information provides opportunities for health care providers to improve patient health outcomes – for health issues wholly or partially caused by work and for health conditions whose management is affected by work. For example, “Usual” (longest-held) I/O information can be key for health care improvement and population-based health investigations, and is already a required data element for cancer reporting.67 Health care providers also can use current I/O information to assess symptoms in the context of work activities and environments, inform patients of risks, obtain information to assist in return-to-work determinations, and evaluate the health and informational needs of groups of patients. (Continued on page #90) |
| **Public Comment Field:**  ER: While there are likely standards for describing occupation that have been developed outside health care, and utilization of those standards would facilitate analysis of data by entities that utilize those standards (e.g. perhaps NIOSH), utilization of SNOMED CT for encoding occupation should be given strong consideration. SNOMED currently has 3,750 distinct codes for occupation. For one thing, since SNOMED CT is already well-established as a health care terminology for use in CEHRT, there may be less overhead in its adoption for encoding occupation data. More importantly, SNOMED’s hierarchical structure facilitates its use for reporting, decision support, and other uses that rely on logic that groups together similar concepts. For instance, there are 462 SNOMED codes for occupation that all fall into the SNOMED sub-hierarchy “healthcare professional”, as varied as “oral surgeon” and “paramedic”. Having occupation data encoded in 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. Note that one option would be to 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. Another option would be to 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**](http://www.federalregister.gov/a/2015-06612/p-405)  **p. 92** |
| --- |
| In the Voluntary Edition proposed rule (79 FR 10924), we outlined rationale for a potential certification criterion that would assess the capability of health IT to enable a user to record, change, and access U.S. military service or all uniformed service (including  commissioned officers of the U.S. Public Health Service (USPHS) and the National Oceanographic and Atmospheric Administration (NOAA) as they too are eligible for military health services, veterans benefits, and related services). We reiterate the rationale here as we continue to believe it is persuasive for adopting such a certification criterion. (Continued on page #93) |
| **Public Comment Field:**  ER: It is unclear why this is necessarily separate from occupational history. Some of the uniformed services (e.g. U.S. Public HealthService or NOAA) do not share the particular hazards or benefits issues particular to military service, and some non-uniformed occupations (e.g. law enforcement, military contractor) ***do*** share them. Of note, SNOMED CT does contain a sub-hierarchy “military personnel” within the “occupation” hierarchy, as well as 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**](http://www.federalregister.gov/a/2015-06612/p-465)  **p. 105** |
| --- |
| For encounter diagnoses, we are carrying over the requirement from the 2014 Edition “ToC” certification criterion that a Health IT Module must enable a user to create a transition of care/referral summary that also includes encounter diagnoses using either SNOMED CT® (Continued on page #106) |
| **Public Comment Field:**  ER: No comment |

| [**Medication Dosing**](http://www.federalregister.gov/a/2015-06612/p-519)  **p. 118** |
| --- |
| In the Voluntary Edition proposed rule, we solicited comment on whether we should propose health IT certification for oral liquid medication dosing to the metric standard (e.g., mL or milliliters) for patient safety reasons (79 FR10926-10927). Use of the metric standard offers more precision in medication dose than the Imperial standard (e.g., teaspoons), which can decrease preventable adverse drug events. A number of health care and standards developing organizations, including the AAP98 and NCPDP,99 support the use of the metric standard for dosing volumetric medications. Additionally, the FDA’s Safe Use Initiative is working with  CDC, NCPDP, and other stakeholders to encourage adoption of the NCPDP’s recommendations for standardizing dosing designations on prescription container labels of oral liquid medications.100 Recent research has demonstrated that parents who used milliliter-only dosing instruments were less likely to make dosing errors than parents who used teaspoons or tablespoon units.101 (Continued on page #119) |
| **Public Comment Field:**  ER: 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. For instance, dosing instructions for topical medications are often by necessity imprecise (apply lightly to affected areas twice daily), or by necessity use non-metric units (e.g. eyedrops, 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. |