September 9, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC  20201

Dear Dr. Mostashari:

The HIT Standards Committee’s (HITSC) Clinical Quality Measures Workgroup (CQMWG) and Vocabulary Task Force (VTF) jointly developed recommendations on the assignment of code sets to clinical concepts [data elements] for use in quality measures.

The CQMWG and VTF held a series of joint meetings to develop the set of recommendations. This letter transmits the recommendations to the Department of Health and Human Services (HHS) on the assignment of code sets to clinical concepts for use in quality measures. On August 17, 2011, the CQMWG and VTF reported on and discussed their findings with the HITSC, which were subsequently approved as outlined below.

BACKGROUND:

The Clinical Quality Measures Workgroup and Vocabulary Task Force proposed a list of recommendations that specifically addressed the 23 categories of clinical concepts [categories of data elements] as defined and proposed by the National Quality Forum’s Quality Data Model version 3.0 (QDM). (See attached QDM Spreadsheet). Each concept was thoroughly discussed and recommendations agreed upon amongst the Clinical Quality Measures Workgroup and Vocabulary Task Force members over the course of six weeks (from mid-June to July 2011). It was recognized that many vocabulary standards exist; however, it was the mission of the Clinical Quality Measures Workgroup and Vocabulary Task Force to evaluate and further recommend the minimum set of vocabulary standard(s) that would apply to each data element for the purpose of reporting clinical quality measures to the Centers for Medicare and Medicaid Services (CMS).

The Joint Clinical Quality Measures Workgroup and Vocabulary Task Force convened on a regular basis to explicitly address the 23 categories of concepts. Each category had been assigned proposed recommended vocabularies based on clinical taxonomy evidence and subject matter expertise contributed by the workgroup members, invited Standards Development Organizations, and others. The Joint Workgroup then proceeded to review the concepts and their corresponding recommendation(s) line-by-line. Thorough discussions occurred weekly to ensure that each
concept was properly vetted, taking into account the expert opinions and objective evidence in an effort to apply the minimum set of vocabulary standards necessary. Verbal consensus among the Joint Workgroup was achieved on each call for the concepts that had been discussed in an effort to finalize the draft recommendations. Please refer to the attached Code Sets spreadsheet for further detail about the concepts and their corresponding recommendations.

The Joint Workgroup used the following foundation concepts to arrive at their recommendations:

- A limited number of code sets would be used for quality measures
- Some code sets may be limited to partial depth
- Future purpose-specific subsets of code sets will be needed
- Certified HIT shall be able to process all legal codes in the code set for a given concept
- Only code sets required in HIT certification would be required for meaningful use incentive payments
- End state target standards are recommended for quality measure purposes, however some code sets will require transition plans
- The recommended code sets are being recommended for quality measures only at this time, not for other EHR functions.

RECOMMENDATIONS:

The Clinical Quality Measures Workgroup and Vocabulary Task Force proposed the following code set recommendations for the 23 categories of concepts in the quality data model:

1. Adverse Effect

The concept of “Adverse Effect” is inclusive of Allergic and Non-Allergic Adverse Effects. The vocabulary standards that have been recommended and would apply are the following:

- Rx Norm for Medications that caused adverse effect
- SNOMED-CT for Non-Medication Substances that caused adverse effect
- SNOMED-CT for Adverse effect itself

2. [Patient] Characteristics

The category of [patient] “Characteristics” includes the concepts of Age, Gender, Socio-economic Status, Ethnicity, Race, and Smoking Status; all of which refer to specific factors about a patient, clinician, provider or facility. The vocabulary standards that have been recommended and would apply are the following:

- ISO 639-2 constrained to elements in ISO 639-1 for Patient’s Preferred Language
- CDC PHIN-VADS HL7 for Administrative Gender
● CDC PHIN-VADS HL7 Race and Ethnicity (use broadest range of code sets within CDC listed for Race, Ethnicity, or both combined)
● LOINC-For assessment instruments, (including tobacco use)
● SNOMED-CT-Appropriate Responses to Instruments (including patient preferences and behaviors)
● (Socio-Economic Status is being further defined by CMS.)
● Payer Typology of the Public Health Data Standards Consortium for characterizing payers

3. Communication
This is inclusive of provision of clinical information from provider to provider, provider to patient, or patient response to provider.

● SNOMED-CT

4. Conditions, Diagnosis, and Problems
● SNOMED-CT

5. Device
● SNOMED-CT

6. [Non-Laboratory] Diagnostic Study
● LOINC for specific study name
● SNOMED-CT for appropriate findings
● UCUM for specific units of measure

7. Encounter
Encounter was considered to include patent-professional interactions that are not limited to face-to-face or billable clinical encounters.

● SNOMED-CT

8. [Patient] Experience
● LOINC for assessment instruments
● SNOMED-CT appropriate responses

9. Family History
● LOINC for assessment instruments
● SNOMED-CT appropriate responses\
10. **Functional Status**
   - ICF (International Classification of Functioning, Disability and Health) for categories of function
   - LOINC for assessment instruments
   - SNOMED-CT for appropriate responses

11. **Health Record Component**
    “Health Record Component” refers to an element of a health IT application.
    - LOINC for naming of the components and for their relationships
    - HL7 for the messaging among systems.

12. **Intervention**
    “Interventions” forms one end of a spectrum with Procedures.
    - LOINC for interactions that produce an assessment or measurable results
    - SNOMED-CT for appropriate results and interventions that do not produce measurable results (e.g., counseling)

13. **Adverse Effect other than Allergy (Intolerance)**
    - RxNorm for medications and inert ingredients associated with the adverse effect
    - SNOMED-CT for Non-medication substances associated with the adverse effect
    - SNOMED-CT for the adverse effect

14. **Laboratory Test**
    - LOINC for the test name and its results.
    - SNOMED-CT for applicable results values
    - UCUM for units of measure

15. **Medication**
    - RxNorm for medications
    - CVX for vaccinations (acknowledging that vaccinations are treated as medications in some contexts and as a separate category in others)

16. **Physical Exam**
    - LOINC for assessment instruments
    - SNOMED-CT for appropriate responses

17. **[Patient] Preference**
    - LOINC for assessment instruments
• SNOMED-CT for appropriate responses

18. Procedure
• SNOMED-CT

19. Risk Evaluation
• LOINC for evaluation instruments
• SNOMED-CT for appropriate responses

20. Substance (non-medications)
• SNOMED-CT

21. Symptom
• SNOMED-CT

22. System Resource

“System Resource” refers to the configuration of an organization (e.g. nurse staff ratios, availability of durable medical equipment, health information technology infrastructure and capabilities, etc.).

• LOINC for healthcare resources (e.g., staffing)
• HL7 for EHR functions
• SNOMED-CT for equipment

23. Transfer
• SNOMED-CT

TRANSITION PLANS

Current EHR products and quality measures utilized in public and private sector programs today, do not necessarily use the recommended code sets for embedded measures. In order to allow for a transition period, some measure concepts will need interim code set recommendations. The combined working group will present at least preliminary recommended transition plans to the HIT Standards Committee at its September meeting. The transition plan will take into consideration the evaluation of the recommended code sets to adequately express the categories of data elements in a variety of settings, the capacity of current EHRs to support the code sets, the implementation challenges for measure developers to incorporate these sets into existing, retooled, and de novo measures, other technical issues that may arise with further review of requirements to specify the code sets, and implications for certification criteria.
CONCLUSION

We believe that these recommendations comprise a minimum necessary set of vocabulary standards that will enable effective expression of quality measures and interoperable electronic health record data elements.

We appreciate the opportunity to provide these recommendations on the assignment of code sets to clinical concepts for use in quality measures, and look forward to discussion next steps.

Sincerely yours,

/s/

Jonathan Perlin, Chair, HIT Standards Committee

/s/

John Halamka, Vice Chair, HIT Standards Committee

Attachment: Glossary of Vocabularies/Standards
Glossary of Vocabularies/Standards

ISO 639-2- Codes for the representation of names of languages — Part 2: Alpha-3 code, is the second part of the ISO 639 standard, which lists codes for the representation of the names of languages. The three-letter codes given for each language in this part of the standard are referred to as "Alpha-3" codes. ISO 639-1 represents commonly-spoken languages with 2-character codes.

CVX/MVX- The CVX code is a numeric string, which identifies the type of vaccine product used. The MVX code is an alphabetic string that identifies the manufacturer of that vaccine. Taken together, the immunization can be resolved to a trade name (the proprietary name of the product).

ICF-International Classification of Functioning, Disability, and Health is a classification of the health components of functioning and disability.

HL7 EHR System Functional Model- The HL7 HER System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Model, through the creation of Functional Profiles, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country).

LOINC-Logical Observation Identifiers Names and Codes (LOINC) is a database and universal standard for identifying medical laboratory observations. LOINC applies universal code names and identifiers to medical terminology related to the Electronic health record. The purpose is to assist in the electronic exchange and gathering of clinical results (such as laboratory tests, clinical observations, outcomes management and research).

Payer Typology- Payer Typology is a standard that allows consistent reporting of payer data to public health agencies for health care services and research.

PHIN-VADS- the CDC Public Health Information Network (PHIN) Vocabulary Access and Distribution System (VADS) that supports the standards based vocabularies of the PHIN to
promote semantic operability and exchange of consistent information. A web based resource provides a system for accessing, searching, and distribution of vocabularies used within PHIN.

**RxNorm**- *RxNorm* provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.

**SNOMED-CT** (*Systematized Nomenclature of Medicine--Clinical Terms*) is a comprehensive clinical terminology, originally created by the College of American Pathologists (CAP) and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organization (IHTSDO), a not-for-profit association in Denmark.

**UCUM**-*The Unified Code for Units of Measure* is a code system intended to include all units of measure being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units.
<table>
<thead>
<tr>
<th>No.</th>
<th>Concept (QDM)</th>
<th>DRAFT Recommendation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adverse Effect:</td>
<td>RX NORM for Medication that caused adverse effect</td>
</tr>
<tr>
<td></td>
<td>Allergy</td>
<td>SNOMED-CT for Non-Medication Substances that caused adverse effect</td>
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<tr>
<td></td>
<td>or</td>
<td>SNOMED-CT for Adverse effect</td>
</tr>
<tr>
<td></td>
<td>Non-Allergy Adverse Effect</td>
<td></td>
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<tr>
<td>2</td>
<td>Characteristics</td>
<td></td>
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<tr>
<td></td>
<td>Age, Gender, Socioeconomic status, ethnicity, race, etc.</td>
<td>ISO 639-2 for patient’s preferred language CDC PHIN-VADS HL7 for Admin Gender CDC PHIN-VADS for Race &amp; Ethnicity LOINC--assessment tool (including smoking) SNOMED-CT-for appropriate responses to instruments (including patient preferences and behaviors) SES referred to CMS Payer topology of the Public Health Data Standards Consortium</td>
</tr>
<tr>
<td>3</td>
<td>Communication</td>
<td>SNOMED-CT</td>
</tr>
<tr>
<td>4</td>
<td>Condition/ Diagnosis/ Problem (Both Active &amp; Inactive)</td>
<td>SNOMED-CT</td>
</tr>
<tr>
<td>5</td>
<td>Device</td>
<td>SNOMED-CT</td>
</tr>
<tr>
<td>6</td>
<td>Non-Laboratory Diagnostic study</td>
<td>LOINC--for the specific study name SNOMED-CT for appropriate findings UCUM for specific units of measure</td>
</tr>
<tr>
<td>7</td>
<td>Encounter (any patient--professional interaction; not restricted to billable event)</td>
<td>SNOMED-CT</td>
</tr>
<tr>
<td>8</td>
<td>(Patient) Experience</td>
<td>LOINC for assessment instruments SNOMED-CT for appropriate responses</td>
</tr>
<tr>
<td>9</td>
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<td>11</td>
<td>Health record component</td>
<td>LOINC---for naming of the components and for their relationships HL7 for the messaging among systems</td>
</tr>
</tbody>
</table>
|   | Intervention (part of spectrum of procedures) | LOINC for interactions that produce an assessment or measurable results  
SNOMED-CT for appropriate results and interventions that do not produce measurable results (e.g. counseling) |
|---|---|---|
| 12 | Adverse effect other than allergy (Intolerance) | Rx NORM for medications and inert ingredients  
SNOMED-CT for Non-medication Substances  
SNOMED-CT for Adverse effect |
| 13 | Laboratory test | LOINC for the test name and its results  
UCUM for units of Measures  
SNOMED-CT for appropriate results |
| 14 | Medication | RxNorm for medications  
CVX for Vaccines as the standard vocabulary  
*note: vaccines are treated as medications in some contexts and as separate category in others* |
| 15 | Physical Exam  
Required for capture:  
Vital signs:  
• Height  
• Weight  
• Blood pressure  
• Calculate and display BMI  
• Plot and display growth charts for children 2–20 years, including BMI. | LOINC for assessment instruments  
SNOMED-CT for appropriate responses |
| 16 | Preference | LOINC for assessment instruments  
SNOMED-CT for appropriate responses |
| 17 | Procedure | SNOMED-CT |
| 18 | Risk evaluation | LOINC for evaluation instruments  
SNOMED-CT for appropriate response |
| 19 | Substance | SNOMED-CT |
| 20 | Symptom | SNOMED-CT |
| 21 | System resources | LOINC for staffing resources  
HL7 for EHR functions  
SNOMED-CT for equipment |
| Transfer [Consider decrementing - incorporate the way to describe a transfer from one location or service to another within the logic of the measure rather than an element of the measure] | SNOMED-CT [Consider Deletion of Concept Category] |