Cancer Reporting Errata and Clarification Document for Electronic Health Record (EHR) Technology Certification

December 2012

National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

Introduction

This supplement, "Cancer Reporting Clarification Document for Electronic Health Record (EHR) Technology Certification," identifies errors and clarifies conformance requirements and other aspects of the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012* (the *Cancer Reporting Implementation Guide*). This supplement does not specify additional requirements. Rather, it clarifies existing requirements given in the *Cancer Reporting Implementation Guide*.

Clarifications and errata

1. Where discrepancies exist, constraints enumerated in the conformance statements take precedence over the constraints enumerated in the table.

2. Section 1.6.3 Use Case Details

    a. Page 8, step 1, business rule 1: add link for ICD 10 CM reportability list VADS link: https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6069.

    b. Page 8, step 2, business rule 3 should read "The Ambulatory Healthcare Provider Cancer Event Report shall contain data elements as defined in the specifications in Section ***2.5*** of this document" instead of "The Ambulatory Healthcare Provider Cancer Event Report shall contain data elements as defined in the specifications in Section ***2.5.4*** of this document."

    c. Page 8, step 2, business rule 3 Remarks/Links should read "Refer to Appendix B, Ambulatory Healthcare Provider Cancer Event Report—Data Elements Table of this document for list of data elements and Section 2.3 for the concepts used to define optionality (SHALL, SHOULD, MAY)" instead of "Refer to specifications in Section 2.5.4 of this document for list of data elements and the concepts used to define optionality (required, recommended, optional)."

3. Cancer Diagnosis Section

    a. Page 29, Table 2-4 Cancer Diagnosis Section and Conformance Statement 2: LOINC Code should read "11450-***4***" instead of "11450-***7***." Implementers are encouraged to use the correct LOINC code "11450-4", but both LOINC codes will be accepted by the conformance test tool.

4. Coverage Entry

    a. Page 50, Conformance Statement 5: "SHALL contain exactly one [1..1] code="35525-4" Financing and Insurance (CodeSystem: LOINC 2.16.840.1.113883.6.1)." This LOINC code is not the same LOINC code that is used by the CCD parent template and therefore breaks a CCD validation rule. The correct LOINC code is "48768-6" "Payment sources," which implementers are encouraged to use. The conformance test tool will not return an error if either LOINC code is used. A change proposal has been submitted to the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) domain that has responsibility for this template.

5. Encounters Entry

   a. Page 52, Conformance Statement 5 and the corresponding row in Table 2-21 Encounters Entry Constraints Overview should read "ValueSet `ActEncounterCode 2.16.840.1.113883.`***`11.13955`***" instead of "ValueSet `ActEncounterCode 2.16.840.1.113883.`***`5.4`***."

6. Medications Entry

   a. Pages 54-55, Table 2-22 Medications Entry Constraints Overview should read:

Name	XPath	Card.	Verb	Data Type	Fixed Value
Dose	doseQuantity	0..1	SHOULD	IVL<PQ>	
	low	1..1	SHALL		
	@value	1..1	~~SHALL~~ SHOULD		
	@unit	0..1	SHOULD		2.16.840.1.113883. 1.11.12839 (HL7 UnitsOfMeasureCaseSensitive)
	translation	0..*	SHOULD	SET<PQR>	
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	high	1..1	SHALL		
	@value	1..1	~~SHALL~~ SHOULD		
	@unit	0..1	SHOULD		2.16.840.1.113883. 1.11.12839 (HL7 UnitsOfMeasureCaseSensitive)
	translation	0..*	SHOULD	SET<PQR>	
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

   b. Page 61, Conformance Statement 12.a should read:

a. "**SHALL** contain exactly one [1..1] **`low`.**
   i. This low **SHOULD** contain zero or more [0..*] **`@value`**.
   ii. This low **SHOULD** contain zero or more [0..*] **`@unit`**, which **SHOULD** be selected from ValueSet HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.11.12839 DYNAMIC.
   iii. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent.
   iv. This low **SHOULD** contain zero or more [0..*] **`translation`**.
      1. This translation **SHOULD** contain zero or one [0..1] **`originalText`**.
         a. The originalText, if present, **SHOULD** contain zero or one [0..1] **`reference/@value`**.
            i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1)."

instead of:

a. "**"SHALL** contain exactly one [1..1] **`low`.**

i. This code **SHOULD** contain zero or one [0..1] **originalText**.
    1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
        a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
            ii. This code **SHOULD** contain zero or more [0..*] **translation**."

c. Page 61, Conformance Statement 12.b should read:

a. **"SHALL** contain exactly one [1..1] **high.**
   i. This high **SHOULD** contain zero or more [0..*] **@value**.
   ii. This high **SHOULD** contain zero or more [0..*] **@unit**, which **SHOULD** be selected from ValueSet HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.11.12839 DYNAMIC.
   iii. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent.
   iv. This high **SHOULD** contain zero or more [0..*] **translation**.
       2. This translation **SHOULD** contain zero or one [0..1] **originalText**.
           a. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
               i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1)."

instead of:

a. **"SHALL** contain exactly one [1..1] **high.**
   i. "This code **SHOULD** contain zero or one [0..1] **originalText**.
       1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
           a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
   ii. This code **SHOULD** contain zero or more [0..*] **translation**."

d. Page 62, Conformance Statement 12.d should be removed:

~~The **doseQuantity**, if present, **SHOULD** contain zero or one [0..1] **@unit**, which **SHALL** be selected from ValueSet HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.11.12839 **DYNAMIC.**~~

~~i. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent.~~

e. **Note:** While it also is valid Clinical Document Architecture (CDA) for the doseQuantity element to have @value and @unit attributes without the low and high child elements when a dose range is not specified, we would not expect to see the doseQuantity element implemented this way since the *Cancer Reporting Implementation Guide* requires the low and high elements.

f. Page 62, Conformance Statement 13.e should read: "ValueSet `HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839" instead of "ValueSet HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.11.12839".`

g. Page 64, Figure 2.28, Medication Example should read:

```
<doseQuantity>
       <low value="" unit="">
              <translation>
                     <originalText>
                            <reference value=""/>
                     </originalText>
              </translation>
       </low>
       <high value="" unit="">
              <translation>
                     <originalText>
                            <reference value""/>
                     </originalText>
              </translation>
       </high>
```

instead of:

```
<doseQuantity value='' unit=''/>
```

7. Payer Entry

a. Page 67, Conformance Statement 5.a.i: ValueSet Source of Payment Typology OID should read "2.16.840.1.11***4222.4.11.3591***" instead of "2.16.840.1.11***3883.221.5***."

b. Page 67, conformance statement 7.c.v.1 and the corresponding row in Table 2-28 Payer Entry Constraints Overview should read: "SHALL contain exactly one [1..1] @***class***Code="ORG"" instead of "SHALL contain exactly one [1..1] @***type***Code="ORG"."

c. Page 69, Figure 2.29 should read: <representedOrganization ***class***Code='ORG'> instead of <representedOrganization ***type***Code='ORG'>.

8. Procedure Activity

a. Page 78, Conformance Statement 2 should read: "…**SHALL** be selected from ***Code System*** MoodCode 2.16.840.1.113883.5.1001" instead of "…**SHALL** be selected from ***ValueSet*** MoodCode 2.16.840.1.113883.5.1001."

9. Product Entry

a. Page 84, Table 2-36 Product Entry Constraints Overview:

i. XPath for "Coded Product Name" should read "code" instead of "Code."
ii. Name should read "Product" instead of "Medication brand name."
iii. Name should read "Product Name and Strength" instead of "Product Name Description."

10. TNM Clinical Stage Information Entry

a. Page 102, Table 2-52 NAACCR TNM Clinical Metastasis Value: LOINC code should read "2190***7-1***" instead of "2190***6-3***."

11. Appendix A Code System Table

a. Should read:

Code System OID	Code System Name	Minimum Standard (version)
2.16.840.1.113883.6.***90***	International Classification of Diseases***, Tenth Revision, Clinical Modification (ICD-10-CM)***	2011 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

instead of:

Code System OID	Code System Name	Minimum Standard (version)
2.16.840.1.113883.6.***3***	International Classification of Diseases	2011 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

b. Add the following rows to the Code System Table:

Code System OID	Code System Name	Minimum Standard (version)
2.16.840.1.113883.221.5	Source of Payment Typology	Version 5.0 – Oct 2011
2.16.840.1.113883.6.103	ICD-9 CM, Volume 3 (Procedures)	FY 2013 (Version 30)
2.16.840.1.113883.6.4	ICD-10 PCS	FY 2013

12. Appendix B

a. Add the following rows to the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Procedures—Narrative Radiation Oncology Section	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.3.14.2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.2']]
	Radiation Oncology Narrative	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.3.14.2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.2']]/text

b. Modify the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-5) for Active Problems Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Start date of problem	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.6	ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']/entry/act/effectiveTime/low/@value

	Stop date of problem	**SHALL** be present for concerns in the completed or aborted state **SHALL NOT** be present otherwise		ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']/entry/act/effectiveTime/high/@value

instead of:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Start and Stop date of problem	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.6	ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']/entry/act/effectiveTime

c. Modify the "Opt" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-6) for Coded Results Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Procedure DateTime	~~**SHALL**~~ **SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/procedure/effectiveTime/*
	Facility	~~**SHALL**~~ **MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/author/assignedAuthor/representedOrganization/name
	Facility ID	~~**SHALL**~~ **MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/author/assignedAuthor/representedOrganization/id

d. Modify the "Opt" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-6) for Procedures Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Body Site of procedure	~~**SHALL**~~ **MAY**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure/targetSiteCode/@*
1200,1210	Procedure DateTime	~~**SHALL**~~ **SHOULD**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure/effectiveTime/*

e. Modify the "Opt" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-7) for Medications Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Rate	~~**SHOULD**~~ **MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/rateQuantity

f. Modify the "Data Element Name" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-7) for Medications Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	~~Medication Brand Name~~ Product	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/name
	~~Strength~~ Product Name and Strength	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/originalText

g. Modify the "Opt" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-7) for Medications Administered Sectionto read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Rate	~~**SHOULD**~~ **MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/rateQuantity

h. Modify the "Data Element Name" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-8) for Medications Administered Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	~~Strength~~ Product Name and Strength	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/originalText
	~~Code~~ Coded product name	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/@*

i. Modify the "Opt" column of the Ambulatory Healthcare Provider Cancer Event Report—Data Elements table (page D-9) for Care Plan Section to read:

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
2420, 2425, 2460, 2470, 2480, 2490, 2500	Provider Referred To	~~**SHALL**~~ **SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.14 [Encounters]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry/encounter/performer/assignedEntity/assignedPerson/name/*