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DSTU Release 1.1 - US Realm

Draft Standard for Trial Use

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Volume 1 — Introductory Material

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Structured Documents

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- NAACCR Standardization and Registry Development Steering Committee
- NAACCR Board
- National Cancer Institute (NCI) Surveillance, Epidemiology, and End-Results (SEER) Program
- HL7 Public Health and Emergency Response Workgroup
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1 Introduction

Population-based cancer surveillance is critical in North America for cancer control activities aimed at reducing the morbidity and mortality of cancer, the second leading cause of death in the United States (U.S.) and the leading cause of death in Canada. Population-based public health central cancer registries across the U.S. and most of Canada are mandated to collect complete and timely cancer diagnostic, treatment, and outcome data from hospitals, physician offices, treatment centers, clinics, laboratories, and other sources. Recent shifts in cancer treatment away from hospital settings and towards ambulatory healthcare settings are increasing the importance of ambulatory (non-hospital) healthcare providers'[1] data for cancer surveillance. As ambulatory healthcare providers adopt modern electronic health record (EHR) systems, the opportunity to automate cancer registry reporting from ambulatory healthcare provider settings is also increasing and becoming more feasible. This document provides clear and concise specifications for electronic reporting from ambulatory healthcare provider EHR systems to public health central cancer registries using Health Level Seven (HL7) Clinical Document Architecture (CDA) based standards. This document is designed to guide EHR vendors and public health central cancer registries in the implementation of standardized electronic reporting. It includes both business rules and standardized specifications.

1.1 Background

Regional, state and territorial public health central cancer registries collect, manage, and analyze data about cancer cases and cancer deaths. Cancer surveillance is a complex system that captures longitudinal data from multiple data sources using a variety of methods. In addition to recording the occurrence of each reportable cancer (or tumor), the reporters provide information to public health central cancer registries on the diagnosis, treatment and vital status. Reporting requirements may vary by hospital, state, district, territory, or province. Please note for the purposes of this implementation guide the term, "reportable cancer" is inclusive of all tumors reportable to a public health central cancer registry. The North American Association of Central Cancer Registries (NAACCR) Standards for Cancer Registries, Volume II, *Data Standards and Data Dictionary*, describes the standards of tumor reportability for national standard-setting organizations in North America (http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx).

[1] For purposes of this document, ambulatory healthcare provider has been defined as any non-hospital, non-laboratory health care practitioner, e.g., physician or dental office, ambulatory surgery center, cancer treatment center, etc. that would be authorized to report a cancer case to the central cancer registry.

Public health central cancer registry data are used for surveillance, development of comprehensive cancer control programs, and healthcare planning and interventions. Improved accuracy and completeness of cancer surveillance data impacts all areas of public health interventions. Data also provide baseline measures and performance measures for cancer-related interventions designed to reduce cancer incidence or improve early detection. Identification of disparities among various population subgroups in stage at diagnosis or in treatment received can inform interventions to reduce these disparities and reduce the cancer morbidity and mortality in minority or disadvantaged populations.

The National Program of Cancer Registries (NPCR), established in 1992 by the U.S. Congress with enactment of the Cancer Registries Amendment Act (Public Law 202-515), is funded and managed by the Centers for Disease Control and Prevention's (CDC) Cancer Surveillance Branch (CSB) in the Division of Cancer Prevention and Control (DCPC). NPCR provides funds and technical assistance to 48 public health central cancer registries to improve cancer registration and cancer surveillance throughout the United States. NPCR data represent 96% of the U.S. population. The Surveillance Epidemiology and End Results (SEER) Program of the National Cancer Institute (NCI), initiated by the National Cancer Act of 1971 (PL 92-218), began collecting population-based cancer incidence data in 1973.SEER provides funds and technical assistance to seventeen population-based public health central cancer registries, representing 28% of the U.S. population. Together, NPCR and SEER programs collect data for the entire U.S. population and produce the annual United States Cancer Statistics (USCS). CDC and NCI build state and national capacity to monitor the burden of cancer, including disparities among various population subgroups, and provide data for research, evaluation of cancer control activities, and planning for future healthcare needs.

Complete and high quality cancer reporting has traditionally relied primarily on data from acute care hospitals and, more recently, pathology laboratories. Advances in medicine and changes in the healthcare delivery system now allow patients to obtain their care outside the acute care hospital setting. Data collection systems from ambulatory healthcare providers such as physician offices and radiation therapy centers are not as standardized or complete with reporting of cancer occurrences and treatment. When reporting does occur, it may be through a manual process of identifying reportable cases and submitting paper copies of the medical record, or the central registry may send certified tumor registrars (CTRs) to ambulatory healthcare provider offices to manually or electronically abstract the information from the paper-based medical records. These processes are very resource-intensive, time-consuming, prone to errors in transcription, and inherently less secure. This leads to under-reporting of certain types of cancers, especially those now diagnosed and treated primarily outside of hospitals, such as in dermatology, urology,

and hematology, as well as under-reporting of treatment information across most types of cancer.

Standards specifications provided in this document are designed to facilitate the implementation of an **automated** electronic process for the identification and reporting of cancer cases, treatment, and outcomes using ambulatory healthcare provider EHR systems to create a cancer event report and submit it to public health central cancer registries. Automated electronic reporting is expected to reduce labor (for the ambulatory healthcare providers and public health central cancer registries), and increase the security, completeness, timeliness and accuracy of cancer surveillance data.

1.2 Legal Mandate for Cancer Reporting

Cancer reporting from all healthcare providers (e.g., hospital, laboratory and ambulatory) for public health surveillance is mandated at the state, territory, and province level. Legislation requiring cancer reporting by healthcare providers exists in all states with some variation in specific requirements. United States federal law Public Health Service Act, as amended authorizing the National Program of Cancer Registries, which covers 45 states, the District of Columbia, and two territories, specifies that each federally-funded registry must have a legislative "means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities…".[2] The National Cancer Act of 1971 gives the Director of NCI the authority to "collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer".[3]

1.3 Purpose

This Implementation Guide (IG) contains the necessary specifications for the ambulatory healthcare provider EHR to create a cancer event report to submit to the public health central cancer registry. A single standardized cancer event report will allow accurate cancer information to be reported to the public health cancer registry while reducing the burden on EHR system-specific or registry-specific implementations.

This IG defines the trigger event and business rules for EHR systems to: identify reportable cancer cases; define the specific data elements to be retrieved and included in the cancer event report; create a valid Health Level 7 Clinical Document Architecture, Release 2 (HL7 CDA R2) cancer event report; and submit the cancer event report to a public health central cancer registry using a secure electronic transmission mechanism.

[2] Public Health Service Act, (42 USC 280e-280e-4; Public Law 102-515), as amended.
[3] National Cancer Act of 1971 (Public Law 92-218),http://legislative.cancer.gov/history/phsa/1971

This document represents a collaborative effort of the CDC NPCR, NCI SEER, public health central cancer registries, EHR vendors, and NAACCR to provide guidance to meet the Centers for Medicaid and Medicare Services (CMS) meaningful use objective for cancer reporting to a public health central cancer registry.

The CDC-NPCR and public health central cancer registry community developed the first IG for electronic physician reporting to cancer registries using CDA R2 within the Integrating the Healthcare Enterprise (IHE) Quality, Research and Public Health (QRPH) domain and the Physician Reporting to a Public Health Repository – Cancer Registry (PRPH-Ca) Profile was successfully tested at multiple IHE Connectathons. The HL7 specification portion of the profile was used as the basis for the development of the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, Release 1.0, August 2012*. This Implementation Guide is identified by the Office of the National Coordinator for Health Information Technology (ONC) Final Rule as the standard to be used for the Meaningful Use Stage 2 Menu Objective.

The current release (R1.1) of this IG is intended to provide technical corrections to issues identified since the publication of the first release (R1). In addition, several large complex templates have been broken down into a set of smaller, nested templates to enable easier implementation and conformance testing of this IG.

The intention of this guide is to facilitate the reporting of standardized cancer patient information from an ambulatory healthcare provider to a public health central cancer registry, either as a part of meaningful use incentive programs or for other ambulatory healthcare provider cancer reporting implementation.

1.4 Audience

This IG is designed to provide EHR vendors with the specifications for developing the functionality of the EHR systems used by ambulatory healthcare providers to report information on cancer patients to the public health central cancer registry. The IG will also be informative to ambulatory healthcare providers practicing in physician offices, ambulatory surgery centers or cancer treatment centers; public health central cancer registry staff; developers, analysts, and managers of public health information systems and data exchanges; and any other individual who seeks guidance on cancer surveillance data elements and reporting format specifications. Users of this IG must be familiar with the details of HL7 CDA R2 document construction.

1.5 Scope of the Implementation Guide

The following areas are In Scope for this IG:

- Definition of a reportable cancer
- Definition of when a cancer event report must be created and transmitted to the public health cancer registry
- The data elements to be retrieved from the EHR to produce the cancer event report
- Structure of the cancer event report using HL7 CDA R2 format

The following areas are Out of Scope for this IG:

- Methods for ambulatory care providers to transmit cancer event reports to the public health cancer registry
- Methods for public health central cancer registries to receive and process cancer event reports
- Specifications for hospital cancer registries and pathology laboratories to create and transmit cancer event reports to the public health cancer registry[4]

1.6 Scope of reporting

1.6.1 Trigger for reporting a Cancer Case

There are two triggers that require a cancer event report to be created and submitted to the central cancer registry, described in more detail below.

Information reported to the provider from another health care provider is not a trigger for reporting (see Scenario 3 below).

1.6.1.1 Patient Encounter/Visit for cancer:

A variety of activities can occur within a cancer patient's encounter/visit that requires a cancer event report to be created and submitted to the central cancer registry. Examples include diagnosis, referral, treatment, and follow-up.

For the purposes of this IG, an encounter/visit is defined as being cancer-related when the diagnosis of cancer is documented in the EHR to be chiefly responsible for the services provided in that encounter[5].

Creation of a report is triggered only when the reason for the encounter/visit is to diagnose, evaluate, and/or treat an active cancer.

[4] Hospital cancer registries report information using the NAACCR Record Layout Format - Standards for Cancer Registries, Volume I Data Exchange Standards and Record Descriptions. Pathology laboratories report information using the NAACCR Record Layout Format - North American Association of Central Cancer Registries, Inc. Standards for Cancer Registries Volume V Pathology Laboratory Electronic Reporting, an HL7 Version 2.5 format.

[5] *ICD-9-CM Official Guidelines for Coding and Reporting (Effective October 1, 2011)*

The following situations are not used to trigger a report:

1. An active cancer that is not the reason the patient is being seen by the physician
   - History of cancer
   - "Chief complaint" or the patient's reason for making the appointment

1.6.1.2 Modification to the cancer patient's EHR:

Some of the data required by this IG may not be available at the time of a patient's encounter/visit. The specification allows these data elements to be populated with values of Null. When any of the required data elements defined in the Cancer Diagnosis Section in Volume 2 [CDAR2_IG_RPT2CANCERREG_R1_D1_2014DEC_V2_Templates] is added to or changed in the patient's EHR, the Use Case is triggered so that the information can be reported to the public health central cancer registry. Cancer Diagnosis Section data elements are:

- Diagnosis Date
- Histologic Type, Behavior, and Grade
- Diagnostic Confirmation
- Primary Site and Laterality
- TNM Stage Information

Information reported to the provider from another health care provider is not a trigger for reporting (See scenario 4 below).

Adding a cancer diagnosis to the EHR Problem List is not a trigger for reporting if the EHR required cancer data elements are not modified.

1.6.2 Scenarios

The following scenarios are examples of patient care where a cancer event report may or may not be required.

Scenario 1:

The medical oncologist sends his patient to the cancer treatment center to initiate the chemotherapy regimen for colon cancer. The antineoplastic drugs are infused and the chemotherapy treatment is documented in the EHR as the reason for the encounter/visit.

The EHR system determines that the reason for the encounter/visit is on the Cancer Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2).

The patient returns to the cancer treatment center to receive the next chemotherapy cycle. The intravenous antineoplastic drugs are infused and the

chemotherapy treatment is documented in the EHR as the reason for the encounter/visit.

The EHR system determines that the reason for the encounter/visit is on the Cancer Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2).

Scenario 2:

In this scenario the primary care physician diagnoses the patient with chronic lymphocytic leukemia (CLL) and decides that no specific treatment is needed at this time. A report to the central cancer registry is required in this situation because the patient is not being referred to another physician (e.g., medical oncologist) for further work-up and/or treatment.

A patient visits his/her physician to be evaluated for fatigue. The physician draws a blood sample and performs a complete blood count and peripheral blood smear. The physician determines that the patient has CLL and documents it in the EHR as the reason for the encounter/visit.

The EHR system determines that the reason for encounter/visit is on the Cancer Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2).

Scenario 3:

A patient with a dark skin ulcer on her arm visits her primary care physician (PCP). The physician determines it is atypical and worrisome and refers the patient to a dermatologist. The physician updates the EHR with atypical mole as the reason for the encounter/visit. The EHR system determines that the reason for encounter/visit is not on the Reportability list, and thus does NOT meet the criteria for reporting to the central cancer registry. No cancer event report is submitted to the central cancer registry.

The dermatologist meets with the patient and performs a biopsy that indicates the patient has a melanoma in situ.

The dermatologist's EHR system determines that the reason for the encounter/visit is on the Cancer Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2).

The PCP receives medical information back from the dermatologist that the patient's atypical mole was a malignant melanoma and has been completely

excised. The documentation also indicates the melanoma was stage 0. The information is added to the patient's EHR. Because this information was reported to the PCP from another health care provider, it does not trigger a report to the central cancer registry.

Scenario 4

A patient visits his primary care physician complaining of shortness of breath and weight loss. The physician orders an X-Ray which indicates a suspicion of malignancy and he refers the patient to a medical oncologist. The PCP documents "possible lung cancer" in the EHR as the reason for the encounter/visit.

The PCP's EHR system determines that the reason for encounter/visit is not on the Cancer Reportability list, and thus does NOT meet the criteria for reporting to the central cancer registry. No cancer event report is submitted to the central cancer registry.

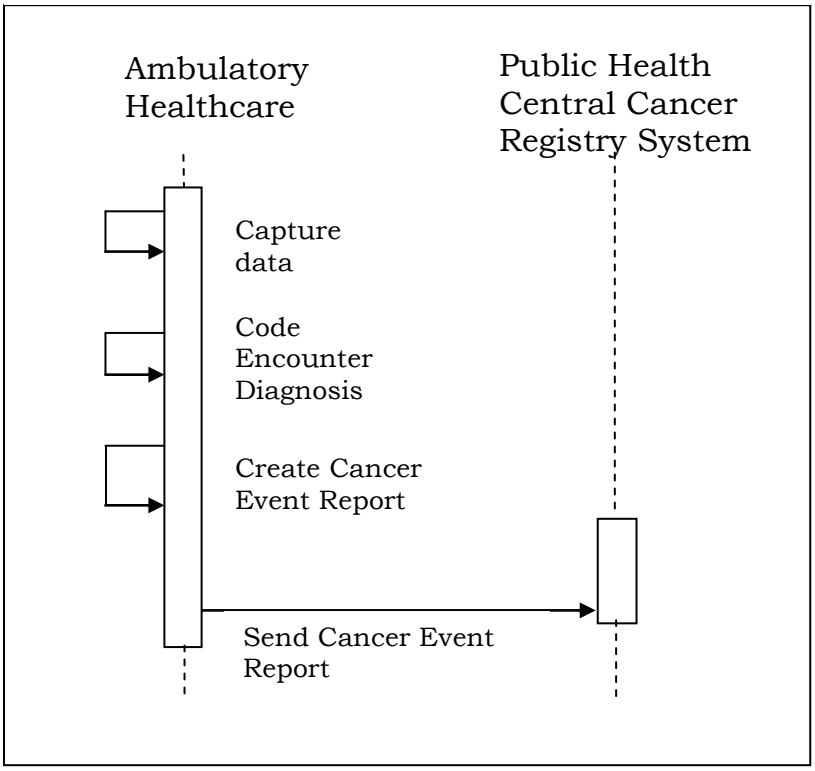
The medical oncologist performs a biopsy on the patient with suspected lung cancer. The pathology report comes back positive with a diagnosis of adenocarcinoma of the lung and the oncologist schedules the patient for further testing to determine stage.

The medical oncologist's EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2). TNM Stage information is not available at this time and therefore the "No Known" TNM Clinical and/or Pathological Stage Observation template(s) is used.

As the results of the further testing become available, the oncologist updates the EHR with the staging information.

The EHR determines that the stage data elements, as defined in the Cancer Diagnosis Section, have been added to patient's record, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR system ***automatically*** creates an ambulatory healthcare provider cancer event report as specified by this IG and reports it to the central cancer registry (See Figure 1.2). TNM Stage information is now available so the TNM Clinical and/or Pathological Stage Observation template(s) is used.

Figure 1: Sequence Diagram



1.6.3 Populating the ambulatory healthcare provider cancer event report as it relates to the use of Null Values:

Every data element in this specification has undergone scrutiny by the US central cancer registry community to ensure that is needed by the cancer registry and can reasonably be expected to be included in an ambulatory provider's EHR.

The cancer registry community has identified a small set of data elements for which a nullFlavor is not allowed. If this information is missing the cancer registry cannot accurately process the cancer event report. These data elements are:

- Primary Anatomic Site
- Histologic Type
    - Specific values have been provided in the Volume II conformance constraints in this IG for primary site and histologic type to assist the implementer in populating these data elements in the Cancer Event Report when the information is unknown.
- Date of Diagnosis
    - Year of diagnosis is known for patients with active cancers.
- Patient Name – Last

- Patient Name – First
- Patient Sex/Gender
- Patient Date of Birth
    - Patient demographic information that is available in the EHR for all cancer patients.
- Date Case Report Exported
    - A timestamp automatically set by the EHR when the report is submitted to the central cancer registry.

Use of Null Value - timing

The optionality of "Shall" has been applied to the majority of data elements in the specification. This allows cancer event reports to be transmitted with as much information as is known at the time of the encounter. As the patient continues on his/her medical course, required information will be collected. When the information is known, it must be included in each cancer event report that is transmitted, regardless of whether it has been included in a previous cancer event report.

Use of Null Value – Data not ever available for a patient

Applying an optionality of "Shall" to certain data elements also allows cancer event reports to be transmitted in the very rare instances when the information will never be present *for a specific patient.*

Example: While the address of a patient is absolutely required in order for a central cancer registry to determine whether the patient should be included in the registry and while virtually all patients who receive care in an ambulatory provider setting provide a physical address, the optionality for patient address is "Shall". This means a cancer event report may successfully be transmitted without a patient address in the rare event that the patient declines to provide an address or does not have an address.

It is not appropriate for ambulatory care providers to populate every cancer event data element with a Null Value to avoid collecting and reporting required data elements.

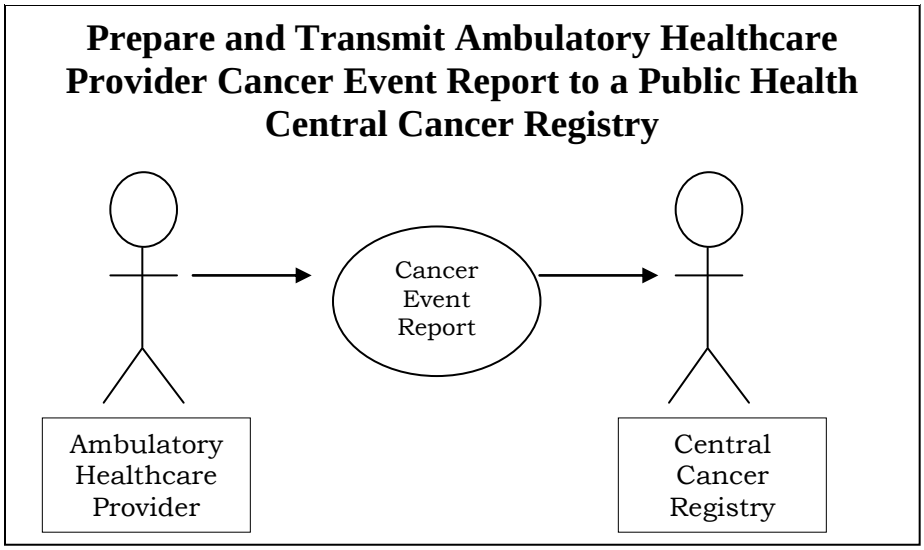
1.6.4 Use Case Overview

Table 1: Prepare and Transmit Ambulatory Healthcare Provider Cancer Event Report for Public Health Central Cancer Registries

ITEM	DETAIL
Description	The Prepare and Transmit Ambulatory Healthcare Provider Cancer Event Report For Public Health Central Cancer Registries Use Case describes the process whereby a healthcare provider submits Ambulatory Healthcare Provider Cancer Event Reports to the Public Health Central Cancer Registry using established criteria for record layout format and required data elements. This Use Case describes the process for preparing and transmitting an Ambulatory Healthcare Provider Cancer Event Report by a trusted Data Source to the Public Health Central Cancer Registry Database System. It is intended for use by Ambulatory Healthcare Provider staff including IT system professionals and Public Health Central Cancer Registry staff.
Actors	Ambulatory Healthcare Provider EHR Providers and Staff – A person who works in the Ambulatory Healthcare Provider Facility and uses the Ambulatory Healthcare Provider EHR software. Ambulatory Healthcare Provider EHR – A system used by the Ambulatory Healthcare Provider to capture clinical information in the patient electronic health record. Central Cancer Registry Staff – A person who works in the Public Health Central Cancer Registry Program and uses the Public Health Central Cancer Registry Software. Central Cancer Registry Software – A system used by the Public Health Central Cancer Registry that captures, processes, and reports data on all reportable cancer cases diagnosed.
Assumptions	1. Infrastructure is in place to allow accurate and secure information exchange between information systems. 2. Providers securely access information through either an EHR or a clinical data system. 3. The EHR contains sufficient information for the system to construct the Cancer Event Report properly. 4. Privacy and security have been implemented at an acceptable level. 5. The Public Health Central Cancer Registry is able to accept electronic Ambulatory Healthcare Provider Cancer Event Reports.

Business Rules	A business rule is a statement that defines or constrains some aspect(s) of the normal course of events. It is intended to assert business structure or to control or influence the behavior of the business. In the context of this document, a business rule describes the constraint, and in some circumstances provides a recommendation; in others, options for consideration and use. Process steps and associated business rules are provided below.

Figure 2: Use Case Model



1.6.5 Use Case Details

Prepare and Transmit Ambulatory Healthcare Provider Cancer Event Report for Central Cancer Registries

1. Ambulatory Healthcare Provider's EHR identifies that a Cancer Event Report needs to be created and submitted. [BR01, BR02, BR03].

BR	Business Rule Statement	Remarks/Links
01	A Cancer Event Report shall be created and submitted when the reason for the encounter/visit is for cancer.	Cancer-related encounter/visits include diagnosing, evaluating, and/or treating an active cancer.
02	The EHR shall use one of the reportability lists of cancer diagnosis codes established by the cancer registry community to identify a patient with cancer.	*Reportability Lists:* 1. *ICD-9-CM* 2. *ICD-10-CM* 3. *SNOMED CT*
03	A Cancer Event Report shall be created and submitted when there is a modification (addition or change) to any of the required data elements in the IG, Volume 2, Cancer Diagnosis Section.	Cancer Diagnosis Section data elements are: • Diagnosis Date • Histologic Type, Behavior, and Grade • Diagnostic Confirmation • Primary Site and Laterality • TNM Stage Information (Volume 2 [CDAR2_IG_RPT2CANCERREG_R1_D1_2014DEC_V2_Templates]) NOTE: Adding a cancer diagnosis to the EHR Problem List does not trigger a Cancer Event Report to be submitted if the EHR cancer data elements are not modified.

2. Ambulatory Healthcare Provider's EHR creates an electronic Cancer Event Report according to the requirements for reporting to the Public Health Central Cancer Registries. [BR04, BR05, BR06, BR07]

BR	Business Rule Statement	Remarks/Links
04	The EHR shall create a valid Cancer Event Report according to the *HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm Volume 2.*	

BR	Business Rule Statement	Remarks/Links
05	The Cancer Event Report shall contain data elements as defined in the *HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm Volume 2.*	An appropriate nullFlavor may be used when the information is not available, except where explicitly prohibited.
06	Required data elements shall be gathered from the EHR and/or alternative information systems such as registration billing systems.	Virtually all data elements required by this IG should be within the EHR already as a part of the regular workflow for patient registration and patient care. Examples include patient address, medications, procedures, and problems.
07	A data element should be collected manually ONLY when the data element is required and cannot be null, and it is not documented discretely in the EHR.	Physicians and EHR vendors should consider adding these data elements to the EHR so they can be completed as part of the physician's routine workflow.

3. Ambulatory Healthcare Provider EHR transmits the Ambulatory Healthcare Provider Cancer Event Report. [BR 08, BR09]

BR	Business Rule Statement	Remarks/Links
08	The EHR should transmit the Ambulatory Healthcare Provider Cancer Event Report as soon as documentation of the patient encounter is completed (real-time reporting). At a minimum, EHR should have the capability to transmit the Ambulatory Healthcare Provider Cancer Event Reports on a daily basis.	The capability to transmit cancer event reports daily is recommended to allow for rapid ascertainment of cancer event reports for special studies. The use of the word "Should" allows registries and physician offices to agree upon an alternative frequency.

BR	Business Rule Statement	Remarks/Links
9	The EHR shall transmit the Ambulatory Healthcare Provider Cancer Event Report using the healthcare industry's security and privacy standards.	Standards used must be in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

4. Central Cancer Registry Software receives the Cancer Event Report. [BR10]

BR	Business Rule Statement	Remarks/Links
10	The Public Health Central Cancer Registries is capable of receiving a Cancer Event Report.	The frequency in which cancer registries processes Ambulatory Healthcare Provider Cancer Event Reports should be based on the Public Health Central Cancer Registry's objectives and workflow.

5. Process Ends.

1.7 Use of Vocabulary Standards

This guide calls for specific vocabulary standards for the exchange of cancer information. Standard vocabularies, particularly coded data items, enable automated decision support for patient healthcare, as well as for public health surveillance of populations. Public Health Information Network (PHIN) Vocabulary Services seeks to promote the use of standards-based vocabulary within PHIN systems and foster the use and exchange of consistent information among public health partners. These standards are supported by the PHIN Vocabulary Access and Distribution System (VADS) for accessing, searching, and distributing standards-based vocabularies used within PHIN to local, state and national PHIN partners.

The data elements in this specification are a subset of items in the North American Association of Central Cancer Registries (NAACCR) data dictionary.[6] They have undergone scrutiny by the US central cancer registry community to

[6] North American Association of Central Cancer Registries Standards for Cancer Registries Volume II: Data Standards and Data Dictionary

ensure that they are needed by the cancer registry and can reasonably be expected to be included in an ambulatory provider's EHR.

The code systems and value sets for the data elements use national vocabularies wherever possible.[7] When a national vocabulary is not available or is inappropriate for use, the NAACCR value set is used.

1.8 HIPAA

The Health Insurance Portability and Accountability Act (HIPAA, or the Act), P.L. 104-191, enacted on August 21, 1996, includes provisions related to insurance coverage and a section that is relevant to electronic reporting of healthcare information. HIPAA requires that standards be adopted for certain uniform financial and administrative transactions, data elements, and security of electronic health information systems. It also includes provisions for adopting standards for the privacy of health information. The regulation implementing the HIPAA privacy provisions allows public health exemptions for disclosure without patient consent of individually identifiable health information. A discussion of HIPAA as it relates to reporting to Cancer Registries can be found at: http://www.naaccr.org/Research/HIPAA.aspx.[8]

2 Design Considerations

The Cancer Event Report uses CDA R2 as its required format. CDA R2 is "… a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange".[9] In addition the Cancer Event Report is aligned with Consolidated CDA Release 2.0 (C-CDA R2.0) in terms of structure of templates, data elements and associated terminology bindings.

2.1 Design principle of Cancer IG

The Cancer IG templates were developed in one of the following ways:

1. **The majority of templates were re-used "*AS-IS*" from C-CDA R2.0 and no further modifications were made.** These templates are recognized by template names that are identical to those in C-CDA R2.0. Example:
    a. Family History Section (V2)
    b. Payers Section (V2)
    c. Results Section (entries required) (V2)

[7] Mapping tables are available to translate the values into the appropriate NAACCR data item values.

[8] The NAACCR Standards for Cancer Registries, Volume V, *Pathology Laboratory Electronic Reporting*, sect.1.3

[9] Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). *HL7 Clinical Document Architecture, Release 2.0*. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available at: http://www.hl7.org.

d. Vital Signs section (entries required) (V2)
e. Etc.…

2. **Some C-CDA R2.0 templates were used "*AS-IS*" but templates nested within such templates were excluded** from the IG because the information is not required for Cancer Event Report.
    a. Example: Cancer IG uses C-CDA R2.0's Plan of Treatment Section (V2) but the following entry-level templates were excluded:
        - Instruction (V2)
        - Nutrition Recommendation
        - Planned Act (V2)
        - Planned Immunization Activity (V2)
        - Planned Observation (V2)
        - Planned Supply (V2)

The following are **all** templates that were *excluded* based on aforementioned rationale:

Table 2: Nested C-CDA R2.0 templates excluded from Cancer Event Report

Nested C-CDA R2.0 templates excluded from Cancer Event Report
Age Observation
Caregiver Characteristics
Characteristics of Home Environment
Cultural and Religious Observation
Drug Monitoring Act
Drug Vehicle
Entry Reference
Estimated Date of Delivery
External Document Reference
Family History Death Observation
Goal Observation
Handoff Communication Participants
Immunization Medication Information (V2)
Instruction (V2)

Medication Dispense (V2)
Medication Supply Order (V2)
Nutrition Recommendations
Planned Act (V2)
Planned Coverage
Planned Immunization Activity
Planned Observation (V2)
Planned Supply (V2)
Precondition for Substance Administration (V2)
Pregnancy Observation
Priority Preference
Procedure Activity Act (V2)
Procedure Activity Observation (V2)
Product Instance
Prognosis Observation
Reaction Observation (V2)
Severity Observation (V2)
Substance Administered Act

3. In some cases, C-CDA R2.0 templates that *require* entries imply templates with *optional* entries. An implied template is one that a template asserts conformance to. In C-CDA R2, this means the "entry required" versions of some templates assert conformance to the "entry optional" version of the template. Many Cancer Reporting specific templates assert conformance to the "entry required" version of the template from C-CDA R2. This means the "entry optional" templates are not directly implied by the Cancer specific templates, but they are indirectly implied because they are implied in the "entry required" version that the Cancer specific templates conform with. **Such *implied* templates with optional entries are excluded from Cancer Event Report**. The following are all such templates that were *excluded*:

Table 3: Implied C-CDA R2.0 templates with optional entries excluded from Cancer Event report

Implied C-CDA R2.0 templates with optional entries excluded from Cancer Event report
Medication Section (entries optional)
Problem Section (entries optional) (V2)
Procedures Section (entries optional) (V2)
Results Section (entries optional) (V2)
Vital Signs Section (entries optional) (V2)

4. **Some templates were re-used from C-CDA R2.0 and further constraints to data elements, attributes and vocabularies were applied**. In all instances, such templates have the following name added to the C-CDA R2.0 template name: "*Cancer IG Specific Constraints*". The constraints in both the C-CDA R2.0 template and the Cancer IG specific constraints must be met. The following are all such templates that were created:

Table 4: C-CDA R2.0 templates with further constraints added

C-CDA R2.0 templates with further constraints added
Indication (V2) - Cancer IG Specific Constraints
Medication Activity (V2) - Cancer IG Specific Constraints
Planned Encounter (V2) - Cancer IG Specific Constraints
Problem Concern Act (V2) - Cancer IG Specific Constraints
Problem Observation (V2) - Cancer IG Specific Constraints
Procedure Activity Procedure (V2) - Cancer IG Specific Constraints
Medications Administered Section (V2) - Cancer IG Specific Constraints
Medications Section (entries required) (V2) - Cancer IG Specific Constraints
Plan of Treatment Section (V2) - Cancer IG Specific Constraints
Problem Section (entries required) (V2) - Cancer IG Specific Constraints
Procedures Section (entries required) (V2) - Cancer IG Specific Constraints
Social History Section (V2) - Cancer IG Specific Constraints
US Realm Address (AD.US.FIELDED) (V2) - Cancer IG Specific Constraints
US Realm Patient Name (PTN.US.FIELDED) - Cancer IG Specific Constraints

5. **Lastly, some templates that are specific to cancer reporting were <u>newly created</u>**. Following templates, and all templates nested *within* these templates were created specifically for Cancer Event Report and can therefore not be found in C-CDA R2.0:

Table 5: Cancer Event Report-specific templates (includes section-level templates and *<u>all</u>* templates nested within)

Cancer Event Report-specific templates (includes section-level templates and *<u>all</u>* templates nested within)
Cancer Diagnosis **Section** (entries required) (V2)
Radiation Oncology **Section**
Employment History **Observation Organizer**

Summary list of all newly created templates in Cancer Event Report

The following table lists all templates that were newly created for or constrained from C-CDA R2.0 for Cancer Event Report (see sections 4 and 5 above). Therefore, any template *not* listed in the table below and that appears in Volume 2 of the Implementation Guide is a C-CDA R2 template that is used "as-is".

Table 6: List of templates newly created for or constrained from C-CDA R2.0 for Cancer Event Report

Template Name	Type	Template ID
Cancer Event Report Document	Document	urn:hl7ii:2.16.840.1.113883.10.13.1: 2015-01-29
Cancer Diagnosis Section	Section	urn:hl7ii:2.16.840.1.113883.10.13.2: 2015-02-05
Cancer Diagnosis Concern Act	Entry	urn:hl7ii:2.16.840.1.113883.10.13.3: 2015-02-05
Cancer Diagnosis Observation	Entry	urn:hl7ii:2.16.840.1.113883.10.13.4: 2015-02-05
TNM Clinical Stage Observation	Entry	urn:hl7ii:2.16.840.1.113883.10.13.5: 2015-02-05
TNM Clinical Stage Group	Entry	urn:hl7ii:2.16.840.1.113883.10.13.35:2015-02-05
Distant Metastases Clinical	Entry	urn:hl7ii:2.16.840.1.113883.10.13.38:2015-02-05
Primary Tumor Clinical	Entry	urn:hl7ii:2.16.840.1.113883.10.13.36:2015-02-05
Regional Lymph Nodes Clinical	Entry	urn:hl7ii:2.16.840.1.113883.10.13.37:2015-02-05
Stager Clinical Cancer	Entry	urn:hl7ii:2.16.840.1.113883.10.13.39:2015-02-05

Template Name	Type	Template ID
TNM Pathology Stage Observation	Entry	urn:hl7ii:2.16.840.1.113883.10.13.7:2014-08-08
TNM Pathologic Stage Group	Entry	urn:hl7ii:2.16.840.1.113883.10.13.40:2015-02-05
Distant Metastases Pathologic	Entry	urn:hl7ii:2.16.840.1.113883.10.13.43:2015-02-05
Primary Tumor Pathologic	Entry	urn:hl7ii:2.16.840.1.113883.10.13.41:2015-02-05
Regional Lymph Nodes Pathologic	Entry	urn:hl7ii:2.16.840.1.113883.10.13.42:2015-02-05
Stager Pathologic Cancer	Entry	urn:hl7ii:2.16.840.1.113883.10.13.44:2015-02-05
No Known TNM Clinical Stage Observation	Entry	urn:hl7ii:2.16.840.1.113883.10.13.31: 2015-04-02
No Known TNM Pathologic Stage Observation	Entry	urn:hl7ii:2.16.840.1.113883.10.13.32: 2015-04-02
Plan of Treatment Section (V2) - Cancer Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.9:2014-08-08
Procedures Section (V2) - Cancer Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.10:2014-08-08
Social History Section (V2) - Cancer Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.11: 2015-01-29
Medications Administered Section (V2) - Cancer IG Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.12:2014-08-08
Medications Section (V2) - Cancer IG Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.13:2014-08-08
Medication Activity (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.14:2014-08-08
Procedure Activity Procedure (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.15:2014-08-08
Employment History Observation Organizer	Entry	urn:hl7ii:2.16.840.1.113883.10.13.16: 2015-01-29
Usual Industry History	Entry	urn:hl7ii:2.16.840.1.113883.10.13.33:2015-01-29
Usual Occupation History	Entry	urn:hl7ii:2.16.840.1.113883.10.13.34:2015-01-29
US Realm Address (AD.US.FIELDED) (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.17:2014-08-08
US Realm Patient Name (PN.US.FIELDED) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.18:2014-08-08
Indication (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.19:2014-08-08
Planned Encounter (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.20:2014-08-08
Problem Section (entries required) (V2) - Cancer IG Specific Constraints	Section	urn:hl7ii:2.16.840.1.113883.10.13.21:2014-08-08

Template Name	Type	Template ID
Problem Concern Act (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.22:2014-08-08
Problem Observation (V2) - Cancer IG Specific Constraints	Entry	urn:hl7ii:2.16.840.1.113883.10.13.23:2014-08-08
Radiation Oncology Section	Section	urn:hl7ii:2.16.840.1.113883.10.13.24:2014-08-08
Radiation Regional Treatment Modality Procedure	Entry	urn:hl7ii:2.16.840.1.113883.10.13.25:2014-08-08
Radiation Boost Modality Procedure	Entry	urn:hl7ii:2.16.840.1.113883.10.13.26:2014-08-08
Radiation Regional Dose - cGy	Entry	urn:hl7ii:2.16.840.1.113883.10.13.27:2014-08-08
Radiation Boost Dose - cGy	Entry	urn:hl7ii:2.16.840.1.113883.10.13.28:2014-08-08
Radiation Regional Treatment Modality Organizer	Entry	urn:hl7ii:2.16.840.1.113883.10.13.29:2014-08-08
Radiation Boost Modality Organizer	Entry	urn:hl7ii:2.16.840.1.113883.10.13.30:2014-08-08

2.2 Use of Attributes in <code> and <value> elements

2.2.1 Consistency

The Cancer Event Report requires more consistent use of attributes than C-CDA R2 for @code, @codeSystem, @displayName and @sdtc:valueSet for <code> and <value> elements in templates that were created specifically for the Cancer Event Report. Typically, the name (observation name) of the template requires @code and @codeSystem, while the value (observation value) requires @code and @codeSystem and strongly recommends providing @displayName and @sdtc:valueSet.

Users are strongly encouraged to provide all of the following attributes and attribute values in the Cancer Event Report for observation code and observation value:

1. @code
2. @displayName (associated with the @code)
3. @codeSystem
4. @codeSystemName (associated with @codeSystem)
5. @sdtc:valueSet (in cases where @code is selected from a value set)

For example, within the “Cancer Diagnosis Observation” template:

- Observation <***code***> for cancer diagnosis:
    - requires @code=“29308-4” and

    - requires @codeSystem=2.16.840.1.113883.6.1
- Observation <***value***> for histologic type:
    - requires @code (selected from Code System "ICD-O-3")
    - requires @codeSystem (selected from code system "ICD-O-3"). Edition"), and
    - strongly recommends @displayName (selected from Code System "ICD-O-3")

2.2.2 Value Set vs Code System

Note that @code value can be selected either from a code system or from a value set (a subset of codes from a code system). If @code value is selected from a value set, @codeSystem is **always** the *code* system OID, and **not** the *value* set OID. Furthermore, in cases where @code value is selected from a value set, @sdtc:valueSet attribute value (value set OID) should be provided as well.

For example,

- "Problem Value Set" (value Set OID: 2.16.840.1.113883.3.88.12.3221.7.4) is a subset of codes drawn from SNOMED CT code system (code system OID: 2.16.840.1.113883.6.96).
- Template "Problem Observation (V2) - Cancer IG Specific Constraints" allows value/@code to be selected from "Problem Value Set" (Value Set OID: 2.16.840.1.113883.3.88.12.3221.7.4). In this case:
    - value/@codeSystem must be the SNOMED CT ***code*** system OID (2.16.840.1.113883.6.96) (and not the Problem ***value*** set OID).
    - value/@sdtc:valueSet must be the Problem ***value*** set OID; the OID SHOULD be provided.

Figure 3: XML example of use of code system and value set OID:

```
<value xsi:type="CD" code="408643008" codeSystem="2.16.840.1.113883.6.96"
displayName="Infiltrating duct carcinoma of breast"
sdtc:valueSet="2.16.840.1.113883.3.88.12.3221.7.4"/>
```

2.2.3 Navigating Volume 2 document

Volume 2 consists of the following high-level chapters:

1 Document

2 Section

3 Entry

4 Participation and other templates

5 Template IDs in this guide

6 Value sets in this guide

7 Code systems in this guide

The core information about the Cancer Event Report document, such as document ID, document code, and other elements, is provided at the beginning of Volume 2, on page 14 (Chapter 1: "Document"). Page 15 provides a table that lists all components of the Cancer Event Report document (header and sections) and the following information: Conformance (optionality), Section Name, and Template Identifier.

Header contents of the Cancer Event Report document are listed in Volume 2 in "Table 2: Cancer Event Report Document Constraints Overview" on page 17 and subsequent pages.

Section contents of the Cancer Event Report document are listed in Volume 2 in "Table 1: Cancer Event Report Document Contents" on page 14 and all section and entry components are listed starting on page 68.

2.2.4 Unknown and No Known Information

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an Emergency Department unconscious and with no identification.

In many cases, the C-CDA standard will stipulate that a piece of information is required (e.g., via a SHALL conformance verb). However, in most of these cases, the standard provides an "out", allowing the sender to indicate that the information isn't known.

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types, Release One specification that accompanies the CDA R2 normative standard. **However, it should be noted that the focus of C-CDA is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.**

Many fields in C-CDA contain a "@nullFlavor" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case where information is unknown. Allowable values for populating the attribute give more details

about the reason the information is unknown, as shown in the following example.

Figure 4: nullFlavor Example

```
<birthTime nullFlavor="UNK"/>   <!--Sender does not know the birthTime, but a
proper value is applicable -->
```

Use null flavors for unknown, required, or optional attributes:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
NAV	Temporarily unavailable. The information is not available, but is expected to be available later.
NASK	Not asked. The patient was not asked.
MSK	There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA normative edition.[10]

Any **SHALL**, **SHOULD** and **MAY** conformance statement may use nullFlavor, unless the nullFlavor is explicitly disallowed (e.g., through another conformance statement which includes a **SHALL** conformance for a vocabulary binding to the @code attribute, or through an explicit **SHALL NOT** allow use of nullFlavor conformance).

[10] *HL7 Clinical Document Architecture (CDA Release 2)* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

Figure 5: Attribute Required (nullFlavor not allowed)

1. **SHALL** contain exactly one [1..1] `code` (CONF:15407).
   a. This `code` **SHALL** contain exactly one [1..1] **`@code`**="`11450-4`" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).
   or
2. **SHALL** contain exactly one [1..1] **`effectiveTime/@value`** (CONF:5256).

Figure 6: Allowed nullFlavors When Element is Required (with xml examples)

1. **SHALL** contain at least one `[1..*] id`
2. **SHALL** contain exactly one `[1..1] code`
3. **SHALL** contain exactly one `[1..1] effectiveTime`

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 7: nullFlavor Not Allowed on Element (with XML example)

1. **SHALL** contain exactly one [1..1] **targetSiteCode** (CONF:1126-32487)
Note: targetSiteCode indicates the anatomic location where the primary tumor originated (referred to as primary site).
    a. This **targetSiteCode SHALL NOT** contain [0..0] **@nullFlavor** (CONF:1126-33247)

```
<targetSiteCode xsi:type="CD" code="181131000"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Entire breast">
```

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know a RIM Class attribute of an Act, that attribute can have a nullFlavor.

Figure 8: Unknown Medication Example

```
<entry>
  <text>patient was given a medication but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

Figure 9: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient received an anticoagulant
          drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

3. If the sender wants to state "no known", a `negationInd` can be used on the corresponding act (`substanceAdministration`, `Procedure`, etc.)

Previously CCD, IHE, and HITSP recommended using specific codes to assert no known content, for example `160244002 No known allergies` or `160245001 No current problems or disability`. Specific codes are still allowed; however, use of these codes is not recommended.

These next examples illustrate additional nuances of representing information that is a negative assertion, where for example, it is not that case that the patient has an allergy or it is not that case that a patient takes a medication. The phrases "no known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 10: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd=”true”>
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

Figure 11: Value Known, Code for Value Not Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 12: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```

Figure 13: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>/>
    </value>
  </observation>
</entry>
```

3 Using this Implementation Guide

The Ambulatory Healthcare Provider Cancer Event Report contains a record of a patient's encounter for diagnosis and/or treatment of cancer. For purposes of this specification,

- the term "cancer" is used in its general sense to denote a neoplastic condition that is reportable to a central cancer registry;
- "ambulatory healthcare provider" has been defined as any non-hospital, non-laboratory health care practitioner, e.g., physician or dental office, ambulatory surgery center, cancer treatment center, etc. that would be authorized to report a cancer case to the central cancer registry.

3.1 Levels of Constraint

The CDA standard describes conformance requirements in terms of three general levels corresponding to three different, incremental types of conformance statements:

- Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
- Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
- Level 3 requirements specify constraints at the entry level within a section. A specification is considered "Level 3" if it requires any entry-level templates.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional levels of reusability could be defined.

The contexts table for each document type lists the sections defined in the document template.

3.2 Conformance Conventions Used in This Implementation Guide

3.2.1 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the `object identifier (OID) or uniform resource name (URN)`, and whether the template is Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published” to indicate the template is unchanged from the previous version or “Draft” to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same `templateId/@root` (`identifier oid`) and `templateId/@extension` as in the previous implementation guide. (In the case of older templates, the `@extension` attribute will not be present.) During a new ballot or update phase, “Published” is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The “Published” designation is removed in the final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. The notation “(Vn)” (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The “(Vn)” designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, “Draft” is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented

on in the update; the “Draft” designation is removed in the final publication versions.

A new version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Chapter 9 “Changes From Previous Version”.

An example of the change log for a versioned template is shown in the following figure. In this example, Medication Activity (2.16.840.1.113883.10.20.22.4.16) has versioned to Medication Activity (V2) (2.16.840.1.113883.10.20.22.4.16:2014-06-09).

Figure 14: Versioned Template Change Log Example

Change	Old	New
Name	Medication Activity	Medication Activity (V2)
Oid	urn:oid:2.16.840.1.113883.10.20.22.4.16	urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09
Description	A medication activity describes ...	A medication activity describes ...
CONF #: 1098-30822 Added		SHALL contain exactly one [1..1] Drug Monitoring Act (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.123) (CONF:1098-30822).
...		
CONF #: 81-7511 Removed	SHALL contain exactly one [1..1] low (CONF:81-7511).	
...		
CONF #: 1098-7516 Modified	SHOULD contain zero or one [0..1] doseQuantity	SHALL contain exactly one [1..1] doseQuantity
...		

Structured Documents Working Group (SDWG) collaborated with Templates Working Group to establish template versioning recommendations, recently published in the following specification: HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. SDWG will leverage that specification to create guidance for template IDs and template versioning for future CDA implementation guides, including future versions of C-CDA, but that work is still in progress. The versioning approach used in this version of C-CDA is likely to be close to the final guidance, but has not been formally approved by SDWG for all implementation guides at this time.

Open and Closed Templates. The `identifier OID` is the `templateId/@root value`; all `templateIds` have an `@root` value. Versioned templates also have an `@extension` value, which is a date identifying the version of this template; such templates are identified by `URN` and the HL7 version (`urn:hl7ii`). The `URN`

identifier includes both the `@root` and `@extension` value for the `templateId` (for example, `identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09`).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

Table 7: Cancer Diagnosis Section Contexts

Contained By:	Contains:
Cancer Event Report Document (required)	Cancer Diagnosis Concern Act Health Status Observation (V2)

Each entry template also includes a constraint overview table to summarize the constraints in the template.

Table 8: Constraints Overview Example

XPath	Card.	Verb	Data Type	CONF#	Value
section (identifier: oid:2.16.840.1.113883.10.13.2)					
templateId	1..1	SHALL		1126-254	
@root	1..1	SHALL		1126-258	2.16.840.1.113883.10.13.2
code	1..1	SHALL		1126-255	
@code	1..1	SHALL		1126-259	72135-7
@codeSystem	1..1	SHALL		1126-260	2.16.840.1.113883.6.1
title	1..1	SHALL		1126-261	
text	1..1	SHALL		1126-262	
entry	1..*	SHALL		1126-253	
@nullFlavor	0..0	SHALL		1126-33244	
act	1..1	SHALL		1126-257	Cancer Diagnosis Concern Act (identifier: oid:2.16.840.1.113883.10.13.3
entry	0..1	MAY		1126-256	
observation	1..1	SHALL		1126-263	Health Status Observation (V2) (identifier:

					urn:hl7ii:2.16.840.1.113883.10.20.22.4.5:2014-06-09

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement so as to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a “where” clause) which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. **SHALL** contain exactly one [1..1] **`templateId`** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **`@root`**="`2.16.840.1.113883.10.20.22.4.31`" (CONF:81-10487).

...is understood as:

> This template **SHALL** contain exactly one [1..1] **`templateId`** where it contains exactly one [1..1] **`@root`**="`2.16.840.1.113883.10.20.22.4.31`".

This means that you must have a template id with **`@root`**="`2.16.840.1.113883.10.20.22.4.31`", but you can also have other template ids with different valued attributes.

The following figure shows a typical template’s set of constraints presented in this guide. The next chapters describe specific aspects of conformance statements—open vs. closed templates, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Table 9: Constraint Conformance Including 'such that it' syntax Example

Cancer Diagnosis Observation - Published

`[observation: identifier urn:hl7ii:2.16.840.1.113883.10.13.4:2014-08-08 (open)]`

1. **SHALL** contain exactly one [1..1] **`@classCode`**="`OBS`" Observation (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:1126-32452).
2. **SHALL** contain exactly one [1..1] **`@moodCode`**="`EVN`" Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:1126-32453).
3. **SHALL** contain exactly one [1..1] **`templateId`** (CONF:1126-32441) such that it
    a. **SHALL** contain exactly one [1..1] **`@root`**="`2.16.840.1.113883.10.13.4`" (CONF:1126-32455).
4. **SHALL** contain at least one [1..*] **`id`** (CONF:1126-32456).
5. **SHALL** contain exactly one [1..1] **`code`** (CONF:1126-32457).
    a. This code **SHALL** contain exactly one [1..1] **`@code`**="`29308-4`" Diagnosis (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) (CONF:1126-33309).
    b. This code **SHALL** contain exactly one [1..1] **`@codeSystem`**="`2.16.840.1.113883.6.1`" (CodeSystem: `LOINC 2.16.840.1.113883.6.1` **STATIC**) (CONF:1126-33310).
6. **SHOULD** contain zero or one [0..1] **`text`** (CONF:1126-32442).
    a. The text, if present, **SHOULD** contain zero or one [0..1] **`reference`** (CONF:1126-32443).
        i. The reference, if present, **SHALL** contain exactly one [1..1] **`@value`** (CONF:1126-32444).
            1. 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) (CONF:1126-32458).
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF:1126-32445).
    a. This statusCode **SHALL** contain exactly one [1..1] **`@code`**="`completed`" Completed (CodeSystem: `ActStatus 2.16.840.1.113883.5.14` **STATIC**) (CONF:1126-32459).

3.2.2 Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published” to indicate the template is unchanged from the previous version or “Draft” to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same `templateId/@root` (`identifier oid`) and `templateId/@extension` as in the previous implementation guide. (In the case of older templates, the `@extension` attribute will not be present.)

During a new ballot or update phase, “Published” is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The “Published” designation is removed in the final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. The notation “(Vn)” (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The “(Vn)” designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, “Draft” is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the “Draft” designation is removed in the final publication versions.

A new version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Chapter 9 “Changes From Previous Version”.

An example of the change log for a versioned template is shown in the following figure. In this example, Medication Activity (2.16.840.1.113883.10.20.22.4.16) has versioned to Medication Activity (V2) (2.16.840.1.113883.10.20.22.4.16:2014-06-09).

Figure 14: Versioned Template Change Log Example

Change	Old	New
Name	Medication Activity	Medication Activity (V2)
Oid	urn:oid:2.16.840.1.113883.10.20.22.4.16	urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09
Description	A medication activity describes ...	A medication activity describes ...
CONF #: 1098-30822 Added		SHALL contain exactly one [1..1] Drug Monitoring Act (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.123) (CONF:1098-30822).
...		
CONF #: 81-7511 Removed	SHALL contain exactly one [1..1] low (CONF:81-7511).	
...		
CONF #: 1098-7516 Modified	SHOULD contain zero or one [0..1] doseQuantity	SHALL contain exactly one [1..1] doseQuantity
...		

Structured Documents Working Group (SDWG) collaborated with Templates Working Group to establish template versioning recommendations, recently published in the following specification: HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. SDWG will leverage that specification to create guidance for template IDs and template versioning for future CDA implementation guides, including future versions of C-CDA, but that work is still in progress. The versioning approach used in this version of C-CDA is likely to be close to the final guidance, but has not been formally approved by SDWG for all implementation guides at this time.

3.2.3 Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

Policy Activity (templateId 2.16.840.1.113883.10.20.22.4.61) is an example of a closed template in this guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

3.2.4 Conformance Verbs (Keywords)

"The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide[11]

1. **SHALL:** an absolute requirement
2. **SHALL NOT:** an absolute prohibition against inclusion [
3. **SHOULD/SHOULD NOT:** best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
4. **MAY/NEED NOT:** truly optional; can be included or omitted as the author decides with no implications

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

Important Note: This implementation guide uses "**SHALL NOT** contain [0..0] `@nullFlavor`" to indicate `nullFlavor` is not allowed for a data element.

[11] HL7, Version 3 Publishing Facilitator's Guide. http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

Table 10: Example conformance statements used by this IG to prohibit nullFlavor

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:1126-32446). a. This **effectiveTime SHALL NOT** contain [0..0] **@nullFlavor** (CONF:1126-33245).

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structuredBody SHOULD contain zero or one [0..1] **component** (CONF:1098-29066) such that it
   i. SHALL contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (SHOULD) that the structuredBody contains a component.
   i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
   ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

a. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it
   i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

3.2.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more

- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 15: Constraints Format – only one allowed

```
1. SHALL contain exactly one [1..1] participant (CONF:2777).
     a. This participant SHALL contain exactly one [1..1] @typeCode="LOC"
        (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)
        (CONF:2230).
```

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

Figure 16: Constraints Format – only one like this allowed

```
1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it
     a. SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem:
        2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).
```

3.2.6 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n] where m >=1 and n >=1 (for example [1..1] or [1..*]). In these cases, the element must be present in the instance. Conformance statements formulated with **SHALL** are considered "required" conformances. If an element is required, but it is not known, the use of the @nullFlavor attribute must be used. See Unknown and No Known Information Section for more information.

3.2.7 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 17: Binding to a Single Code

2. **SHALL** contain exactly one [1..1] **code** (CONF:15403).
a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:15408).
b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF: 31141).

The notation conveys the actual code (`11450-4`), the code's `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 18: XML Expression of a Single-code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the HL7 V3 Normative Edition 2010[12] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy between the HL7 R1 Data Types and this guide in the implementation of translation code versus the original code. The R1 data type requires the original code in the root. The convention agreed upon for this implementation guide specifies a code from the required value set be used in the element and other codes not included in the value set are to be represented in a translation for the element. This discrepancy is resolved in HL7 Data Types R2.

[12] *HL7 Version 3 Interoperability Standards*, http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

In the next example, the conformant code is SNOMED-CT code 206525008.

Figure 19: Translation Code Example

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are present below a template, or are referenced if they occur elsewhere in the specification, when there are value set bindings in the template. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a **DYNAMIC** stability, implementers creating a CDA document must go to the location in the URL to check for the most current version of the value set expansion.

Figure 20: Example Value Set Table (Referral Types)

Value Set: Referral Types 2.16.840.1.113883.11.20.9.56

A value set of SNOMED CT codes descending from "3457005" patient referral (procedure).

Valueset Source:
http://vtsl.vetmed.vt.edu/TerminologyMgt/RF2Browser/ISA.cfm?SCT_ConceptID=3457005

Code	Code System	Print Name
44383000	SNOMED CT	Patient referral for consultation
391034007	SNOMED CT	Refer for falls assessment (procedure)
86395003	SNOMED CT	patient referral for family planning (procedure)
306106002	SNOMED CT	referral to intensive care service (procedure)
306140002	SNOMED CT	referral to clinical oncology service (procedure)
396150002	SNOMED CT	Referral for substance abuse (procedure)
...		

NOTE: In this Implementation Guide, values are selected from standard code systems where available. Most of the Value Sets are maintained in the Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) for use in Public Health. The main purpose of PHIN VADS is to distribute vocabulary subsets needed in Public Health. The latest version of most of the value sets referenced in this Implementation Guide can be obtained from PHIN VADS [specific URL to be determined].

3.2.8 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition[13]. All attributes of a data type are allowed unless explicitly prohibited by this specification.

3.3 XML Conventions Used in This Guide

3.3.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[14] in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

[13] *HL7 Clinical Document Architecture (CDA Release 2).* http://www.hl7.org/implement/standards/cda.cfm

[14] http://www.w3.org/TR/xpath/

Figure 21: XML Document Example

```
<author>
  <assignedAuthor>
  ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
          code='17561000' displayName='Cardiologist' />
  ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the code could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

```
author/assignedAuthor/code/@code
```

3.3.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in `this monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (. . .) as shown in the example below.

Figure 23: ClinicalDocument Example

```
<ClinicalDocument xmls="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

4 Appendix A: Resources/References

Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available at: http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip.

HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2 (Publication pending)

NAACCR Standards for Cancer Registries, Volume II: Data Standards and Data Dictionary, Sixteenth Edition (http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx)

Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) (https://phinvads.cdc.gov/vads/SearchHome.action)

For individual Central Cancer Registry contact information, see:
http://apps.nccd.cdc.gov/dcpc_Programs/default.aspx?NPID=3

5 Appendix B: Acronyms

AJCC	American Joint Committee on Cancer
BR	Business Rule
BRM	Biological Response Modifier
CDA	Clinical Document Architecture
CDA R2	Clinical Document Architecture, Release 2.0
CDC	Centers for Disease Control and Prevention
CLL	Chronic Lymphocytic Leukemia
CMS	Centers for Medicare and Medicaid Services
CPO	Clinic/Physician Office
CPT-4	Common Procedure Terminology 4
CTR	Certified Tumor Registrar
CSB	Cancer Surveillance Branch
DCPC	Division of Cancer Prevention and Control
DSTU	Draft Standard for Trial Use
EHR	Electronic Health Record
EMR	Electronic Medical Record
HCPCS	Healthcare Common Procedure Coding System
HIPAA	Health Insurance Portability & Accountability Act
HL7	Health Level Seven
ICD-9-CM Modification	International Classification of Diseases, Ninth Revision, Clinical
ICD-10-CM Modification	International Classification of Diseases, Tenth Revision, Clinical
ICD-O-3 Edition	International Classification of Diseases for Oncology, Third
IG	Implementation Guide
IHE	Integrating the Health Enterprise International
LOINC	Logical Observation Identifiers Names and Codes
NAACCR	North American Association of Central Cancer Registries
NAICS	North American Industry Classification System
NCI SEER	National Cancer Institute Surveillance, Epidemiology, and End Results
NPCR	National Program of Cancer Registries
NPCR-AERRO	National Program of Cancer Registries Advancing E-cancer Reporting and Registry Operations
NPI	National Provider Identifier
OID	Object Identifier
PHIN	Public Health Information Network
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
PL	Public Law
PRPH-Ca	Physician Reporting to a Public Health Repository - Cancer Registry

QRPH	Quality, Research and Public Health
SOC	Standard Occupational Classification
SNOMED CT	Systematized Nomenclature of Medicine--Clinical Terms
TNM	Tumor/Nodes/Metastasis
USCS	United States Cancer Statistics
XDS	Cross Enterprise Document Sharing
XML	Extensible Markup Language
XPath	XML Path Language

6 Appendix C: EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

- `sdtc:raceCode` - The `raceCode` extension allows for multiple races to be reported for a patient.
- `sdtc:deceasedInd` - The `deceasedIndextension` (= "true" or "false") in recordTarget Patient is used to indicate if the patient is deceased.
- `sdtc:deceasedTime` - The `deceasedTime` extension in the recordTarget Patient allows for reporting the date and time the patient died.
- `sdtc:id` - The id extension in the family history organizer on the related subject allows for unique identification of the family member(s).
- `sdtc:deceasedInd` - The `deceasedIndextension` (= "true" or "false") in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
- `sdtc:deceasedTime` - The `deceasedTime` extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
- `sdtc:birthTime` - The `sdtc:birthTime` element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
- `sdtc:dischargeDispositionCode` - The `sdtc:dischargeDispositionCode` element allows the provider to record a discharge disposition in an encounter activity.
- `sdtc:signatureText` - The `sdtc:signatureText` element provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the `Participation.typeCode`. Details of what goes in the field are described in the HL7 CDA Digital Signature Standard balloted in Fall of 2013.
- `sdtc:valueSet` - The `sdtc:valueSet` extension attribute allows the implementer to reference a particular value set from which a code was drawn. This extension represents a pre-adoption of the HL7 R2 Datatypes valueSet attribute.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.

- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.

  An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

7 Appendix D: Glossary

Ambulatory Healthcare Provider: For purposes of this document, ambulatory healthcare provider has been defined as any non-hospital, non-laboratory health care practitioner, e.g., physician or dental office, ambulatory surgery center, cancer treatment center, etc. that would be authorized to report a cancer case to the central cancer registry.

Ambulatory Healthcare Provider Cancer Event Report: An HL7 CDA R2 document that conforms to the specifications of this Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries. It contains the required and recommended information about a patient's cancer diagnosis and treatment, and is submitted by an ambulatory healthcare provider to a central cancer registry. [See Cancer case report]

American Joint Commission on Cancer (AJCC): Author of the TNM staging system (See TNM Stage).

Business Rule (BR): A business rule is a statement that defines or constrains some aspect(s) of the normal course of events. It is intended to assert business structure or to control or influence the behavior of the business. In the context of this document, a business rule describes the constraint, and in some circumstances provides a recommendation; in others, options for consideration and use.

Source: NPCR-AERRO Glossary (http://www.cdc.gov/cancer/npcr/informatics/aerro2/glossary.htm)

Biological response modifier (BRM): See Immunotherapy.

Cancer case: A reportable cancer diagnosis, as defined by selected codes from the World Health Organization's *International Classification of Diseases for Oncology (ICD-O)* manual.

Cancer event report: A general term to describe a record of information for a cancer case, including patient demographics, diagnosis, co-morbidity, staging, treatment, referral and vital status. [See Cancer Event Report]

Cancer Control: Actions taken to "to reduce the number of cancer cases and deaths and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment, and palliation, making the best use of available resources."

Source: http://www.who.int/cancer/nccp/en/

Cancer reporting: Actions taken to submit information on a cancer case to a public health agency, or its bona fide agent.

Cancer Event Report: See Ambulatory Healthcare Provider Cancer Event Report.

Central Cancer Registries: Population-based public health surveillance programs that collect data on all cancer cases in a defined population, including data on the occurrence of cancer, primary site, histology, stage at diagnosis, first course of treatment, and vital status.

Source: NPCR Program Manual:
http://www.cdc.gov/cancer/npcr/pdf/program_manual.pdf

Certified Tumor Registrar (CTR): A nationally certified data collection and management expert with the training and specialized skills to provide the high quality data required in all avenues of cancer statistics and research.

Source: http://www.ncra-usa.org/i4a/pages/index.cfm?pageid=3301

Chemotherapy regimen: A collection of drugs administered in a highly organized manner for treating cancer. It includes information on doses, scheduling, and duration of administration.

Co-morbidity: The presence of preexisting medical conditions, factors influencing health status, and/or complications in addition to cancer.

Source: Commission on Cancer *Facility Oncology Registry Data Standards, Revised for 2011*.

Confirmed diagnosis (synonym: definitive diagnosis): A histologic or cytologic confirmation of reportable tumor or malignancy, or a determination by a medical practitioner that the patient has a reportable tumor or malignancy.

Cytology: Microscopic examination of cells.

Electronic Health Record (EHR): The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.

Source: http://www.himss.org/ASP/topics_ehr.asp

For purposes of this IG, EHR can also be interpreted to refer to applications that some vendors may call an Electronic Medical Record (EMR).

Encounter: An interaction between a patient and care provider(s) for the purpose of providing healthcare-related service(s). Healthcare services include health assessment. Examples: outpatient visit to multiple departments, home health support (including physical therapy), inpatient hospital stay, emergency room visit, field visit (e.g., traffic accident), office visit, chemotherapy and radiation therapy, occupational therapy, or telephone call.

Source: IHE Patient Care Coordination Technical Framework Supplement – CDA Content Modules, copyright IHE International, Inc.

Health Insurance Portability & Accountability Act (HIPAA):The Health Insurance Portability & Accountability Act of 1996 (August 21), Public Law 104-191, which amended the Internal Revenue Service Code of 1986.

Source: *www.hipaadvisory.com/regs/HIPAAprimer.htm*

Histologic Type: Name and/or code of a type of cancer, usually based on a microscopic examination of tissue/fluids. Example: adenocarcinoma, leukemia, mesothelioma.

Health Level 7 (HL7):

> **Organization**: "Health Level Seven International (HL7) is a not-for-profit, ANSI [American National Standards Institute]-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services."
>
> **Standard**:"HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world."

Source: http//www.hl7.org

HL7 Clinical Document Architecture (CDA): "The HL7**Clinical Document Architecture** (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. CDA is part of the HL7 version 3 standard. It was developed using the HL7 Development Framework (HDF) and it is based on the HL7 Reference Information Model (RIM). CDA documents are persistent in nature. The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document contents) and optional structured parts (for software processing)." (Source: http://hl7book.net/index.php?title=CDA). The structured portion of CDA uses coding systems (such as SNOMED for answers and LOINC for section headers and observations) to represent concepts. (Adapted from http://hl7book.net/index.php?title=CDA)

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM): "ICD-9-CM is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9). ICD-9-CM is the official system of assigning codes to diagnoses and

procedures associated with hospital utilization in the United States." Source: http://www.cdc.gov/nchs/icd/icd9cm.htm

International Classification of Diseases, Tenth Revision, Clinical Modification(ICD-10-CM): "The National Center for Health Statistics (NCHS), the Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States, has developed a clinical modification of the classification for morbidity purposes."

Source: http://www.cdc.gov/nchs/icd/icd10cm.htm

Integrating the Health Enterprise International (IHE): "IHE International is composed of Member Organizations interested in improving the interoperability of healthcare information systems. An organization that becomes a member of IHE International may designate representatives to participate in Domain Committees and National/Regional Deployment Committees relevant to its interests."

Source: http://www.ihe.net/governance/index.cfm#membership.

Immunotherapy: Treatment that stimulates the body's immune system to fight tumors; also called biological response modifier (BRM) therapy.

North American Association of Central Cancer Registries (NAACCR): A collaborative umbrella organization for cancer registries, governmental agencies, professional organizations, and private groups in North America interested in enhancing the quality and use of cancer registry data.

National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER): The SEER Program works to provide information on cancer statistics in an effort to reduce the burden of cancer among the U.S. Population.

Source: http://seer.cancer.gov/about/

National Program of Cancer Registries (NPCR): Established by Congress through the Cancer Registries Amendment Act in 1992 and administered by the Centers for Disease Control and Prevention (CDC), the National Program of Cancer Registries (NPCR) collects data on the occurrence of cancer; the type, extent, and location of the cancer; and the type of initial treatment.

Source: http://www.cdc.gov/cancer/npcr/about.htm

NPCR Advancing E-cancer Reporting and Registry Operations (NPCR-AERRO): A collaborative effort to advance automation of cancer registration by developing a set of cancer surveillance models, requirements, and products.

Public Health Information Network (PHIN): "The CDC Public Health Information Network (PHIN) is a national initiative to improve the capacity of

public health to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements.

PHIN strives to improve public health by enhancing research and practice through best practices related to efficient, effective, and interoperable public health information systems." Source: http://www.cdc.gov/phin/about/index.html

Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS): **"**PHIN VADS provides standard vocabularies to CDC and its Public Health Partners in one place! PHIN VADS is a web-based enterprise vocabulary system for accessing, searching, and distributing vocabularies used within the PHIN. It promotes the use of standards-based vocabulary within PHIN systems to support the exchange of consistent information among Public Health Partners . . . To access VADS, go to: http://phinvads.cdc.gov."

Source: http://www.cdc.gov/phin/tools/PHINvads/.

Quality, Research and Public Health (QRPH): "IHE Quality, Research and Public Health Domain (QRPH) addresses the infrastructure and content necessary to:

1. share information relevant to quality improvement,
2. improve the liaison between the primary care system and clinical research and
3. provide population base health surveillance."

Source: http://wiki.ihe.net/index.php?title=Quality

Stage: The extent of involvement of organs and tissues by tumor (e.g. how far the cancer has spread in the body.

Tumor/Nodes/Metastasis (**TNM) Stage**: A system to classify the extent of disease based mostly on anatomic information on the extent of the primary tumor, regional lymph nodes and distant metastasis.

Use Case: The specification of sequences of actions, including variant sequences and error sequences, that a system, subsystem, or class can perform by interacting with outside objects to provide a service of value. Source: NPCR-AERRO Glossary.

Extensible Markup Language (XML): **"**a simple, very flexible text format derived from SGML (ISO 8879). Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere." Source: http://www.w3.org/XML/

XML Path Language (XPath): **"**XPath is the result of an effort to provide a common syntax and semantics for functionality shared between XSL

Transformations [XSLT] and XPointer. The primary purpose of XPath is to address parts of an XML document."

Source: http://www.w3.org/TR/xpath/#section-Introduction.