Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries

HL7 Clinical Document Architecture (CDA)

Release 1.0

August 2012

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

Copyright and Trademarks

- **HL7 and Health Level Seven are registered trademarks of Health Level Seven, Inc. Reg. U.S. Pat and TM Off**
- **Copyright IHE International, Inc.**

Acknowledgements

This guide was produced and developed through a collaborative effort of the Centers for Disease Control and Prevention (CDC), National Cancer Institute (NCI) Surveillance, Epidemiology, and End-Results (SEER) Program, public health central cancer registries, EHR vendors, and the North American Association of Central Cancer Registries (NAACCR) to develop a guide for Ambulatory Healthcare Provider Cancer Event Reporting to Cancer Registries. A list of core data elements for Cancer Registries was developed by the NAACCR in collaboration with the CDC. CDC provided funding to support these activities and staff within the Cancer Surveillance Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health promotion led the development of this implementation guide and served as primary editors. A draft of the specification was reviewed by many national and state public health organizations, standards development organizations and vendors. The contributing editors would like to express gratitude to these reviewers for their thoughtful comments and support during development of this guide. In addition, special thanks needs to be expressed to the following groups:

- CDC's NPCR-Advancing E-cancer Reporting and Registry Operations (AERRO) Clinic/Physician Office (CPO) Workgroup
- CDC's Office of Surveillance, Epidemiology, and Laboratory Services (OSELS)
- NAACCR Physician Reporting Workgroup
- NAACCR Interoperability Adhoc Committee
- NAACCR Board
- Integrating the Healthcare Enterprise (IHE) Quality, Research and Public Health (QRPH) Domain
- IHE Patient Care Coordination (PCC) Domain
- IHE International
- National Cancer Institute (NCI) Surveillance, Epidemiology, and End-Results (SEER) Program
- American College of Surgeons (ACoS) Commission on Cancer (CoC)

For information about this Guide, contact: cancerehrreporting@cdc.gov

Table of Contents

Table of Figures

Table of Tables

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 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).

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.

[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.

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 from ambulatory healthcare provider EHR systems 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 implementation of standardized data transmissions from an ambulatory healthcare provider EHR to the public health central cancer registry. A single standardized method will allow efficient and accurate transmission of cancer information 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 transmit the cancer event report to a public health central cancer registry over a secure electronic transmission mechanism.

This document represents a collaborative effort of the CDC NPCR, NCI SEER, public health central cancer registries, EHR vendors, and the North American Association of Central Cancer Registries (NAACCR) to provide guidance to meet the Centers for Medicaid and Medicare Services (CMS) criterion demonstrating a meaningful use objective for cancer reporting to a public health central cancer registry. The intention of this guide is to facilitate the transmission of 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. This IG is not intended for use for implementation of cancer reporting from hospitals or pathology laboratories. Users of this IG must be familiar with the details of HL7 CDA R2 document construction. This guide is NOT intended to be a tutorial on HL7 CDA R2.

1.5 Scope

This IG is intended to facilitate the development of systems that allow for automated transmission of cancer case data from ambulatory healthcare providers' EHRs to public health central cancer registries. It contains the specifications for identifying reportable cancers,

---

[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

describes the standard HL7 CDA R2 format and structure of the data elements to be retrieved from the EHR to produce the cancer event report, and indicates when a cancer event report must be transmitted. Specific reportability and timing requirements for cancer event reports may vary by public health central cancer registry. Methods for public health central cancer registries to receive and process cancer event reports from ambulatory healthcare providers and transport mechanisms between EHRs and public health central cancer registries are **NOT** included in the scope of this IG. Methods for public health central cancer registries to receive and process these reports will be addressed in other documents.

1.6 Use Case, Scenarios, Diagrams

1.6.1 Scenarios

There are a variety of scenarios in which a patient encounter includes activities related to cancer, including diagnosis, referral, treatment, and follow-up. For purposes of this document, an encounter is defined as an interaction between a patient and care provider(s) for the purpose of providing healthcare-related service(s). Office visits, chemotherapy and radiation therapy, and telephone calls are each considered forms of encounters. Regardless of the encounter activity, the Use Case is triggered every time the encounter's first-listed diagnosis is cancer.

Scenario 1:

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 this is Chronic Lymphocytic Leukemia (CLL). The physician documents the diagnosis for this encounter in the EHR. The first-listed diagnosis code for this encounter is 204.10: "Chronic lymphoid leukemia, without mention of having achieved remission".

The EHR determines that the first-listed diagnosis code is on the Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR automatically creates an ambulatory healthcare provider cancer event report as specified by this IG and securely transmits the cumulative report to the central cancer registry (See Figure 1.2).

Scenario 2:

A patient with colon cancer presents to the cancer treatment center to initiate his/her chemotherapy regimen. The antineoplastic drugs are infused and the chemotherapy treatment is documented in the ambulatory healthcare provider EHR and the encounter is given a first-listed diagnosis code of V58.11 "Encounter for antineoplastic chemotherapy".

The EHR determines that the first-listed diagnosis code is on the Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR automatically creates an ambulatory healthcare provider cancer event report as specified by this IG and securely transmits the cumulative report to the central cancer registry (See Figure 1.2).

The patient returns to the cancer treatment center to receive his/her the next chemotherapy cycle. The intravenous antineoplastic drugs are infused and the chemotherapy treatment is documented in the ambulatory healthcare provider EHR and the encounter is given a first-listed diagnosis code of V58.11 "Encounter for antineoplastic chemotherapy".

The EHR determines that the diagnosis code is on the Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR automatically creates an ambulatory healthcare provider cancer event report as specified by this IG and securely transmits the cumulative report 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. The physician determines it is atypical and worrisome and refers the patient to a dermatologist. The physician records the first-listed diagnosis for this encounter in the EHR as 707.9 "Skin ulcer." The EHR determines that the first-listed diagnosis code is not on the Reportability list, and thus does NOT meet the criteria for reporting to the central cancer registry.

Six weeks later, the primary care physician 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 physician updates the patient's EHR.

IF the primary care physician or the EHR ***updates the first-listed diagnosis code*** for the patient, assigning 172.6 "melanoma in situ of the arm", the EHR determines that the first-listed diagnosis code is on the Reportability List, thus meeting the criteria for reporting to the central cancer registry as specified by this IG. The EHR automatically creates an ambulatory healthcare provider cancer event report as specified by this IG and securely transmits the cumulative report to the central cancer registry. (See Figure 1.2)

IF the primary care physician or the EHR ***does NOT update the first-listed diagnosis code*** for the patient's medical condition to reflect the diagnosis of malignant melanoma and to record the stage, the addition of the information in the EHR will not meet the criteria for reporting to the central cancer registry. The central registry will receive the information from the dermatologist, instead of the primary care physician, who is also required to report cancer diagnoses to the central cancer registry.

1.6.2 Use Case Overview

Use Case: 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.

Use Case: Prepare and Transmit Ambulatory Healthcare Provider Cancer Event Report For Public Health Central Cancer Registries	
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	• Infrastructure is in place to allow accurate and secure information exchange between information systems. • Providers securely access information through either an EHR or a clinical data system. • The EHR contains sufficient information for the system to construct the Cancer Event Report properly. • Privacy and security have been implemented at an acceptable level. • 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.

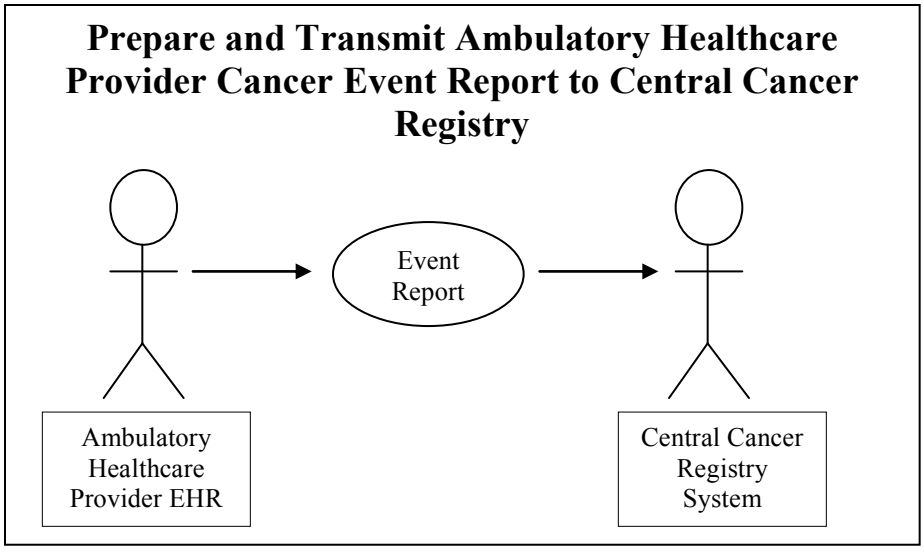

Figure 1.1 Use Case Model

1.6.3 Use Case Details

This "Prepare and Transmit Ambulatory Healthcare Provider Cancer Event Report for Central Cancer Registries" use case model begins when the ambulatory healthcare provider EHR system identifies that there is a cancer patient encounter.

For purposes of this document, an encounter is defined as 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), emergency room visit, field visit (e.g., traffic accident), office visit, chemotherapy and radiation therapy, occupational therapy, or telephone call[4].

1. Ambulatory Healthcare Provider EHR identifies a current encounter for a patient with cancer as his/her ***first-listed*** diagnosis. [BR 01]

   The first-listed diagnosis for an outpatient/ambulatory encounter is the diagnosis, condition, problem, or other reason for encounter/visit shown in the medical record to be chiefly responsible for the services provided. It may be the presenting reason or complaint or it may be the diagnosis that is known at the end of the encounter. In some cases, the first-listed diagnosis may be the treatment performed during the encounter (e.g., V58.1: "Encounter or admission for chemotherapy").

[4] IHE Patient Care Coordination Technical Framework Supplement – CDA Content Modules, copyright IHE International, Inc. (http://www.ihe.net/Technical_Framework/upload/IHE_PCC_Suppl_CDA_Content_Modules_Rev2-1_TI_2011-09-02.pdf)

BR	Business Rule Statement	Purpose	Remarks/Links
01	The EHR shall use the list of reportable cancer diagnosis codes established by the cancer registry community to identify an encounter for a patient with cancer	To ensure completeness of reporting.	*Automated eligibility criteria include:* • *ICD-9-CM Diagnosis Codes* • *ICD-10-CM Diagnosis Codes* Reportability Code Lists are available at PHIN VADS: (https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.3.520.4.16)

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. [BR 02, 03, 04]

BR	Business Rule Statement	Purpose	Remarks/Links
02	The EHR shall create a valid HL7 CDA R2 document according to the specifications in Section 2.5 of this document.	To achieve uniformity and consistency.	
03	The Ambulatory Healthcare Provider Cancer Event Report shall contain data elements as defined in the specifications in Section 2.5.4 of this document. Data elements that are not in the EHR but are in an alternative information system should be retrieved for inclusion in the ambulatory healthcare provider cancer event report or entered manually.		Refer to specifications in Section 2.5.4 of this document for list of data elements and the concepts used to define optionality (required, recommended, optional).
04	The Cancer Event Report shall be cumulative.		The Ambulatory Healthcare Provider Cancer Event Report shall be cumulative, including any information that has been added or changed since the last event report submitted.

3. Ambulatory Healthcare Provider EHR transmits the Ambulatory Healthcare Provider Cancer Event Report. [BR 05, 06]

BR	Business Rule Statement	Purpose	Remarks/Links
05	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.	To ensure timely reporting.	The capability to transmit 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.
06	The EHR shall transmit the Ambulatory Healthcare Provider Cancer Event Report using the healthcare industry's security and privacy standards	To ensure confidentiality	Standards used must be in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

4. Central Cancer Registry Software receives the event report. [BR 07]

BR	Business Rule Statement	Purpose	Remarks/Links
07	The Public Health Central Cancer Registries is capable of receiving an HL7 CDA R2 Ambulatory Healthcare Provider Cancer Event Report document.	To ensure receipt of transmitted information.	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.

1.6.3.1 Sequence Diagram

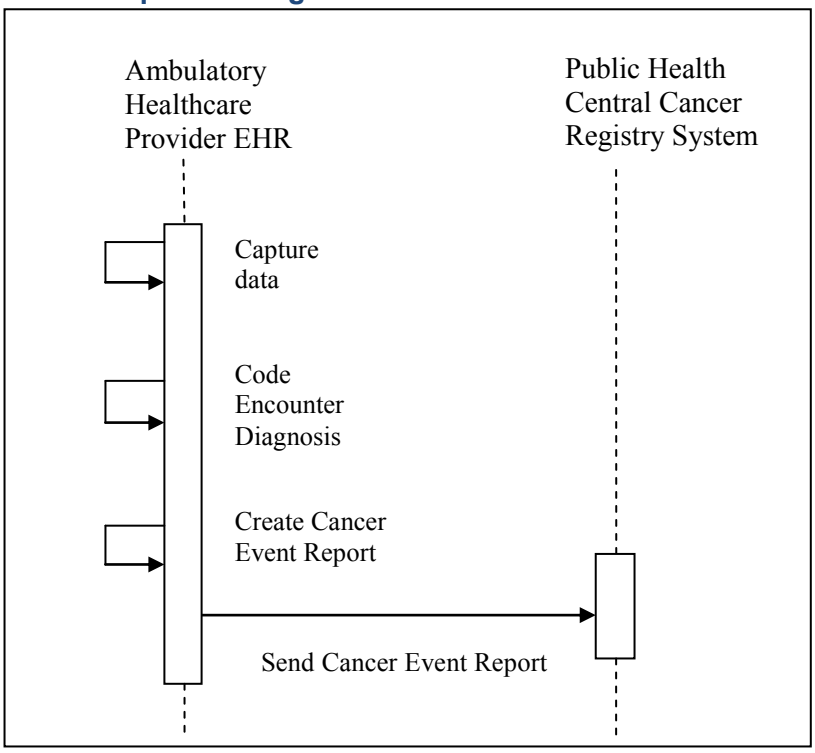

Figure 1.2 Sequence Diagram

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.

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 Act preempts state laws and imposes civil monetary penalties and prison terms for certain violations. 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.[5]

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

2 Ambulatory Healthcare Provider Cancer Event Report Specification

2.1 Introduction

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, "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. This specification 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".[6]

This specification collects information from several IHE Technical Frameworks and Profiles (copyright IHE International, Inc.) and the HL7 Continuity of Care Document (CCD) IG into one document. These include:

- IHE QRPH Technical Framework Supplement – Physician Reporting to a Public Health Repository - Cancer Registry (QRPH–PRPH-Ca), copyright IHE International, Inc.
- IHE Patient Care Coordination Technical Framework, Volume 2 (PCC TF-2), copyright IHE International, Inc.
- IHE Patient Care Coordination Technical Framework Supplement – CDA Content Modules, copyright IHE International, Inc.
- IHE Cardiology Technical Framework Supplement–Cardiac Imaging Report Content (CARD-CIRC), copyright IHE International, Inc.
- HL7 CCD Implementation Guide, copyright HL7

2.2 Organization of the Specification

2.2.1 Conventions

Conventions describe the rules adhered to in this specification.

2.2.2 Document Content Module for the Ambulatory Healthcare Provider Cancer Event Report

The Document Content Module describes the constraints for the CDA header and sections. The Ambulatory Healthcare Provider Cancer Event Report requires that a CDA structured body element be used.

[6] 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.

2.2.3 Section Content Module

The Section Content Module specifies section-level constraints. For example, the Cancer Diagnosis Section contains a `templateId` element, a `code` element, and several Cancer-type Observations.

2.2.4 Entry Content Module

The Entry Content Module defines the core semantic units of the ambulatory healthcare provider cancer event report—the conformance requirements for CDA clinical statements including associated vocabularies and value sets.

2.2.5 Vocabularies and Value Sets

Vocabularies are groups of terms that are used to create the document. Some of the vocabularies are in general use in the healthcare community; others have been created by the cancer registry community] specifically for cancer reporting. A value set is a subset of the vocabulary chosen as appropriate for cancer reporting. Conformance statements indicate whether a specific vocabulary or value is required.

2.3 Conventions Used in This Implementation Guide

2.3.1 Conformance (Optionality Constraints)

The optionality constraints in this implementation guide use the HL7 Consolidated CDA conformance verbs (copyright 2011 Health Level Seven International):

"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 (http://www.hl7.org).

- **SHALL:** an absolute requirement
- **SHALL NOT:** an absolute prohibition against inclusion
- **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
- **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.

The subject of a conformance verb (keyword) in a top-level constraint is the template itself; In nested constraints, the subject is the element in the containing constraint."[7]

[7] HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1; (US Realm) Draft Standard for Trial Use. December 2011

2.3.2 Cardinality

Cardinality expresses the number of times an attribute or association may appear in a CDA document instance that conforms to the specifications described within section 6. Cardinality is expressed as a minimum and a maximum value separated by '..', and enclosed in '[ ]', e.g., '[0..1]'.

Minimum cardinality is expressed as an integer that is equal to or greater than zero. If the minimum cardinality is zero, the element need only appear in message instances when the sending application has data with which to value the element. Mandatory elements must have a minimum cardinality greater than zero.

The maximum cardinality is expressed either as a positive integer (greater than zero and greater than or equal to the minimum cardinality) or as unlimited using an asterisk ("*").

The cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 1..* as one or more present
- 0..* as zero to many present

2.3.3 Null Flavor

The Null Flavor definitions in this implementation guide use the HL7 Consolidated CDA Null Flavor (copyright 2011 Health Level Seven International)[8]:

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. In HL7, a flavor of null, or nullFlavor, describes the reason for missing data.

For example, if a patient arrives at an Emergency Department unconscious and with no identification, we would use a null flavor to represent the lack of information. The patient's birth date would be represented with a null flavor of "NAV", which is the code for "temporarily unavailable". When the patient regains consciousness or a relative arrives, we expect to know the patient's birth date.

Figure 2.1 nullFlavor Example

```
<birthTime nullFlavor="NAV"/>   <!--coding an unknown birthdate-->
```

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.

[8] HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1; (US Realm) Draft Standard for Trial Use. December 2011

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.

This above list 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[9].

Any **SHALL** conformance statement may use `nullFlavor`, unless the attribute is required or the `nullFlavor` is explicitly disallowed. **SHOULD** and **MAY** conformance statement may also use `nullFlavor`.

Figure 2.2 nullFlavor attribute required Example

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

Figure 2.3 Allowed nullFlavors when element is required

```
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="NAV">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

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

Figure 2.4 nullFlavor explicitly disallowed example

1. **SHALL** contain exactly one [1..1] **effectiveTime.**
    a. **SHALL NOT** contain [0..0] nullFlavor.

2.4 Unknown Information

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

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 2.5 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 2.6 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.)

Figure 2.6 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>
```

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.

2.4.1 Code Systems and Value Sets (Vocabulary)

The templates in this document use terms from several code systems; details can be found in Appendix A. Value-set constraints can be "static," meaning that they are bound to a specified version of a value set, or "dynamic," meaning that they are bound to the most current version of the value set. A simplified constraint is used when the binding is to a single code. Unless otherwise specified, value sets are specified with STATIC stability, as defined in the HL7 Core Principles and Properties of v3 Models.

NOTE: In this Implementation Guide, values are selected from standard code sets where available. Where HL7 value sets and code systems are referenced, please refer to the HL7 Standard for complete listings. The Value Sets are maintained in the 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 value sets referenced in this Implementation Guide can be obtained from PHIN VADS (http://phinvads.cdc.gov/vads/ViewView.action?name=Meaningful Use Healthcare Provider Reporting to Central Cancer Registries).

2.4.2 Example XML Code

Extensible Markup Language (XML) code examples are shown in boxed figures. Portions of the XML content may be elided for brevity, as shown here.

Figure 2.7 An Example of XML Code Example

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  ...
</ClinicalDocument>
```

2.4.3 XPath Notation

This IG uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied.

2.5 Ambulatory Healthcare Provider Cancer Event Report Content Module Specification

This section contains the Document, Section and Entry Content Modules that describe the content requirements of the Ambulatory Healthcare Provider Cancer Event Report.

The material in this section is reproduced from the IHE QRPH PRPH-Ca profile, IHE PCC TF-2, and IHE PCC CDA Content Modules(copyright IHE International, Inc.), and the HL7 CCD IG.

2.5.1 CDA Document Module

2.5.1.1 Ambulatory Healthcare Provider Cancer Event Report (1.3.6.1.4.1.19376.1.7.3.1.1.14.1)

The Ambulatory Healthcare Provider Cancer Event Report contains a cumulative record of a patient's encounters for diagnosis and/or treatment of cancer. This content module inherits from the Medical Documents content module, and so must conform to the requirements of that template as well.

Parent Template

The Ambulatory Healthcare Provider Cancer Event Report uses the Medical Document template (1.3.6.1.4.1.19376.1.5.3.1.1.1) as its parent template and inherits all of the constraints from that template.

LOINC Code

The LOINC code for this document is 72134-0 Cancer Event Report.

Standards

CDAR2	HL7 CDA Release 2.0
LOINC	Logical Observation Identifiers, Names and Codes
NAACCR	North American Association of Central Cancer Registries
CDTHP	CDA for Common Document Types History and Physical Notes (DSTU)

Table 2-1 Document Specification Table

Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.14.1			
Parent Template	Medical Document 1.3.6.1.4.1.19376.1.5.3.1.1.1			
General Description	The Ambulatory Healthcare Provider Cancer Event Report contains a record of a patient's encounter for diagnosis and/or treatment of cancer. This content module inherits from the Medical Documents content module, and so must conform to the requirements of that template as well.			
Document Code	LOINC = 72134-0 Cancer Event Report			
Conformance (Optionality)	**Data Element or Section Name**	**Section Template ID**	**Internal IG Location (Section Number) & External Specification Document**	**Further Constraints applied by Ambulatory Healthcare Provider Cancer Event Report Specification**
SHALL [1..1]	**Header Section**	2.16.840.1.113883.10.20.3	2.5.2 General Header Constraints for CDA R2	
[1..*]	Header Section: Address	1.3.6.1.4.1.19376.1.7.3.1.1.14.1	2.5.2.1.1	Useable Period element SHALL be present to indicate the beginning and ending dates the patient indicated that the address was used: ClinicalDocument/recordTarget/patientRole/addr/useablePeriod Use attribute SHOULD be present to indicate the purpose of the address (e.g., mailing, home): ClinicalDocument/recordTarget/patientRole/addr/@use
MAY [0..*]	Header Section: sdtc:raceCode	2.16.840.1.113883.10.20.22.1.1	2.5.2.1.2 HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1	ClinicalDocument/recordTarget/patientRole/patient/sdtc:raceCode/@*
SHALL [1..1]	Header Section: Provider Referred From	1.3.6.1.4.1.19376.1.4.1.3.1	2.5.2.1.3 Cardiac Imaging Report Content (CIRC) Supplement	Provider Referred From element SHALL be present. An appropriate distinction of "None" is permitted: ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant//*
SHALL [1..1]	Header Section: Birthplace	1.3.6.1.4.1.19376.1.7.3.1.1.14.1	2.5.2.1.4 PRPH-Ca Supplement	Birthplace element SHALL be present. An appropriate distinction of "None" is permitted: ClinicalDocument/recordTarget/patientRole/patient/birthplace//*
SHALL [1..1]	**Active Problems Section**	1.3.6.1.4.1.19376.1.5.3.1.3.6	2.5.3.1 PCC TF-2	No Further Constraints

SHALL [1..1]	**Cancer Diagnosis Section** This section documents the ambulatory healthcare provider's diagnosis of the malignancy after review of all relevant diagnostic examinations and studies. Includes information about the date of diagnosis, the location of the cancer, its histologic type and the stage of the cancer.	1.3.6.1.4.1.19376.1.7.3.1.3.14.1	2.5.3.2 PCC Content Module Supplement	This is the key section for the Ambulatory Healthcare Provider Cancer Event Report and therefore SHALL NOT be null.
SHALL [1..1]	**Care Plan** Includes narrative or coded description of planned referral status, including hospitalization status, name of hospital, name of Radiation Therapy Facility, and name of specialist.	1.3.6.1.4.1.19376.1.5.3.1.3.31	2.5.3.3 PCC TF-2	The Care Plan Section SHALL contain at least one entry for an encounter for the patient's planned healthcare encounter(s). An appropriate distinction of "None" is permitted. ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]//entry/encounter/performer//*
SHALL [1..1]	**Coded Results Section**	1.3.6.1.4.1.19376.1.5.3.1.3.28	2.5.3.4 PCC TF-2	The Coded Results Section SHALL contain at least one entry for a simple observation for the test result. An appropriate distinction of "None" is permitted. ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13']]

SHALL [1..1]	**Coded Social History Section**	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	2.5.3.5 PCC Content Module Supplement	Social History Observations for Occupation, Industry, and Smoking Status SHALL be present [3..*]. An appropriate distinction of "None" is permitted. **Occupation**: ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/code[@code='21843-8']] **Industry**: ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/code[@code='21844-6']] **Smoking Status**: ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/code[@code='72166-2']]
SHALL [1..1]	**Medications Section** Includes chemotherapy, hormone therapy, immunotherapy (biological response modifiers) and endocrine therapy.	1.3.6.1.4.1.19376.1.5.3.1.3.19	2.5.3.6 PCC TF-2	An appropriate distinction of "None" is permitted.
SHALL [1..1]	**Medications Administered Section** Includes chemotherapy, hormone therapy, immunotherapy (biological response modifiers) and endocrine therapy.	1.3.6.1.4.1.19376.1.5.3.1.3.21	2.5.3.7 PCC TF-2	An appropriate distinction of "None" is permitted.
SHALL [1..1]	**Payers Section**	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7	2.5.3.8 PCC TF-2	No Further Constraints
SHALL [1..1]	**Procedures Section**	2.16.840.1.113883.10.20.1.12	2.5.3.9 CCD 3.1.4 Procedures	The Procedures Section MAY contain radiation oncology therapeutic procedures.

SHALL [1..1]	**Procedures– Narrative Radiation Oncology Section** Includes narrative description of the radiation treatment performed by a Radiation Oncologist.	1.3.6.1.4.1.19376.1.7.3.1.3.14.2	2.5.3.10	An appropriate distinction of “None” is permitted.
SHALL [1..1]	**Progress Note Section**	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7	2.5.3.11 PCC Content Module Supplement	No Further Constraints

Figure 2.8 Ambulatory Healthcare Provider Cancer Event Report Document Example

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" moodCode="EVN"
xmlns="urn:hl7-org:v3">
   <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
   <!-- OIDS for Medical Document, H&P and PRPH-Ca -->
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
      <templateId root=’2.16.840.1.113883.10.20.3’/>
   <templateId root=’1.3.6.1.4.1.19376.1.7.3.1.1.14.1’/>
   <id root=' ' extension=' '/>
   <code code='72134-0' displayName='Cancer Event Report'
     codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
   <title> Ambulatory Healthcare Provider Report to Cancer Registry </title>
   <effectiveTime value='20100506012005'/>
   <confidentialityCode code='N' displayName='Normal'
     codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
   <languageCode code='en-US'/>

   <!-- one or more patient -->
   <recordTarget><patientRole> .. </patientRole></recordTarget>

   <!-- one or more author -->
   <author> .. </author>

   <!-- the organization issuing this report and in charge with its lifecycle -->
   <custodian> .. </custodian>

   <!—one or more health care providers who referred the patient to this provider for care -->
   <componentOf><encompassingEncounter><encounterParticipant>..</encounterParticipant></encompas
     singEncounter></componentOf>

   <!—one or more birthplace observations -->
   <recordTarget><patientRole><patient><birthplace><place>..</place></birthplace></patient>
     </patientRole></recordTarget>

 <component>
  <structuredBody>
     <component>
      <section>
        <templateId root=’1.3.6.1.4.1.19376.1.5.3.1.3.6’/>
        <!-- Required Active Problems -->
      </section>
   </component>

  <component>
      <section>
        <templateId root=’1.3.6.1.4.1.19376.1.7.3.1.3.14.1’/>
        <!-- Required Cancer Diagnosis -->
```

```
      </section>
   </component>

   <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.31'/>
        <!-- Required Care Plan -->
      </section>
   </component>

  <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
        <!-- Required Coded Results -->
      </section>
   </component>


   <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1'/>
        <!-- Required Coded Social History -->
      </section>
   </component>

  <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
        <!-- Required Medications -->
      </section>
   </component>

   <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.21'/>
        <!-- Required Medications Administered -->
      </section>
   </component>

    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7'/>
        <!-- Required Payers -->
      </section>
   </component>


  <component>
      <section>
        <templateId root='2.16.840.1.113883.10.20.1.12'/>
        <!-- Required Procedures -->
      </section>
   </component>

  <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.7.3.1.3.14.2'/>
        <!-- Required Narrative Radiation Oncology  -->
      </section>
   </component>

   <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7'/>
        <!-- Required Progress Note -->
      </section>
   </component>

  </structuredBody>
 </component>
</ClinicalDocument>
```

2.5.1.2 Document Constraints

The Ambulatory Healthcare Provider Cancer Event Report Document uses sections found in HL7 CCD and in IHE-PCC (copyright IHE International, Inc.) documents. Additional constraints have been placed on certain sections and entries and one new section has been created. All sections and further constraints are fully described and specified in the Section Content Module section of the IG.

2.5.2 CDA Header Content Modules

The CDA Content Header includes requirements for various header elements; name, address and telecom elements for identified persons and organizations; and basic participations record target, author, and legal authenticator.

The Ambulatory Healthcare Provider Cancer Event Report uses the Header Constraints from the Medical Document Template Specification with two additional constraints, detailed further below:

- Required Provider Referred From element
- Required Birth Place element

The constraints for encoding of the CDA Header (Level 1) can be found in the CDA for Common Document Types History and Physical Implementation Guide, in the section 2. CDA Header -- General Constraints.

IHE Medical Documents **SHALL** follow all constraints found in that section with the exception of the constraint on realmCode found in **CONF-HP-10**.

IHE Medical Documents which are implemented for the US Realm **SHALL** follow ALL constraints found in that section, and **SHALL** use both the IHE Medical Document templateId (1.3.6.1.4.1.19376.1.5.3.1.1.1) and the HL7 General Header Constraints templateId (2.16.840.1.113883.10.20.3).

Table 2-2 Header Constraints

Realm	Constraints	Template IDs Required
Universal	CONF-HP-1 through CONF-HP-9 CONF-HP-11 through CONF-HP-40	1.3.6.1.4.1.19376.1.5.3.1.1.1
US	CONF-HP-1 through CONF-HP-40	1.3.6.1.4.1.19376.1.5.3.1.1.1 2.16.840.1.113883.10.20.3

2.5.2.1 Further Header Constraints

2.5.2.1.1 Address Further Constraints

1. **SHALL** conform to **`Postal Address (AD)`** to specialize **`Address Part (ADXP)`.**
    a. Postal Address is used to provide a series of addresses, including the purpose of the address (e.g., mailing, home, office addresses), and the beginning and ending dates the patient indicated that the address was used.
    b. **SHALL** contain at least one [1..*] **`usablePeriod`** with **`@xsi:type="IVL_TS"`** to indicate patient's address history, such that it
        i. **SHALL** contain exactly one [1..1] **`low`** to indicate the time when the patient began living at the address.
        ii. **SHALL** contain exactly one [1..1] **`high`** to indicate the time when the patient stopped living at the address.

c. **SHOULD** contain exactly one [1..1] **@use** to indicate the purpose of the address, which **SHALL** be selected from ValueSet PostalAddressUse 2.16.840.1.113883.1.11.10637 STATIC 2005-05-01.

2. **address/city SHALL** be selected from ValueSet USGS GNIS (Geocodes) 2.16.840.1.114222.4.11.973.
3. **address/state SHALL** be selected from ValueSet FIPS 5-2 2.16.840.1.114222.4.11.830.
4. **address/country SHALL** be selected from ValueSet ISO 3166-1 2.16.840.1.114222.4.11.828.

Figure 2.9 Address Example

```
<addr use="WP">
  <streetAddressLine>800 Main Street</streetAddressLine>
  <city>Aurora</city>
  <state>MN</state>
  <postalCode>55705</postalCode>
  <country>US</country>
  <useablePeriod xsi:type="IVL_TS">
        <low value="20040815"/>
        <high value="20090123"/>
  </useablePeriod>
</addr>
```

2.5.2.1.2 Multiple Races

The raceCode extension (**sdtc:raceCode**) allows for multiple races to be reported for a patient.

1. **MAY** appear after **raceCode** to report multiple races.
2. **MAY** contain zero or more [0..*] **sdtc:raceCode** to report multiple races, which **SHALL** be selected from ValueSet CDC Detailed Race 2.16.840.1.114222.4.11.876 **DYNAMIC** (PHIN VADS link).

Figure 2.10 sdtc:raceCode Example

```
<sdtc:raceCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
<sdtc:raceCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
```

2.5.2.1.3 Provider Referred From

This observation records the provider that referred the patient to the reporting facility.

1. **SHALL** be included as an **encounterParticipant** in the header of the CDA document in the event the patient was referred to this ambulatory healthcare provider.
   a. An appropriate **null flavor** is permitted.
   b. If present, **SHALL** contain the **name** of the provider that referred the patient to the reporting facility.
   c. If present, **SHALL** contain the **assignedEntity@id** for the physician's National Provider Identifier (NPI) number, which **SHALL** be selected from CodeSystem NPI 2.16.840.1.113883.4.6.
2. **SHALL** contain a **typeCode**="REF".

Figure 2.11 Provider Referred From Example

```
<componentOf>
  <encompassingEncounter xmlns:ihecard='urn:ihe:card'>
    <templateId root='1.3.6.1.4.1.19376.1.4.1.3.1'/>
    <effectiveTime value="20110407"/>
    <responsibleParty>
       …
    </responsibleParty>
    <encounterParticipant typeCode="REF">
      <assignedEntity>
        <id root="2.16.840.1.113883.4.6" extension=" " />
        <code code=" " codeSystem="2.16.840.1.113883.6.101"
         codeSystemName="nuccProviderCodes" displayName=" "/>
        <addr>referring physician address</addr>
        <telecom>referring physician phone</telecom >
        <assignedPerson>
          <name>referring physician name</name>
        </assignedPerson>
      </assignedEntity>
    </encounterParticipant>
    <location>
       …
    </location>
    …
  </encompassingEncounter >
</componentOf>
```

2.5.2.1.4 Birthplace

This observation records the birthplace of the patient.

1. **SHALL** be included in the patient section of the header of the CDA document.
    a. An appropriate **`null flavor`** is permitted.

Figure 2.12 Birthplace Example

```
<recordTarget>
   <patientRole>
   …
   <patient>
       …
       <birthplace>
          <place>
             <addr>
             <city></city>
             <state></state>
             <country></country>
             </addr>
          </place>
       /birthplace>
    </patient>
   /patientRole>
</recordTarget>
```

2.5.3 CDA Section Content Modules

The Ambulatory Healthcare Provider Cancer Event Report uses the HL7 CCD and IHE PCC templates (copyright IHE International, Inc.) described below, with additional constraints where indicated.

2.5.3.1 Active Problems Section

Table 2-3 Active Problems Section 1.3.6.1.4.1.19376.1.5.3.1.3.6

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.6	
Parent Template	CCD 3.5 (2.16.840.1.113883.10.20.1.11)	
General Description	The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
11450-4	R (SHALL)	PROBLEM LIST
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R (SHALL)	Problem Concern Entry

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.6".
    b. **SHALL** conform to CCD Problem Section template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.11".
2. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHALL** contain at least one [1..*] **entry**.
    a. **SHALL** contain exactly one [1..1] **Problem Concern Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.5.2).

Figure 2.13 Active Problems Section Example

```
<component>
   <section>
      <templateId root='2.16.840.1.113883.10.20.1.11'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
      <id root=' ' extension=' '/>
      <code code='11450-4' displayName='PROBLEM LIST'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
         Text as described above
      </text>
      <entry>
         :
         <!-- Required Problem Concern Entry element -->
           <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
         :
      </entry>
   </section>
</component>
```

2.5.3.2 Cancer Diagnosis Section

This is the key section for the Ambulatory Healthcare Provider Cancer Event Report and, therefore, **SHALL NOT** be null.

Table 2-4 Cancer Diagnosis Section 1.3.6.1.4.1.19376.1.7.3.1.3.14.1

Template ID	1.3.6.1.4.1.19376.1.7.3.1.3.14.1	
Parent ID	PCC Active Problem Section 1.3.6.1.4.1.19376.1.5.3.1.3.6 CCD 3.5 2.16.840.1.113883.10.20.1.11	
General Description	This section contains specific detailed information about cancer diagnosis(es) that are currently being monitored for the patient. A separate entry for each cancer diagnosis SHALL be provided.	
LOINC Code	**Opt**	**Description**
11450-7	R (SHALL)	Problem List
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R (SHALL)	Problem Concern Entry
1.3.6.1.4.1.19376.1.7.3.1.4.14.1	R (SHALL)	Cancer Diagnosis Entry

Specification

1. **SHALL** contain exactly three [3..3] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] `@root="1.3.6.1.4.1.19376.1.7.3.1.3.14.1"`.
   b. **SHALL** conform to PCC Active Problem Section template and contain exactly one [1..1] **@root**`="1.3.6.1.4.1.19376.1.5.3.1.3.6"`.
   c. **SHALL** conform to CCD Problem Section template and contain exactly one [1..1] **@root**`="2.16.840.1.113883.10.20.1.11"`.
2. **SHALL** contain exactly one [1..1] **code/@code**`="11450-7"` Cancer Diagnosis (CodeSystem: `LOINC 2.16.840.1.113883.6.1`).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.

5. **SHALL** contain exactly one [1..1] **Problem Concern Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.5.2) such that it
    a. **SHALL** contain at least one [1..*] **entryRelationship**
        i. This entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ".
        ii. This entryRelationship **SHALL** contain exactly one [1..1] **@inversionInd**="false".
        iii. This entryRelationship **SHALL** contain one or more [1..*] **Cancer Diagnosis Entry** (1.3.6.1.4.1.19376.1.7.3.1.4.14.1).

Figure 2.14 Cancer Diagnosis Section Example

```
<component>
   <section>
      <templateId root='2.16.840.1.113883.10.20.1.11'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
           <templateId root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1'/>
      <id root=' ' extension=' '/>
      <title>"Cancer Diagnosis"</title>
      <code code=' 11450-7' displayName='Problem List'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
      <entry>
        <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.27'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
        <code nullFlavor='NA'/>
        <statusCode code='active'/>
      <effectiveTime>
        <low value='20110101'/>
        <high nullFlavor="NA" />
      </effectiveTime>

      <entryRelationship>
      <!-- Required Cancer Diagnosis Entry element -->
         <templateId root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1'/>
         :
      </entryRelationship>
          </entry>
   </section>
</component>
```

2.5.3.3 Care Plan Section

Table 2-5 Care Plan Section 1.3.6.1.4.1.19376.1.5.3.1.3.31

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.31	
Parent Template	CCD 3.16 (2.16.840.1.113883.10.20.1.10)	
General Description	The care plan section shall contain a narrative description of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.	
LOINC Code	**Opt**	**Description**
18776-5	R (SHALL)	PLAN OF TREATMENT

Entries	Opt	Description
1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1	O (MAY)	Observation Requests The care plan may include observation requests in intent, goal or proposal mood to identify intended observations that are part of the care plan, goals of the plan, or proposed observations (e.g., from clinical decision support).
1.3.6.1.4.1.19376.1.5.3.1.4.7	O (MAY)	Medication The care plan may include medication entries to identify those medications that are or are proposed to be part of the care plan.
1.3.6.1.4.1.19376.1.5.3.1.4.12	O (MAY)	Immunization The care plan may include immunization entries to identify those immunizations that are or are proposed to be part of the care plan.
1.3.6.1.4.1.19376.1.5.3.1.4.19	O (MAY)	Procedure The care plan may include procedure entries to identify those procedures that are or are proposed to be part of the care plan.
1.3.6.1.4.1.19376.1.5.3.1.4.14	O (MAY)	Encounter The care plan may include encounter entries in to identify those encounters that are or are proposed to be part of the care plan.

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.31".
    b. **SHALL** conform to CCD Plan of Care Section and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.10".
2. **SHALL** contain exactly one [1..1] **code/@code**="18776-5" Plan of Treatment (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **MAY** contain zero or more [0..*] **entry** such that it
    a. **SHALL** contain exactly one [1..1] Observation Request Entry (1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1).
6. **MAY** contain zero or more [0..*] **entry** such that it
    a. **SHALL** contain exactly one [1..1] **Medications Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.7).
7. **MAY** contain zero or more [0..*] **entry** such that it
    a. **SHALL** contain exactly one [1..1] Immunization Entry (1.3.6.1.4.1.19376.1.5.3.1.4.12).
8. **MAY** contain zero or more [0..*] **entry** such that it
    a. **SHALL** contain exactly one [1..1] **Procedure Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.19).
9. **MAY** contain zero or more [0..*] **entry** such that it
    a. **SHALL** contain exactly one [1..1] **Encounters Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.14).

2.5.3.3.1 Care Plan Section Further Conformance Constraints

The Ambulatory Healthcare Provider Cancer Event Report uses the IHE PCC Care Plan Section, with one additional constraint:

10. **SHALL** contain at least one [1..*] **Encounters Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.14).

Figure 2.15 Care Plan Section Example

```
<component>
   <section>
      <templateId root='2.16.840.1.113883.10.20.1.10'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.31'/>
      <id root=' ' extension=' '/>
      <code code='18776-5' displayName='TREATMENT PLAN'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
      <entry>
         :
        <!-- Required Encounters element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.14'/>
         :
      </entry>

   </section>
</component>
```

2.5.3.4 Coded Results Section

Table 2-6 Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.28	
General Description	The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
30954-2	R (SHALL)	Relevant diagnostic tests/laboratory data
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	R (SHALL)	Procedure Entry
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2 (SHOULD)	References Entry
1.3.6.1.4.1.19376.1.5.3.1.4.13	O (MAY)	Simple Observation

Specification

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.28".
2. **SHALL** contain exactly one [1..1] **code/@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHALL** contain at least one [1..*] **entry** such that it

a. **SHALL** contain at least one [1..*] **Procedure Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.19).
b. **SHOULD** contain at least one [1..*] References Entry (1.3.6.1.4.1.19376.1.5.3.1.4.4).
c. **MAY** contain at least one [1..*] **Simple Observation Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.13).

2.5.3.4.1 Coded Results Section Further Conformance Constraints

The Ambulatory Healthcare Provider Cancer Event Report uses the IHE PCC Coded Results Section, with one additional constraint:

6. **SHALL** contain at least one [1..*] **Simple Observation Entry** for the test result.

Figure 2.16 Coded Results Section Example

```
<component>
   <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
      <id root=' ' extension=' '/>
      <code code='30954-2' displayName='Relevant diagnostic tests/laboratory data'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
      <entry>
         :
        <!-- Required Procedure Entry element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
         :
      </entry>
      <entry>
         :
        <!-- Required if known References Entry element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
         :
      </entry>
      <entry>
         :
        <!-- Required Simple Observation element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
         :
      </entry>

   </section>
</component>
```

2.5.3.5 Coded Social History Section

Table 2-7 Coded Social History Section 1.3.6.1.4.1.19376.1.5.3.1.3.16.1

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	
Parent Template	Social History (1.3.6.1.4.1.19376.1.5.3.1.3.16)	
General Description	The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits. It shall include Social History Observations.	
LOINC Code	**Opt**	**Description**
29762-2	R (SHALL)	SOCIAL HISTORY
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.4	R (SHALL)	Social History Observation

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.16.1".
    b. **SHALL** conform to IHE Social History Section template and contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.16".
2. **SHALL** contain exactly one [1..1] **code/@code**="29762-2" Social History (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHALL** contain one or more [1..*] **entry** such that it
    a. **SHALL** contain at least one [1..*] **Social History Observation** (1.3.6.1.4.1.19376.1.5.3.1.4.13.4).

Figure 2.17 Coded Social History Section Example

```
<component>
   <section>
   <templateId root='11.3.6.1.4.1.19376.1.5.3.1.3.16'/>
   <templateId root='11.3.6.1.4.1.19376.1.5.3.1.3.16.1'/>
   <id root=' ' extension=' '/>
   <code code='29762-2' displayName='SOCIAL HISTORY'
     codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
   <text>
      Text as described above
   </text>
   <entry>
        :
        <!--Required Social History Observation for Occupation-->
        <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>
        :
   </entry>
   <entry>
        :
        <!--Required Social History Observation for Industry-->
        <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>
        :
   </entry>
   <entry>
        :
        <!--Required Social History Observation for Smoking Status-->
        <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>
        :
   </entry>
   </section>
</component>
```

2.5.3.5.1 Coded Social History Section Further Conformance Constraints

The Ambulatory Healthcare Provider Cancer Event Report uses the IHE PCC Coded Social History Section, with three additional constraints, detailed further below in the Entry Content Module Section of this IG:

1. **SHALL** contain three or more [3..*] **entry** such that it
    b. **SHALL** contain at least one [1..*] social history observation for the patient's **usual occupation**.
    a. **SHALL** contain at least one [1..*] social history observation for the patient's **usual industry**.

b. **SHALL** contain at least one [1..*] social history observation for the patient's **smoking status**.

2.5.3.6 Medications Section

Table 2-8 Medications Section 1.3.6.1.4.1.19376.1.5.3.1.3.19

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.19	
Parent Template	CCD 3.9 (2.16.840.1.113883.10.20.1.8)	
General Description	The medications section shall contain a description of the relevant medications for the patient, e.g., an ambulatory prescription list. It shall include entries for medications as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
10160-0	R (SHALL)	HISTORY OF MEDICATION USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R (SHALL)	Medications

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.19".
   b. **SHALL** conform to CCD Medications Section and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.8".
2. **SHALL** contain exactly one [1..1] **@code**="10160-0" History of medication use (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHALL** contain at least one [1..*] **entry** such that it
   a. **SHALL** contain exactly one [1..1] **Medications Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.7).

Figure 2.18 Medications Section Example

```
<component>
   <section>
      <templateId root='2.16.840.1.113883.10.20.1.8'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
      <id root=' ' extension=' '/>
      <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
       Text as described above
      </text>
      <entry>
         :
         <!-- Required Medications element -->
           <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
         :
      </entry>

   </section>
</component>
```

2.5.3.7 Medications Administered Section

Table 2-9 Medications Administered Section 1.3.6.1.4.1.19376.1.5.3.1.3.21

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.21	
General Description	The medications administered section shall contain a narrative description of the relevant medications administered to a patient during the course of an encounter. It shall include entries for medication administration as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
18610-6	R (SHALL)	MEDICATION ADMINISTERED
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R (SHALL)	Medications

Specification

1. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.21".
2. **SHALL** contain exactly one [1..1] **code/@code**="18610-6" Medications Administered (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHALL** contain at least one [1..*] **entry** .
    a. **SHALL** contain exactly one [1..1] **Medications Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.7).

Figure 2.19 Medications Administered Section Example

```
<component>
   <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.21'/>
      <id root=' ' extension=' '/>
      <code code='18610-6' displayName='MEDICATION ADMINISTERED'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
      <entry>
         :
        <!-- Required Medications element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
         :
      </entry>

   </section>
</component>
```

2.5.3.8 Payers Section

Table 2-10 Payers Section 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7	
Parent Template	CCD 3.1 (2.16.840.1.113883.10.20.1.9)	
General Description	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	
LOINC Code	**Opt**	**Description**
48768-6	R (SHALL)	PAYMENT SOURCES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.17	R2 (SHOULD)	Coverage Entry

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7".
   b. **SHALL** conform to CCD Payers Section and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.9".
2. **SHALL** contain exactly one [1..1] **code/@code**="48768-6" Payers (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.
5. **SHOULD** contain zero or more [0..*] **entry** such that it
   a. **SHALL** contain exactly one [1..1] **Coverage Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.17).

Figure 2.20 Payers Section Example

```
<component>
   <section>
       <templateId root='2.16.840.1.113883.10.20.1.9'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7'/>
       <id root=' ' extension=' '/>
       <code code='48768-6' displayName='PAYMENT SOURCES'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
       <text>
         Text as described above
      </text>
      <entry>
         :
        <!-- Required if known Coverage Entry element -->
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.17'/>
         :
      </entry>

   </section>
</component>
```

2.5.3.9 Procedures Section

Table 2-11 Procedures Section 2.16.840.1.113883.10.20.1.12

Template ID	CCD 2.16.840.1.113883.10.20.1.12	
General Description	This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments, pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures. Note: Radiation oncology therapy can be included in this section.	
LOINC Code	**Opt**	**Description**
47519-4	R (SHALL)	History of procedures
Entries	**Opt**	**Description**
2.16.840.1.113883.10.20.1.29	R (SHALL)	Procedure Activity

Specification

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.12".
2. **SHALL** contain exactly one [1..1] **code/@code**="47519-4" History of procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title.**
4. **SHALL** contain exactly one [1..1] **text.**
5. **SHALL** contain at least one [1..*] **entry** such that it
   a. **SHALL** contain at least one [1..*] **Procedure Activity** (2.16.840.1.113883.10.20.1.29).

2.5.3.9.1 Procedures Section Further Conformance Constraints

The Ambulatory Healthcare Provider Cancer Event Report uses the HL7 CCD Procedures Section, with one additional constraint:

6. **MAY** contain radiation oncology therapeutic procedures.

Figure 2.21 Procedures Section Example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.10.20.1.12"/>
      <id root=" "/>
      <code code="47519-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        displayName="History of Procedures"/>
      <text>
        Text as described above
      </text>
      <entry>
        :
        <!-- Required Procedure Activity element -->
        <templateId root="2.16.840.1.113883.10.20.1.29"/>
        :
      </entry>
   </section>
</component>
```

2.5.3.10 Procedures– Narrative Radiation Oncology Section

Table 2-12 Procedures– Narrative Radiation Oncology Section 1.3.6.1.4.1.19376.1.7.3.1.3.14.2

Template ID	1.3.6.1.4.1.19376.1.7.3.1.3.14.2	
General Description	The Narrative Radiation Oncology Section shall contain a narrative description of the radiation treatment performed by a Radiation Oncologist. Information should include: beginning and ending dates of radiation treatment, Treatment Volume, Number of Treatment Volume, Regional Modality, Regional Dose (cGY), Boost Modality, Boost Dose (cGY), and treatment notes.	
LOINC Code	**Opt**	**Description**
34832-6	R (SHALL)	Radiation Oncology Evaluation And Management Note

Specification

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.3.14.2".
2. **SHALL** contain exactly one [1..1] **code/@code**="34832-6" Radiation Oncology Evaluation And Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.

Figure 2.22 Procedures – Narrative Radiation Oncology Section Example

```
<component>
   <section>
      <templateId root='1.3.6.1.4.1.19376.1.7.3.1.3.14.2'/>
      <id root=' ' extension=' '/>
      <code code='34832-6' displayName='RADIATION ONCOLOGY EVALUATION AND MANAGEMENT NOTE'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>
   </section>
</component>
```

2.5.3.11 Progress Note Section

Table 2-13 Progress Note Section 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7	
General Description	The Progress Note section shall contain a narrative description of the sequence of events from initial assessment to discharge for an encounter.	
LOINC Code	**Opt**	**Description**
18733-6	R (SHALL)	SUBSEQUENT EVALUATION NOTE (ATTENDING PHYSICIAN)

Specification

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7".

2. **SHALL** contain exactly one [1..1] **code/@code**="18733-6" Subsequent Evaluation Note (Attending Physician) (CodeSystem: LOINC 2.16.840.1.113883.6.1).
3. **SHALL** contain exactly one [1..1] **title**.
4. **SHALL** contain exactly one [1..1] **text**.

Figure 2.23 Progress Note Section Example

```
<component>
   <section>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7'/>
      <id root=' ' extension=' '/>
      <code code='18733-6' displayName='SUBSEQUENT EVALUATION NOTE (ATTENDING PHYSICIAN)'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <text>
        Text as described above
      </text>

   </section>
</component>
```

2.5.4 CDA Entry Content Modules

The Ambulatory Healthcare Provider Cancer Event Report uses the HL7 CCD and IHE PCC (copyright IHE International, Inc.) templates described below, with additional constraints where indicated.

2.5.4.1 Cancer Diagnosis Entry 1.3.6.1.4.1.19376.1.7.3.1.4.14.1

A Cancer Diagnosis entry collects details of the patient's cancer diagnosis, including histology, behavior, primary site, laterality, diagnosis date, TNM Stage, and Best Method of Confirmation.

Standards

CCD	ASTM/HL7 Continuity of Care Document
NAACCR	North American Association of Central Cancer Registries Volume II: Data Standards and Data Dictionary, Record

Parent Template

The parent of this template is Problem Entry (1.3.6.1.4.1.19376.1.5.3.1.4.5).

Table 2-14 Cancer Diagnosis Entry Constraints Overview

Note: The cancer Diagnosis Entry is contained within the **Problem Concern Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.5.2), therefore, the Constraints Overview and Specification begin at the level of the entry relationship of the Cancer Diagnosis Entry.

Name	XPath	Card.	Verb	Data Type	Fixed Value
	observation[templateId/@root = '1.3.6.1.4.1.19376.1.7.3.1.4.14.1']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN

Name	XPath	Card.	Verb	Data Type	Fixed Value
	templateId	3..3	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.7.3.1.4.14.1
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.5
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.28
	Code	1..1	SHALL	CD	2.16.840.1.113883.6.96 (SNOMED CT) = 282291009
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Diagnosis Date	effectiveTime	1..1	SHALL	TS or IVL<TS>	
Histologic Type	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.6.43.1 (International Classification of Diseases for Oncology, Third Edition (ICD-O-3)) WHO website link OR 2.16.840.1.114222.4.11.6038 (International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Appendix A-Morphology of Neoplasms) PHIN VADS link OR 2.16.840.1.113883.6.90 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) CDC NCHS Website link OR 2.16.840.1.113883.6.96 (Systematized Nomenclature of Medicine--Clinical Terms SNOMED CT)
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
Behavior	qualifier	1..1	SHALL	SET<CS>	
	name	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 31206-6
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.14 (NAACCR Behavior Code) PHIN VADS link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

Name	XPath	Card.	Verb	Data Type	Fixed Value
Diagnostic Confirmation	qualifier	1..1	SHALL		
	name	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 21861-0
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.3 (NAACCR Diagnostic Confirmation) PHIN VADS link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
Primary Site	targetSiteCode	1..1	SHALL	SET<CD>	
	code	1..1	SHALL		2.16.840.1.113883.6.103 (International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volume 1 & 2) CDC NCHS Website OR 2.16.840.1.113883.6.90 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) CDC NCHS Website link OR 2.16.840.1.113883.3.88.12.3221.8.9 Body Site (SNOMED CT) PHIN VADS link
Laterality	qualifier	1..1	SHALL		
	name	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 20228-3
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.1 (NAACCR Laterality at Diagnosis) PHIN VADS link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
TNM Clinical Stage information	entryRelationship	0..1	SHOULD		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		true

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly three [3..3] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.4.14.1".
    b. **SHALL** conform to IHE Problem Entry template and contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5".
    c. **SHALL** conform to CCD Problem Observation template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.28".
4. **SHALL** contain exactly one [1..1] **code**="282291009" Diagnosis (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96).
5. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
6. **SHALL** contain exactly one [1..1] **effectiveTime** that records the date of initial diagnosis by a recognized medical practitioner for the cancer being reported.
7. **SHALL** contain exactly one [1..1] **value** to record Histologic Type, which is the cell type of the tumor/cancer (e.g., carcinoma, melanoma, sarcoma, lymphoma, leukemia), with **@xsi:type**="CD".
    a. This value **SHOULD** contain zero or one [0..1] **code**, such that
        i. If uncoded, **SHALL** be a string value describing the histologic type of the tumor/cancer.
        ii. If coded, **SHALL** be selected from one of the following:
            1. CodeSystem International Classification of Diseases for Oncology, Third Edition (ICD-O-3) 2.16.840.1.113883.6.43.1 **DYNAMIC**
            2. CodeSystem International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Appendix A-Morphology of Neoplasms) 2.16.840.1.114222.4.11.6038 **DYNAMIC**
            3. CodeSystem International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2.16.840.1.113883.6.90 **DYNAMIC**
            4. CodeSystem Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) 2.16.840.1.113883.6.96 **DYNAMIC**
    b. This value **SHOULD** contain zero or one [0..1] **originalText**.
        i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
            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).
8. **SHALL** contain exactly one [1..1] **qualifier** that provides Behavior information, indicating whether the tumor is benign, in situ, malignant or metastatic, such that

a. This qualifier **SHALL** contain exactly one [1..1] **name**="31206-6" Behavior ICD-O-3 Cancer (CodeSystem: LOINC 2.16.840.1.113883.6.1) .
b. This qualifier **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" .
    i. This value **SHOULD** contain zero or one [0..1] **code**, such that
        1. If uncoded, **SHALL** be a string value describing the behavior of the tumor/cancer.
        2. If coded, **SHALL** be selected from ValueSet NAACCR Behavior Code 2.16.840.1.113883.3.520.4.14 **DYNAMIC.**
    ii. This value **SHOULD** contain zero or one [0..1] **originalText**.
        1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
            a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

9. **SHALL** contain exactly one [1..1] **qualifier** that provides Diagnostic Confirmation information, indicating the best method used to confirm the presence of the cancer being reported, such that
    a. This qualifier **SHALL** contain exactly one [1..1] **name**="21861-0" Dx confirmed by (CodeSystem: LOINC 2.16.840.1.113883.6.1) .
    b. This qualifier **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD".
        i. This value **SHOULD** contain zero or one [0..1] **code**, such that
            1. If uncoded, **SHALL** be a string value describing the best method of diagnosis of the tumor/cancer.
            2. If coded, **SHALL** be selected from ValueSet NAACCR Diagnostic Confirmation 2.16.840.1.113883.3.520.4.3 **DYNAMIC.**
        ii. This value **SHOULD** contain zero or one [0..1] **originalText**.
            1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
                a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

10. **SHALL** contain exactly one [1..1] **targetSiteCode with @xsi:type="CD"** to indicate the anatomic location where the primary tumor originated.
    a. The targetSiteCode **SHALL** contain exactly one [1..1] @**code**, where the **@code SHALL** be selected from one of the following:
        i. Code System International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)Volume 1 & 2 2.16.840.1.113883.6.103 **DYNAMIC**
        ii. Code System International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2.16.840.1.113883.6.90 **DYNAMIC**
        iii. Value Set Body Site (SNOMED CT) 2.16.840.1.113883.3.88.12.3221.8.9 **DYNAMIC**

11. **SHALL** contain exactly one [1..1] **qualifier** that provides Laterality information, which indicates the side of a paired organ or side of the body on which the reportable tumor originated, such that
    a. This qualifier **SHALL** contain exactly one [1..1] **name**="20228-3" Anatomic part Laterality (CodeSystem: LOINC 2.16.840.1.113883.6.1) .
    b. This qualifier **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD".
        i. This value **SHOULD** contain zero or one [0..1] **code**, such that
            1. If uncoded, **SHALL** be a string value describing the laterality of the tumor/cancer.
            2. If coded, **SHALL** be selected from ValueSet NAACCR Laterality at Diagnosis 2.16.840.1.113883.3.520.4.1 **DYNAMIC**.
        ii. This value **SHOULD** contain zero or one [0..1] **originalText**.
            1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
                a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
12. **SHOULD** contain zero or one [0..1] **entryRelationship** providing information on the TNM Clinical Stage.
    a. The entryRelationship **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="true" true .
    c. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **TNM Clinical Stage Information entry** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.4.14.2).

Table 2-15 NAACCR Behavior Code Value Set

Value Set: NAACCR Behavior Code 2.16.840.1.113883.3.520.4.14 **DYNAMIC**	
PHINVADS link to Behavior	
Code System:	NAACCR Behavior Code 2.16.840.1.113883.3.520.3.14
LOINC:	31206-6 Behavior ICD-O-3 Cancer
Description:	Indication whether the tumor is benign, in situ, malignant or metastatic.
Code	**Meaning**
0	Benign
1	Uncertain whether benign or malignant
2	In situ; non-invasive
3	Malignant, primary
6	Malignant, metastatic
9	Malignant, uncertain whether primary or metastatic

Table 2-16 NAACCR Diagnostic Confirmation Value Set

Value Set: NAACCR Diagnostic Confirmation 2.16.840.1.113883.3.520.4.3 **DYNAMIC**	
PHINVADS link to Diagnostic Confirmation	
Code System:	NAACCR Diagnostic Confirmation 2.16.840.1.113883.3.520.3.3
LOINC:	21861-0 Dx confirmed by
Description:	Describes whether the cancer/tumor was microscopically confirmed or alternatively, the method of diagnosis.
Code	**Meaning**
1	Positive histology
2	Positive cytology, no positive histology
3	Positive histology Plus positive immunophenotyping and/or positive genetic studies
4	Positive microscopic confirmation, method not specified
5	Positive laboratory test/marker study
6	Direct visualization without microscopic confirmation
7	Radiography and other imaging techniques without microscopic confirmation
8	Clinical diagnosis only (other than 5, 6, or 7)
9	Unknown; not stated in patient's record

Table 2-17 NAACCR Laterality at Diagnosis Value Set

Value Set: NAACCR Laterality at Diagnosis 2.16.840.1.113883.3.520.4.1 **DYNAMIC**	
PHINVADS link to Laterality	
Code System:	NAACCR Laterality at Diagnosis 2.16.840.1.113883.3.520.3.1
LOINC:	20228-3 Anatomic part Laterality
Description:	Code for the side of a paired organ, or the side of the body on which the reportable tumor originated.
Code	**Meaning**
0	Not a paired site
1	Right: origin of primary
2	Left: origin of primary
3	Only one side involved, right or left origin unspecified
4	Bilateral involvement, lateral origin unknown; stated to be single primary; including both ovaries involved simultaneously, single histology; bilateral retinoblastomas; bilateral Wilms' tumors
5	Midline of Tumor
9	Paired site, but no information concerning laterality, midline tumor

Figure 2.24 Cancer Diagnosis Example

```
<entryRelationship typeCode="SUBJ" inversionInd="false" >
        <observation classCode='OBS' moodCode='EVN' negationInd="false">
        <templateId root='2.16.840.1.113883.10.20.1.28'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
        <templateId root="1.3.6.1.4.1.19376.1.7.3.1.4.14.1"/>
        <code code="282291009" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
         displayName="Diagnosis"/>
        <text><reference value="" ></reference></text>
        <statusCode code="completed"/>
        <effectiveTime>
```

```
            <low value="20110101"/>
            <high nullFlavor="NI"/>
          </effectiveTime>

<!--The <value> is the condition that was found.-->
   <value xsi:type="CD" code="8742" codeSystem="2.16.840.1.113883.6.43.1" codeSystemName="ICD-O-
3" displayName="Lentigo Maligna">

<!--Behavior Qualifier-->
   <qualifier>
     <name code="31206-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="Behavior ICD-O-3"/>
      <value code="2" codeSystem="2.16.840.1.113883.3.520.3.14" codeSystemName="NAACCR Behavior
   Code" displayName="In Situ"/>
      </qualifier>

<!--Best Method of Diagnosis Qualifier-->
   <qualifier>
     <name code="21861-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="Diagnostic Confirmation"/>
      <value xsi:type="CD" code="2" codeSystem="2.16.840.1.113883.3.520.3.3"
        codeSystemName="NAACCR Diagnostic Confirmation" displayName="Positive cytology, no
        positive histology"/>
   </qualifier>
</value>

<!--Primary Site -->
   <targetSiteCode code="162.9" codeSystem="2.16.840.1.113883.6.103" codeSystemName="ICD-9CM
     (diagnoses)" displayName="">

<!—Laterality Qualifier-->
      <qualifier>
         <name code="20228-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
           displayName="Anatomic part Laterality"/>
         <value code="1" codeSystem="2.16.840.1.113883.3.520.3.1" codeSystemName="NAACCR
           Laterality at Diagnosis" displayName="origin of primary: right"/>
      </qualifier>
   </targetSiteCode>

<!--zero or one entry relationships providing TNM Clinical Stage Information-->
   <entryRelationship typeCode="SUBJ" inversionInd="true">
     :
   </entryRelationship>
      </act>
   </entry>
</section>
```

2.5.4.2 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1

This event represents an act of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) or allergies and intolerances (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.3). Additional references can be provided having additional information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	ClinStat HL7 Clinical Statement (DRAFT)

Table 2-18 Concern Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	act[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.5.1']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.5.1
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.27
	id	1..1	SHALL	II	
	code	1..1	SHALL	CD	
	@nullFlavor	1..1	SHALL		NA
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode) = active|suspended|aborted|completed
	effectiveTime	1..1	SHALL	TS or IVL<TS>	
	low	1..1	SHALL	TS	
	high	0..1	SHALL	TS	See conformance statements below for specific conditions
Problem Concern	entryRelationship	1..*	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly two [2..2] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5.1".
   b. **SHALL** conform to CCD Problem Act template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.27".
4. **SHALL** contain exactly one [1..1] **id**.
5. **SHALL** contain exactly one [1..1] **code** such that it
   a. **SHALL** contain exactly one [1..1] **@nullFlavor**="NA".
6. **SHALL** contain exactly one [1..1] **statusCode**, where the **@code SHALL** be selected from ValueSet ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 **STATIC** 2011-09-09.
   a. A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states.

Specific uses of the suspended and aborted states are left to the implementation.

Table 2-19 ProblemAct statusCode

Value Set: ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 **STATIC** 2011-09-09	
Code System(s):	ActStatus 2.16.840.1.113883.5.14
Code	**Meaning**
active	A concern that is still being tracked.
suspended	A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved.
aborted	A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice.
completed	The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.

7. **SHALL** contain exactly one [1..1] **effectiveTime**.
    a. The effectiveTime element records the starting and ending times during which the concern was active.
    b. This effectiveTime **SHALL** contain exactly one [1..1] **low**.
    c. This effectiveTime **SHALL** contain exactly one [1..1] **high** for concerns in the completed or aborted state and **SHALL NOT** be present otherwise.
8. **SHALL** contain at least one [1..*] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. Each concern is about one or more related problems or allergies. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section **Problem Entry** or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern.
    c. **SHALL** contain exactly one [1..1] **Problem Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.5).

Figure 2.25 Concern Entry Example

```
<act classCode='ACT' moodCode='EVN'>
   <templateId root='2.16.840.1.113883.10.20.1.27'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
   <id root='' extension=''/>
   <code nullFlavor='NA'/>
   <statusCode code='active|suspended|aborted|completed'/>
   <effectiveTime>
      <low value=''/>
      <high value=''/>
   </effectiveTime>
   <!-- one or more entry relationships identifying problems of concern -->
   <entryRelationship typeCode='SUBJ' inversionInd='false'>
     :
   </entryRelationship>
</act>
```

2.5.4.3 Coverage Entry 1.3.6.1.4.1.19376.1.5.3.1.4.17

Payers shall be recorded as described in CCD: 3.1.2.1.1.

Standards

CCD	ASTM/HL7 Continuity of Care Document

Table 2-20 Coverage Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	act[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.17']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = DEF
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.17
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.20
	id	1..*	SHALL	II	
	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 35525-4
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Payer Information	entryRelationship	1..*	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	sequenceNumber/@value	0..1	MAY		

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" Definition (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly one [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.17".
    b. **SHALL** conform to CCD Coverage Activity and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.20".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code**="35525-4" Financing and Insurance (CodeSystem: LOINC 2.16.840.1.113883.6.1).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
7. **SHALL** contain at least one [1..*] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **MAY** contain zero or one [0..1] **sequenceNumber/@value**.

c. **SHALL** contain at least one [1..*] **Payer Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.18).

Figure 2.26 Coverage Entry Example

```
<act classCode='ACT' moodCode='DEF'>
<templateId root='2.16.840.1.113883.10.20.1.20'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.17'/>
<id root='' extension='' />
   <code code='48768-6' displayName='Payment Sources'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
   <statusCode code='completed'/>
   <entryRelationship typeCode='COMP'>
<sequenceNumber value=''/>
      :
   </entryRelationship>
</act>
```

2.5.4.4 Encounters Entry 1.3.6.1.4.1.19376.1.5.3.1.4.14

This content module describes an Encounters Entry. An Encounter is 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, occupational therapy, or telephone call.

Standards

CCD ASTM/HL7 Continuity of Care Document

Table 2-21 Encounters Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	encounter[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.14']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = APT|ARQ|EVN
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.14
	@root	1..1	SHALL		See conformance statements below for instructions
	id	1..*	SHALL	II	
Encounter Type	code	1..1	SHALL	CD	
	code	1..*	SHOULD		2.16.840.1.113883.5.4 (ActEncounterCode)
	text	1..1	SHALL		
	reference/@value	1..1	SHALL		
	effectiveTime	1..*	SHOULD	TS or IVL<TS>	

Name	XPath	Card.	Verb	Data Type	Fixed Value
	priorityCode	0..1	MAY	CE	CS
Provider of Service	performer	1..*	SHOULD		
Provider Location Information	participant	0..*	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) =LOC
	participantRole	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.111 (RoleCode) =SDLOC
	id	0..*	MAY		
	code	0..*	MAY	CE	
	addr	0..*	SHOULD	SET<AD>	
	telecom	0..*	SHOULD	SET<TEL>	
	playingEntity	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.41 (EntityClass) = PLC
Encounter Location	name	1..1	SHALL	PN	

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="APT|ARQ|EVN" (CodeSystem: HL7ActMood 2.16.840.1.113883.5.1001) such that it
    a. **MAY** be APT to indicated a scheduled appointment.
    b. **MAY** be ARQ to describe a request for an appointment that has been made but not yet scheduled by a provider.
    c. **MAY** be EVN, to describe an encounter that has already occurred.
3. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.14".
    b. When the encounter is in event mood (**moodCode**='EVN'), this entry **SHALL** conform to the CCD template 2.16.840.1.113883.10.20.1.21.
    c. When the encounter is in other moods, this entry **SHALL** conform to the CCD template 2.16.840.1.113883.10.20.1.25.
4. **SHALL** contain one or more [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code**, where the **@code SHOULD** be selected from ValueSet ActEncounterCode 2.16.840.1.113883.5.4 **DYNAMIC**.
6. **SHALL** contain exactly one [1..1] **text**.
    a. The text **SHALL** contain exactly one [1..1] **reference/@value**.

i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

7. **SHOULD** contain exactly one [1..1] **effectiveTime to** record the time over which the encounter occurred (in EVN mood), or the desired time of the encounter in ARQ or APT mood, such that
    a. When encounter is in EVN or APT mood, **SHOULD** contain exactly [1..1] **effectiveTime**.
    b. When encounter is in ARQ mood, **MAY** contain exactly one [1..1] **effectiveTime**.
        i. When effectiveTime is not present, **MAY** contain exactly one [1..1] **priorityCode** to indicate that a callback is needed to schedule the appointment.
8. **SHOULD** contain at least one [1..*] **performer** such that it
    a. **SHOULD** contain at least one [1..*] **performer** to identify the provider of the service given during the encounter when the encounter is in EVN mood.
    b. **MAY** contain at least one [1..*] **performer** to indicate a preference for a specific provider when the encounter is in ARQ mood.
    c. **MAY** contain at least one [1..*] **performer** to indicate which provider is scheduled to perform the service (provider referred to) when in APT mood.
9. **MAY** contain zero or more [0..*] **participant** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **participantRole** such that it
        i. **SHALL** contain exactly one [1.1] **@classCode**="SDLOC" Service Delivery Location (2.16.840.1.113883.5.111).
        ii. **MAY** contain exactly one [1.1] **id**.
        iii. **MAY** contain exactly one [1..1] **code** to classify the Service Delivery Location.
        iv. **SHOULD** contain exactly one [1..1] **addr**.
        v. **SHOULD** contain exactly one [1..1] **telecom**.
        vi. **SHALL** contain exactly one [1..1] **playingEntity**.
            1. This playingEntity **SHALL** contain exactly one [1.1] **@classCode**="PLC" Place (2.16.840.1.113883.5.41.
            2. This playingEntity **SHALL** contain exactly one [1..1] **name**.

Figure 2.27 Encounters Entry Example

```
<encounter classCode='ENC' moodCode='APT|ARQ|EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.14'/>
 <templateId root='2.16.840.1.113883.10.20.1.21'/>
 <templateId root='2.16.840.1.113883.10.20.1.25'/>
 <id root='' extension=''/>
 <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActEncounterCode' />
 <text><reference value='#xxx'/></text>
 <effectiveTime>
   <low value=''/>
   <high value=''/>
 </effectiveTime>
 <priorityCode code=''/>
 <performer typeCode='PRF'>
```

```
   <time><low value=''/><high value=''/></time>
   <assignedEntity>...</assignedEntity>
 </performer>
 <author />
 <informant />
 <participant typeCode='LOC'>
   <participantRole classCode='SDLOC'>
     <id/>
     <code/>
     <addr>...</addr>
     <telecom value='' use=''/>
     <playingEntity classCode='PLC' determinerCode='INST'>
       <name></name>
     </playingEntity>
   </participantRole>
 </participant>
</encounter>
```

2.5.4.5 Medications Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7

This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

This section makes use of the linking, severity and instruction entries.

Medications are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed.

This profile identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. Table 2-27 Medication Fields identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

Standards

Pharmacy	HL7 Pharmacy Domain (Normative)
CCD	ASTM/HL7 Continuity of Care Document

Table 2-22 Medications Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	substanceAdministration[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.7']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.7
	@root	1..1	SHALL		See conformance statement below for a list of appropriate templateIds.
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.24
	id	1..*	SHALL	II	
	code	0..1	MAY	CD	
	text	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

Name	XPath	Card.	Verb	Data Type	Fixed Value
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Medication Date/Time	effectiveTime	0..1	SHOULD	IVL<TS>	
	@xsi:type	1..1	SHALL		IVL_TS
Medication Start Date	low	1..1	SHALL	TS	
Medication Stop Date	high	1..1	SHALL	TS	
Administration Timing (Frequency)	effectiveTime	0..1	SHOULD	TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS	
	@operator	1..1	SHALL		A
Route	routeCode	0..1	SHOULD	CE	2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set) PHIN VADS link
Site of Medication Administration	approach SiteCode	0..1	MAY	SET<CD>	2.16.840.1.114222.4.11.3370 (Administrative Site) PHIN VADS link
	code	0..1	MAY		
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
Dose	doseQuantity	0..1	SHOULD	IVL<PQ>	
	low	1..1	SHALL		
	@value	1..1	SHALL		
	high	1..1	SHALL		
	@value	1..1	SHALL		
	@unit	0..1	SHOULD		2.16.840.1.113883.11.12839 (HL7 UnitsOfMeasureCaseSensitive)
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	translation	0..*	SHOULD	SET<PQR>	
Rate	rateQuantity	0..1	MAY	IVL<PQ>	
	low	1..1	SHALL		
	@value	1..1	SHALL		
	high	1..1	SHALL		
	@value	1..1	SHALL		
	@unit	0..1	SHALL		2.16.840.1.113883.11.12839 (HL7 UnitsOfMeasureCaseSensitive)
	consumable	1..1	SHALL		

Name	XPath	Card.	Verb	Data Type	Fixed Value
Prescription Activity	entry Relationship	0..*	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
Dosing	entry Relationship	0..*	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	sequenceNumber	1..*	SHALL		
Patient Instructions	entry Relationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		true
Reasons for Use	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	precondition	0..*	MAY		
	text	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="SBADM" Substance Administration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 **STATIC** 2011-04-03.
    a. The general model is to record each prescribed medication in a <substanceAdministration> intent (**moodCode**='INT').
    b. Medications that have been reported by the patient or administered (instead of prescribed), are recorded in the same element, except that this is now an event (**moodCode**='EVN').
3. **SHALL** contain exactly two [3..3] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.7".
    b. **SHALL** conform to CCD Medication Activity template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.24".
    c. **SHALL** contain exactly one [1..1] **@root** which **SHALL** be selected from the values in Table 2-23 Substance Administration.

Table 2-23 Substance Administration

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.8	A <substanceAdministration> act that records tapered dose information in subordinate <substanceAdministration> act.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.10	A <substanceAdministration> act that records conditional dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

d. The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see below). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element. There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. A chemotherapy regimen is an example in which the information could be represented through the subordinate elements. When the dosage changes, then additional entries are required for each differing dosage. The last case deals with combination medications.

Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1

This template identifier is used to identify medication administration events that do not require any special processing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. Medications that use this template identifier shall not use subordinate <substanceAdministation> acts.

Tapered Doses 1.3.6.1.4.1.19376.1.5.3.1.4.8

This template identifier is used to identify medication administration events that require special processing to handle tapered dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A tapered dose is often used for certain medications where abrupt termination of the medication can have negative consequences. Tapered dosages may be done by adjusting the dose frequency, the dose amount, or both.

When merely the dose frequency is adjusted, (e.g., Prednisone 5mg b.i.d. for three days, then 5mg. daily for three days, and then 5mg every other day), then only one medication entry is needed, multiple frequency specifications recorded in <effectiveTime> elements. When the dose varies (e.g., Prednisone 15mg daily for three days, then 10

mg daily for three days, the 5 mg daily for three days), subordinate medication entries should be created for each distinct dosage.

Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).

In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

Conditional Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.10

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A conditional dose is often used when the dose amount differs based on some measurement (e.g., an insulin sliding scale dose based on blood sugar level). In this case a subordinate <substanceAdministration> entry is required for each different dose, and the condition should be recorded.

Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units.

In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail"), in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

4. **SHALL** contain at least one [1..*] **id**.
5. **MAY** contain zero or one [0..1] **code**.

a. The **code** element is used to supply a code that describes the <substanceAdminstration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in CPT-4 (and often used for billing), or may describe the method of medication administration, such as by intravenous injection. The type of medication is coded in the consumable; do not supply the code for the medication in this element. This element is optional.
b. If patient is either not on medications, or medications are unknown, **code SHALL** be one of the following values from CodeSystem SNOMEDCT 2.16.840.1.113883.6.96 **DYNAMIC**:

Table 2-24 List of values for Indicating Lack of Medication Information

Entry Type	Code	Display Name	Description
Medication	182904002	Drug Treatment Unknown	To indicate lack of knowledge about drug therapy
Medication	182849000	No Drug Therapy Prescribed	To indicate the absence of any prescribed medications
Medication	408350003	Patient Not On Self-Medications	To indicate no treatment

6. **SHOULD** contain zero or one [0..1] **text**.
   a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
      i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
7. **SHALL** contain exactly one [1..1] **statusCode="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
8. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
   a. **SHALL** contain exactly one [1..1] **@xsi:type**, where the **@code**="IVL_TS".
      i. This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems.
   b. **SHALL** contain exactly one [1..1] **low** to represent the start time for the medication.
      i. If the low value is unknown, **@nullFlavor SHALL** be "UNK".
   c. **SHALL** contain exactly one [1..1] **high** to represent the stop time for the medication**.** The high value records the end of the medication regime according to the information provided in the prescription or order.
      i. If the high value is unknown, **@nullFlavor SHALL** be "UNK".
   d. Example: if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later then the <low> value. The rationale is that a provider, seeing an un-refilled prescription would normally assume that the medication is no longer being taken, even if the intent of the treatment plan is to continue the medication indefinitely.
9. **SHOULD** contain zero or one [0..1] **effectiveTime** to record the frequency of administration, such that it
   a. **SHALL** contain exactly one [1..1] **@xsi:type**="TS", "PIVL_TS", "EIVL_TS", "PIVL_PPD_TS", or "SXPR_TS".

b. **SHALL** contain exactly one [1..1] `@operator="A"`.
c. **MAY** be selected from the list of frequency expressions that appear in Table 2-25 below.

Table 2-25 Specifying Medication Frequency

Freq	Description	XML Representation
b.i.d.	Twice a day	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'><period value='12' unit='h' /></effectiveTime>
q12h	Every 12 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'><period value='12' unit='h' /></effectiveTime>
Once	Once, on 2005-09-01 at 1:18am.	<effectiveTime xsi:type='TS' value='200509010118'/>
t.i.d.	Three times a day, at times determined by the person administering the medication.	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'><period value='8' unit='h' /></effectiveTime>
q8h	Every 8 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'><period value='8' unit='h' /></effectiveTime>
qam	In the morning	<effectiveTime xsi:type='EIVL' operator='A'><event code='ACM'/></effectiveTime>
	Every day at 8 in the morning for 10 minutes	<effectiveTime xsi:type='PIVL_TS' operator='A'><phase><low value="198701010800" inclusive="true"/><width value="10" unit="min"/></phase><period value='1' unit='d'/></effectiveTime>
q4-6h	Every 4 to 6 hours.	<effectiveTime xsi:type='PIVL_PPD_TS' institutionSpecified='false' operator='A'><period value='5' unit='h' /><standardDeviation value='1' unit='h'></effectiveTime>

d. The last frequency specification is about as bad as it gets, but can still be represented accurately within the HL7 V3 datatypes. The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the difference between the high and low values, with an unspecified distribution. The type attribute of the <effectiveTime> element describes the kind of frequency specification it contains. More detail is given for each type in the table below.

Table 2-26 Data types used in Frequency Specifications

xsi:type	Description
TS	An xsi:type of TS represents a single point in time, and is the simplest of all to represent. The value attribute of the <effectiveTime> element specifies the point in time in HL7 date-time format (CCYYMMDDHHMMSS)
PIVL_TS	An xsi:type of PIVL_TS is the most commonly used, representing a periodic interval of time. The <low> element of <phase> may be present. If so it specifies the starting point, and only the lower order components of this value are relevant with respect to the <period>. The <width> element represents the duration of the dose administration (e.g., for IV administration). The <period> indicates how often the dose is given. Legal values for the unit attribute of <period> are s, min, h, d, wk and mo representing seconds, minutes, hours, days, weeks, and months respectively.

xsi:type	Description
EIVL_TS	An xsi:type of EIVL_TS represents an event based time interval, where the event is not a precise time, but is often used for timing purposes (e.g., with meals, between meals, before breakfast, before sleep). Refer to the HL7 TimingEvent vocabulary for the codes to use for the <event> element. This interval may specify an <offset> which provides information about the time offset from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10' unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.
PIVL_PPD_TS	An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same.
SXPR_TS	An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g., to intersect or form the union of two sets).

10. **SHOULD** contain zero or one [0..1] **routeCode**, where the **@code SHALL** be selected from ValueSet `Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7` **DYNAMIC.**
11. **MAY** contain zero or one [0..1] **approachSiteCode** that describes the site of medication administration, where the **@code MAY** be coded to a controlled vocabulary that lists such sites.
    a. **SHOULD** be selected from one of the following:
        i. ValueSet `Administrative Site 2.16.840.1.114222.4.11.3370` **DYNAMIC.**
        ii. CodeSystem `SNOMEDCT 2.16.840.1.113883.6.96` **DYNAMIC.**
    b. **SHOULD** contain zero or one [0..1] **originalText.**
        i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
            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).
12. **SHOULD** contain zero or one [0..1] **doseQuantity** such that it
    a. **SHALL** contain exactly one [1..1] **low.**
        i. This code **SHOULD** contain zero or one [0..1] **originalText**.
            1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
                a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
        ii. This code **SHOULD** contain zero or more [0..*] **translation**.
    b. **SHALL** contain exactly one [1..1] **high.**
        i. This code **SHOULD** contain zero or one [0..1] **originalText**.
            1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.

a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

ii. This code **SHOULD** contain zero or more [0..*] **translation**.

c. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the low and high bounds are specified in their respective elements, otherwise both low and high have the same value.

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

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

13. **MAY** contain zero or one [0..1] **rateQuantity**.
    a. **SHALL** contain exactly one [1..1] **low.**
    b. **SHALL** contain exactly one [1..1] **high.**
    c. If a rate range is given then the low and high bounds are specified in their respective elements, otherwise they contain same value.
    d. The rate is given in units that have measure over time. In this case, the units should be specified as a string made up of a unit of measure, followed by a slash (/), followed by a time unit (s, min, h or d).
    e. The **rateQuantity**, if present, **SHALL** contain exactly one [1..1] **@unit**, which **SHALL** be selected from ValueSet HL7 UnitsOfMeasureCaseSensitive 2.16.840.1.113883.11.12839 **DYNAMIC**.
14. **SHALL** contain exactly one [1..1] **consumable**.
    a. This consumable **SHALL** contain exactly one [1..1] **Product Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.7.2).
15. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] Supply Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) for related prescription activity.
16. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **MAY** contain one or more [1..*] related components, either to handle split, tapered or conditional dosing, or to support combination medications.
    c. **MAY** contain zero or more [0..*] **sequenceNumber.**
        i. The value of the sequenceNumber **SHALL** be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component.
        ii. Components **SHALL** be sent in sequenceNumber order.
17. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" True

c. **SHALL** contain exactly one [1..1] `Patient Medication Instructions (1.3.6.1.4.1.19376.1.5.3.1.4.3)`. Instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, etc.).

18. **MAY** contain zero or one [0..1] **`entryRelationship`** such that it
    a. **SHALL** contain exactly one [1..1] **`@typeCode`**`="RSON"` Reason (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002`).
    b. **SHALL** identify the concern that was the reason for the medication use.
    c. **SHALL** contain exactly one [1..1] `Internal Reference (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)`.
        i. The extension and root of each observation **SHALL** match the identifier of a concern entry contained elsewhere in the CDA document.
        ii. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.

19. **MAY** contain zero or one [0..1] **`precondition`**
    a. The value attribute of the <reference> element **SHALL** be a URL that points to the CDA narrative describing those preconditions.

Table 2-27 Medication Fields

Field	Opt	CDA Tag	Description
Start and Stop Date	R2	<effectiveTime>	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown).
Frequency	R2	<effectiveTime>	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening. The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used, these may be found in subordinate <substanceAdministration> elements.
Route	R2	<routeCode>	The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
Dose	R2	<doseQuantity>	The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified, no units are specified. It may be a range.
Site	O	<approachSiteCode>	The site where the medication is administered, usually used with IV or topical drugs.
Rate	R2	<rateQuantity>	The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.

Product	R[1]	<consumable> <name> </consumable>	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
Strength	R2	<consumable> <code> <originalText/> </code> </consumable>	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text.Note: Due to restrictions of the CDA schema, there is no way to separately record the strength.
Code	R2	<consumable> <code/> </consumable>	A code describing the product from a controlled vocabulary, such as RxNorm, First DataBank, et cetera.
Instructions	R2	<entryRelationship>	A place to put free text comments to support additional relevant information, or to deal with specialized dosing instructions. For example, "take with food", or tapered dosing.
Indication	O	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

Figure 2.28 Medication Example

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
   <templateId root='2.16.840.1.113883.10.20.1.24'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
   <templateId root=''/>
   <id root='' extension=''/>
   <code code='' codeSystem='' displayName='' codeSystemName=''/>
   <text><reference value='#med-1'/></text>
   <statusCode code='completed'/>
   <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
   </effectiveTime>
   <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
   </effectiveTime>
   <routeCode code='' codeSystem='' displayName='' codeSystemName=''/>
   <doseQuantity value='' unit=''/>
   <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''/>
   <rateQuantity value='' unit=''/>
   <consumable>
    :
    .
   </consumable>
   <!-- 0..* entries describing the components -->
   <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
   </entryRelationship>
   <!-- An optional entry relationship that indicates the the reason for use -->
   <entryRelationship typeCode='RSON'>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
        <id root='' extension=''/>
      </act>
   </entryRelationship>
   <!-- An optional entry relationship that provides prescription activity -->
```

```
   <entryRelationship typeCode='REFR'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
   </entryRelationship>
   <precondition>
      <criterion>
        <text><reference value=''></text>
      </criterion>
   </precondition>
</substanceAdministation>
```

2.5.4.6 Payer Entry 1.3.6.1.4.1.19376.1.5.3.1.4.18

The payer entry allows information about the patient's sources of payment to be recorded.

Standards

CCD ASTM/HL7 Continuity of Care Document

Table 2-28 Payer Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	act[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.18']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.18
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.26
	id	1..*	SHALL	II	
	code	0..1	SHOULD	CD	
Payer Type	code	0..1	SHOULD	CE	2.16.840.1.114222.4.11.3591 (Source of Payment Typology) PHIN VADS link OR 2.16.840.1.113883.6.255.1336 (X12 Data Element 1336 Insurance Type Code)
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Payer	performer	1..1	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7ParticipationType) = PRF
	assignedEntity	1..1	SHALL		
	id	0..*	SHOULD	II	
	code	1..1	SHALL	CE	
	code	1..1	SHALL	CE	2.16.840.1.113883.1.11.10416 (FinanciallyResponsiblePartyType) = PAYOR|GUAR|PAT
	addr	1..1	SHALL	SET<AD>	

Name	XPath	Card.	Verb	Data Type	Fixed Value
	telecom	1..1	SHALL	SET<TEL>	
	representedOrganization	1..1	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7ParticipationType)= ORG
Payer Organization Name	name	1..1	SHALL	PN	
Patient Information	participant	1..1	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7ParticipationType) = COV
	participantRole	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.110 (HL7RoleClass) = PAT
	id	0..1	SHOULD	II	
	code	1..1	SHALL	CE	
Patient's Relationship to Subscriber	code	1..1	SHOULD		2.16.840.1.113883.1.11.18877 (HL7 Coverage Role Type)
	addr	0..1	SHOULD	SET<AD>	
	telecom	0..1	SHOULD	SET<TEL>	
	playingEntity	0..1	SHOULD		
	name	0..1	SHOULD	PN	
Subscriber Information	participant	0..1	SHOULD		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7ParticipationType) = HLD
	participantRole	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7ParticipationType) = IND
Subscriber ID	id	1..1	SHALL	II	
	addr	1..1	SHALL	SET<AD>	
	telecom	1..1	SHALL	SET<TEL>	
	playingEntity	1..1	SHALL		
Subscriber Name	name	1..1	SHALL	PN	
Health Plan Information	entryRelationship	0..*	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT

Name	XPath	Card.	Verb	Data Type	Fixed Value
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = DEF
Health Plan Identifier	id	1..1	SHALL	II	
	text	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.18".
    b. **SHALL** conform to CCD Policy Activity template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.26".
4. **SHALL** contain at least one [1..*] **id**.
    a. This id represents the policy or group number of the coverage. That identifier shall appear in the extension attribute.
5. **SHOULD** contain zero or one [0..1] **code**.
    a. The code, if present, **SHOULD** be selected from one of the following ValueSets:
        i. ValueSet Source of Payment Typology 2.16.840.1.113883.221.5 **DYNAMIC**
        ii. ValueSet HL7 ActCoverageType 2.16.840.1.113883.5.4 **DYNAMIC**
        iii. ValueSet X12 Data Element 1336 2.16.840.1.113883.6.255.1336 **DYNAMIC**
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
7. **SHALL** contain exactly one [1..1] **performer** such that it
    a. represents the Payer of the coverage.
    b. **SHALL** contain exactly one [1..1] **@typeCode**="PRF" Performer (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90).
    c. **SHALL** contain exactly one [1..1] **assignedEntity**.
        i. This assignedEntity **SHOULD** contain zero or more [0..*] **id**.
        ii. This assignedEntity **SHALL** contain exactly one [1..1] **code**.
            1. The code **SHALL** contain exactly one [1..1] **code**, where the **@code SHALL** be one of PAYOR|GUAR|PAT from ValueSet HL7FinanciallyResponsiblePartyType 2.16.840.1.113883.1.11.10416 **DYNAMIC**.
        iii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** to record the address of the payer.

iv. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** to record the phone number of the payer.
v. This assignedEntity **SHALL** contain exactly one [1..1] **representedOrganization** such that
1. **SHALL** contain exactly one [1..1] **@typeCode**="ORG" (CodeSystem: HL7 ParticipationType 2.16.840.1.113883.5.90).
2. **SHALL** contain exactly one [1..1] **name**.

8. **SHALL** contain exactly one [1..1] **participant** to provide information about the patient with respect to the policy or program, such that it
a. **SHALL** contain exactly one [1..1] **@typeCode**="COV" Coverage target (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90).
b. **SHALL** contain exactly one [1..1] **participantRole**.
i. This participantRole **SHALL** be present when the patient is a member of a policy or program.
ii. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="PAT" Patient (CodeSystem: RoleClass 2.16.840.1.113883.5.110).
iii. This participantRole **SHOULD** contain zero or more [0..*] **id**.
1. This participantRole **SHALL** contain exactly one [1..1] **code** which **SHOULD** be selected from ValueSet Coverage Role Type ValueSet 2.16.840.1.113883.1.11.18877 **DYNAMIC**.
iv. This participantRole **SHOULD** contain zero or one [0..1] **addr** when different from that recorded in the **patientRole** element**.**
v. This participantRole contain zero or one [0..1] **telecom** when different from that recorded in the **patientRole** element**.**
vi. This participantRole **SHOULD** contain zero or one [0..1] **playingEntity** such that it
1. **SHOULD** contain exactly one [0..1] **name** to record member name when it is different from that recorded in the **patient** element.

9. **SHOULD** contain zero or one [0..1] **participant** such that it
a. **SHALL** contain exactly one [1..1] **@typeCode**="HLD" Holder (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) when the subscriber is different from the patient.
b. **SHALL** contain exactly one [1..1] **participantRole** when the subscriber is different from the patient.
i. This participantRole **SHALL** contain at least one [1..*] **id**.
1. This id is a unique identifier for the subscriber of the coverage when the subscriber is not the patient.
ii. **SHALL** contain exactly one [1..1] **@classCode**="IND" Indirect (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) when the subscriber is different from the patient.
iii. This participantRole **SHALL** contain exactly one [1..1] **addr**.
iv. This participantRole **SHALL** contain exactly one [1..1] **telecom.**
v. This participantRole **SHALL** contain exactly one [1..1] **playingEntity**.

a. The playingEntity **SHALL** contain exactly one [1..1] **name** to record the name of the subscriber if it is not the patient.

10. **MAY** contain zero or more [0..*] **entryRelationship** to record plan information such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
    c. **SHALL** contain exactly one [1..1] **@moodCode**="DEF" (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
    d. **SHALL** contain exactly one [1..1] **id** to record the health plan identifier.
    e. **SHOULD** contain zero or one [0..1] **text.**
        i. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
            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).

Table 2-29 Payer Type Vocabularies

Vocabulary	Description	OID
Source of Payment Typology	The Public Health Data Standards Consortium Source of Payment Typology provides a standard for reporting payer type. (http://phdsc.org/standards/payment-typology-source.asp)	2.16.840.1.113883.221.5
HL7 ActCoverageType	The HL7 ActCoverageType vocabulary describes payers and programs. Note that HL7 does not have a specific code to identify an individual payer, e.g., in the role of a guarantor or patient.	2.16.840.1.113883.5.4
X12 Data Element 1336	The X12N 271 implementation guide includes various types of payers. This code set does include a code to identify individual payers.	2.16.840.1.113883.6.255.1336

Figure 2.29 Payer Entry Example

```
<act classCode='ACT' moodCode='EVN'>
   <templateId root='2.16.840.1.113883.10.20.1.26'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.18'/>
   <id root='' extension=''/>
   <code code='' displayName='' codeSystem='' codeSystemName=''/>
   <statusCode code='completed'/>
   <performer typeCode='PRF'><!-- payer -->
     <assignedEntity classCode='ASSIGNED'>
      <id root='' extension=''/>
      <code code='PAYOR|GUAR|PAT' displayName=''
        codeSystem='2.16.840.1.113883.5.110' codeSystemName='RoleClass'/>
      <addr></addr>
      <telecom value='' use=''/>
      <representedOrganization typeCode='ORG'>
        <name></name>
      </representedOrganization>
     </assignedEntity>
   </performer>
   <participant typeCode='COV'><!-- member -->
     <participantRole classCode='PAT'>
      <id root='' extension=''/>
      <code code='' displayName=''
```

```
        codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
      <addr></addr>
      <telecom value='' use=''/>
      <playingEntity><name></name></playingEntity>
     </participantRole>
   </participant>
   <participant typeCode='HLD'><!-- subscriber -->
     <participantRole classCode='PAT'>
      <id root='' extension=''/>
      <playingEntity><name></name></playingEntity>
     </participantRole>
   </participant>
   <entryRelationship typeCode='REFR'>
     <act classCode='ACT' moodCode='DEF'>
      <id root='' extension=''/>
      <code code='' displayName='' codeSystem='' codeSystemName=''/>
      <text><reference value=''/></text>
     </act>
   </entryRelationship>
</act>
```

2.5.4.7 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem.

Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

Parent Template

The parent of this template is Concern Entry. This template is compatible with the IHE Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1. and the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27.

Table 2-30 Problem Concern Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	act[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.5.2']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	3..3	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.5.2
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.5.1
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.27
	id	1..1	SHALL	II	
	code	1..1	SHALL	CD	
	@nullFlavor	1..1	SHALL		= NA
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode) = active|suspended|aborted|completed

Name	XPath	Card.	Verb	Data Type	Fixed Value
	effectiveTime	1..1	SHALL	TS or IVL<TS>	
	low	1..1	SHALL	TS	
	high	0..1	SHALL	TS	See conformance statements below for specific conditions
Problem Concern	entryRelationship	1..*	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		=false

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly two [3..3] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5.2".
   b. **SHALL** conform to IHE Concern Entry template and contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5.1".
   c. **SHALL** conform to CCD Problem Act template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.27".
4. **SHALL** contain at least one [1..1] **id**.
5. **SHALL** contain exactly one [1..1] **statusCode**, where the **@code SHALL** be selected from ValueSet ProblemAct statusCode 2.16.840.1.113883.11.20.9.19.
   a. A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation.
6. **SHALL** contain exactly one [1..1] **effectiveTime**.
   a. The effectiveTime element records the starting and ending times during which the concern was active.
   b. This effectiveTime **SHALL** contain exactly one [1..1] **low**.
   c. This effectiveTime **SHALL** contain exactly one [1..1] **high** for concerns in the completed or aborted state and **SHALL NOT** be present otherwise.
7. **SHALL** contain one or more [1..*] **entryRelationship** identifying problems of concern, such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
   b. **SHALL** contain exactly one [1..1] **@inversionInd**="false" False.
   c. **SHALL** contain exactly one [1..1] **Problem Entry** (1.3.6.1.4.1.19376.1.5.3.1.4.5).

Figure 2.30 Problem Concern Entry Example

```
<act classCode='ACT' moodCode='EVN'>
   <templateId root='2.16.840.1.113883.10.20.1.27'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
   <id root=' ' extension=' '/>
   <code nullFlavor='NA'/>
   <statusCode code='active|suspended|aborted|completed'/>
   <effectiveTime>
      <low value=' '/>
      <high value=' '/>
   </effectiveTime>
   <!-- 1..* entry relationships identifying problems of concern -->
   <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
   <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
         :
   </observation>
   </entryRelationship>
   <!-- optional entry relationship providing more information about the concern -->
   <entryRelationship type='REFR'>
   </entryRelationship>
</act>
```

2.5.4.8 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary. An example appears below in the figure below.

Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

Parent Template

This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.28

Table 2-31 Problem Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	observation[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.5']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	0..1	MAY		=false|true
	templateId	2..2	SHALL		

Name	XPath	Card.	Verb	Data Type	Fixed Value
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.5
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.28
	id	1..*	SHALL	II	
Problem Type	code	0..1	SHOULD	CD	2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type)
Problem Description	text	1..1	SHALL	ED	
	reference/@value	0..1	SHOULD		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Problem Date	effectiveTime	0..1	SHOULD	IVL<TS>	
	@low	1..1	SHALL		
	@high	1..1	SHALL		
Problem Code	value	1..1	SHALL	CD	See conformance statement below
	originalText	1..1	SHALL		
	reference/@value	1..1	SHALL		
Severity	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		=true
Clinical Status	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	@inversionInd	1..1	SHALL		=false
Health Status	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	@inversionInd	1..1	SHALL		=false
	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	@inversionInd	1..1	SHALL		=false
Comments	entryRelationship	0..*	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		=true

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).

2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **MAY** contain zero or one [0..1] **@negationInd**.
    a. **negationInd**="true" **SHALL** be used to represent that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed).
    b. The value of **negationInd** should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations, or which do not allow the negation to be recorded with post-coordinated coded terminology.
4. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5".
    b. **SHALL** conform to CCD Problem Observation template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.28".
5. **SHALL** contain at least one [1..*] **id**.
    a. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>).
6. **SHOULD** contain zero or one [0..1] **code**, where the **@code SHOULD** be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 **STATIC** 2008-12-18.
    a. The <code> describes the process of establishing a problem. The code element should be used as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom).
    b. When a physical exam observation is being recorded the code used should be “Finding.”
    c. When a review of systems observation is being recorded the code used should be “Symptom.”
7. **SHALL** contain exactly one [1..1] **text**.
    a. The text **SHOULD** contain zero or one [0..1] **reference/@value**.
        i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
8. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
9. **SHOULD** contain zero or one [0..1] **effectiveTime** to record the time interval over which the <observation> is known to be true.
    a. The **low** value of the **effectiveTime** element, when known, **SHALL** be used to record the earliest point for which the condition is known to have existed.
    b. The **high** value of the **effectiveTime** element, when present, **SHALL** be used to record the time at which the observation was no longer known to be true.

c. The ***implication*** is made that if the **high** value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the **low** value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the **low** and **high** values may represent only an approximation of the true onset and resolution (respectively) times.

i. For example, it may be the case that onset occurred prior to the **low** value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The **low** value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the **effectiveTime** element shall have a **low** element with a nullFlavor attribute set to 'UNK'. The **high** value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).

10. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD" to record the condition that was found, where the **@code** should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others.
    a. The table below is an incomplete listing of acceptable values for the codeSystem attribute, along with the codeSystemName:

Table 2-32 List of controlled Vocabularies

CodeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnoses)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.

    b. **SHOULD** be selected from ValueSet Problem List HITSP (based upon SNOMEDCT) 2.16.840.1.113883.3.88.12.3221.7.4 **DYNAMIC** (PHIN VADS link).
    c. If uncoded, all attributes other than **xsi:type**="CD" must be absent.
    d. In cases where information about a problem or allergy is unknown or where there are no problems or allergies, an entry **SHALL** use codes from Table 2-33 below to record this fact.

Table 2-33 List of Values to Represent Lack of Problem Information

Entry Type	Code	Display Name	Description
Problem	396782006	Past Medical History Unknown	To indicate unknown medical history
Problem	407559004	Family History Unknown	To indicate that the patient's family history is not known.

Entry Type	Code	Display Name	Description
Problem	160243008	No Significant Medical History	To indicate no relevant medical history
Problem	160245001	No current problems or disability	To indicate that the patient has no current problems (as distinct from **no history**).
Allergy	409137002	No Known Drug Allergies	To indicate that there are no known **Drug** allergies for this patient.
Allergy	160244002	No Known Allergies	To indicate that there are no known allergies for this patient.
Allergy	64970000	Substance Type Unknown	To indicate the state where there is a known allergy or intollerance to an unknown substance

11. **SHALL** contain exactly one [1..1] **originalText** such that
    a. The **reference/@value SHALL** link the coded value to the problem narrative text (minus any dates, comments, et cetera).
        i. The **reference/@value SHALL** contain a URI in value attribute. This URI points to the free text description of the problem in the CDA document.
12. **MAY** contain zero or one [0..1] **entryRelationship** indicating the severity of the problem, such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" True.
    c. **SHALL** contain exactly one [1..1] Severity Entry (1.3.6.1.4.1.19376.1.5.3.1.4.1).
13. **MAY** contain zero or one [0..1] **entryRelationship** indicating the clinical status of the problem, e.g., resolved, in remission, active, such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="false" False.
    c. **SHALL** contain exactly one [1..1] Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1).
14. **MAY** contain zero or one [0..1] **entryRelationship** referencing the health status of the patient, e.g., alive and well, symptom free, chronically ill, disabled, , such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="false" False.
    c. **SHALL** contain exactly one [1..1] Health Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.2.
15. **MAY** contain zero or many [0..*] **entryRelationships** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. contain exactly one [1..1] **@inversionInd**="true" True.
    c. **SHALL** contain exactly one [1..1] Comments template (1.3.6.1.4.1.19376.1.5.3.1.4.2).

Figure 2.31 Problem Entry Example

```
<observation classCode='OBS' moodCode='EVN' negationInd=' false|true '>
 <templateId root='2.16.840.1.113883.10.20.1.28'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' '
   codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
 <text><reference value=' '/></text>
 <statusCode code='completed'/>
 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>
 <value xsi:type='CD' code=' '
   codeSystem=' ' displayName=' ' codeSystemName=' '>
   <originalText><reference value=' '/></originalText>
 </value>
 <
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      identifying the health status of concern -->
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      containing clinical status -->
 <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'> elements
      containing comments -->
</observation>
```

2.5.4.9 Procedure Activity 2.16.840.1.113883.10.20.1.29

Standards

CCD ASTM/HL7 Continuity of Care Document

Table 2-34 Procedure Activity Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	procedure[templateId/@root = '2.16.840.1.113883.10.20.1.29']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = ACT|OBS|PROC
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (MoodCode)= EVN|INT
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.29
Procedure ID	id	1..*	SHALL	II	
Procedure Type	code	1..1	SHALL	CD	

	code	1..1	SHOULD		2.16.840.1.113883.6.1 (LOINC) OR 2.16.840.1.113883.6.96 (SNOMED CT) OR 2.16.840.1.113883.6.12 (CPT-4) OR 2.16.840.1.113883.6.104 (ICD9 Procedures) OR 2.16.840.1.113883.6.4 (ICD10 Procedure Coding System)
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.1.11.20.15 (ProcedureStatusCode)
Procedure DateTime	effectiveTime	1..1	SHOULD	TS or IVL<TS>	
	methodCode	1..*	MAY	SET<CD>	
Body Site	targetSiteCode	1..*	MAY	SET<CD>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site (SNOMED CT)) PHIN VADS link
	participant	1..*	MAY		templateId 2.16.840.1.113883.10.20.1.45
	Performer	1..*	MAY		
Reason for Procedure	entryRelationship	1..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
Patient Age	entryRelationship	1..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
Medications	entryRelationship	1..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT|OBS|PROC" Act|Observation|Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN", which **SHALL** be selected from ValueSet MoodCode 2.16.840.1.113883.5.1001 **STATIC** 2011-04-03.
3. **SHALL** contain exactly [1..1] **templateId** 2.16.840.1.113883.10.20.1.29.
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code**.
    a. This code in a Procedure Activity Entry **SHOULD** be selected from one of the following CodeSystems:
        i. CodeSystem LOINC 2.16.840.1.113883.6.1 **DYNAMIC**

ii. `CodeSystem Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) 2.16.840.1.113883.6.96` **DYNAMIC**

b. And **MAY** be selected from one of the three CodeSystems:

i. `CodeSystem CPT-4 2.16.840.1.113883.6.12` **DYNAMIC**

ii. `CodeSystem ICD-9 Procedures 2.16.840.1.113883.6.104` **DYNAMIC**

iii. `CodeSystem ICD-10 Procedure Coding System 2.16.840.1.113883.6.4` **DYNAMIC**

6. **SHALL** contain exactly one [1..1] **statusCode** which **SHALL** be selected from ValueSet `ProcedureStatusCode 2.16.840.1.113883.1.11.20.15` **STATIC** 2006-10-17.
7. **SHOULD** contain exactly one [1..1] **effectiveTime.**
8. **MAY** contain one or more [1..*] **methodCode** if the method isn't inherent in [Observation | Procedure] / code or if there is a need to further specialize the method in [Observation | Procedure] / code.
    a. The **methodCode SHALL NOT** conflict with the method inherent in [Observation | Procedure] / code.
9. **MAY** contain one or more [1..*] **targetSiteCode** to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in [Observation | Procedure] / code or if there is a need to further specialize the site [Observation | Procedure] / code**.**
    a. **SHALL** contain exactly one [1..1] **@code** which **SHOULD** be selected from ValueSet: `BodySite(SNOMED CT) 2.16.840.1.113883.3.88.12.3221.8.9` **DYNAMIC**.
    b. The **targetSiteCode SHALL NOT** conflict with the site inherent in [Observation | Procedure] / code.
10. **MAY** contain one or more [1..*] location participations (templateId 2.16.840.1.113883.10.20.1.45) (see CCD section 3.15.2.2 Encounter location), to represent where the procedure was performed.
11. **MAY** contain one or more [1..*] **performer** to represent those practitioners who performed the procedure**.**
12. **MAY** contain exactly one [1..1] **entryRelationship** which represents the indication or reason for the procedure, such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" .
    b. **SHALL** have a target of **problem act** (templateId `2.16.840.1.113883.10.20.1.27`), **problem observation** (templateId `2.16.840.1.113883.10.20.1.28`), or some other clinical statement.
13. **MAY** contain one or more [1..*] **patient instructions** (templateId `2.16.840.1.113883.10.20.1.49)` (see CCD section 3.9.2.2.2 Patient instructions), to represent any additional information provided to a patient related to the procedure.
14. **MAY** contain one or more [1..*] associated consents represented in the CCD Header as **ClinicalDocument/authorization/consent**.
15. Within a procedure activity, a procedure **MAY** contain one or more [1..*] **specimen** reflecting the specimens that were obtained as part of the procedure.

a. The **procedure/specimenRole/id SHOULD** be set to equal an **Organizer/specimen/specimenRole/id** to indicate that the Procedure and the Results are referring to the same specimen (see CCD section 3.13 Results).

16. **MAY** contain exactly one [1..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002.
    b. **SHALL** contain exactly one [1..1] Age Observation (2.16.840.1.113883.10.20.1.38).
    c. **MAY** contain exactly one [1..1] **@inversionInd** to distinguish relationship source vs. target.
17. **MAY** contain exactly one [1..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. Its target is a medication activity (templateId 2.16.840.1.113883.10.20.1.24) (see CCD section 3.9.2.1.1 Medication activity), to describe substances administered during the procedure.
18. A procedure activity **SHALL** contain one or more [1..*] sources of information, as defined in CCD section 5.2 Source.

Figure 2.32 Procedure Activity Example

```
<entry typeCode="DRIV">
  <procedure classCode="PROC" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.29"/>
        <id root=" "/>
        <code code="52734007" codeSystem="2.16.840.1.113883.6.96" displayName="Total hip
replacement">
                <originalText><reference value="#Proc1"/></originalText>
                <qualifier>
                <name code="272741003" displayName="Laterality"/>
                <value code="7771000" displayName="Left"/>
                </qualifier>
        </code>
        <statusCode code="completed"/>
        <effectiveTime value=" "/>
        <participant typeCode="DEV">
                <participantRole classCode="MANU">
                </participantRole>
        </participant>
  </procedure>
</entry>
```

2.5.4.10 Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19

The procedure entry is used to record procedures that have occurred, or which are planned for in the future.

Standards

CCD	ASTM/HL7 Continuity of Care Document

Table 2-35 Procedure Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	procedure[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.19']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = PROC
	@moodCode	1..1	SHALL		2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)= 'EVN|INT'
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.19
	@root	1..1	SHALL		See conformance statements below for instructions
Procedure ID	id	1..*	SHALL	II	
Procedure Type	Code	1..1	SHALL	CD	
	Code	1..1	SHOULD		2.16.840.1.114222.4.11.3204 (Non-Laboratory Intervention and Procedure (SNOMED CT)) PHIN VADS link OR 2.16.840.1.113883.6.104 (International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) – Volume 3 procedures) CDC NCHS Website OR 2.16.840.1.113883.6.12 (Current Procedure Terminology 4 (CPT-4)) AMA website link OR 2.16.840.1.113883.6.1 (LOINC) OR 2.16.840.1.113883.6.4 (ICD10 Procedure Coding System)
Procedure Description	text	1..1	SHALL	ED	
	reference/@value	1..1	SHALL		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode)= completed|active|aborted|cancelled
Procedure DateTime	effectiveTime	0..1	SHOULD	TS or IVL<TS>	
	priorityCode	0..1	MAY	CE	2.16.840.1.113883.1.11.16866 (ActPriority)
	approachSiteCode	0..1	MAY	SET<CD>	

Name	XPath	Card.	Verb	Data Type	Fixed Value
Body Site of Procedure	targetSiteCode	0..*	MAY	SET<CD>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site (SNOMED CT)
Related Encounter	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	@inversionInd	1..1	SHALL		true
Reason for Procedure	entryRelationship	0..1	MAY		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN|INT", which **SHALL** be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 **STATIC** 2011-04-03.
3. **SHALL** contain exactly two [2..2] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.19".
    b. When the procedure is in event mood (**moodCode**="EVN"), this entry **SHALL** conform to the CCD template 2.16.840.1.113883.10.20.1.29.
    c. When the procedure is in intent mood (**moodCode**="INT"), this entry **SHALL** conform to the CCD template 2.16.840.1.113883.10.20.1.25.
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code**.
    a. This code in a procedure entry **SHOULD** be selected from one of the following:
        i. ValueSet Non-Laboratory Intervention and Procedure(SNOMEDCT) 2.16.840.1.114222.4.11.3204 **DYNAMIC**
        ii. CodeSystem International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) – Volume 3 procedures 2.16.840.1.113883.6.104 **DYNAMIC**
        iii. CodeSystem Current Procedure Terminology 4 (CPT-4) 2.16.840.1.113883.6.12 **DYNAMIC**
        iv. CodeSystem LOINC 2.16.840.1.113883.6.1 **DYNAMIC**
        v. CodeSystem ICD-10 Procedure Coding System 2.16.840.1.113883.6.4 **DYNAMIC**
    b. This code **SHALL** contain exactly one [1..1] **text**
        i. **SHALL** contain exactly one [1..1] **reference/@value**.
            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).
6. **SHALL** contain exactly one [1..1] **statusCode**=completed|active|aborted|cancelled.

a. **SHALL** have the value `'completed'` for procedures that have been completed.

b. **SHALL** have the value `'active'` for procedures that are still in progress.

c. **SHALL** have the value `'aborted'` for procedures that were stopped prior to completion.

d. **SHALL** have the value `'cancelled'` for procedures that were cancelled before being started.

7. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
   a. **SHALL** record the time at which the procedure occurred (in `EVN` mood).
   b. **SHALL** record the desired time of the procedure (in `INT` mood).
8. **MAY** contain zero or one [0..1] **priority code** such that it
   a. **SHALL** contain exactly one [1..1] **priorityCode** when **@moodCode**=`"INT"` and **effectiveTime** is not provided.
   b. **MAY** contain zero or one [0..1] **priorityCode** where the **@code SHALL** be selected from ValueSet `ActPriority 2.16.840.1.113883.1.11.16866` **DYNAMIC**.
9. **MAY** contain zero or one [0..1] **approachSiteCode.**
10. **MAY** contain zero to many [0..*] **targetSiteCode.**
11. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@inversionInd**=`"true"` true.
    b. **SHALL** contain exactly one [1..1] **@typeCode**=`"COMP".`
    c. **SHALL** point to the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.
12. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**=`"RSON"`.
    b. **SHALL** point to the concern that was the reason for the procedure and shall contain an internal reference to the concern.

Figure 2.33 Procedure Entry Example

```
<procedure classCode='PROC' moodCode='EVN|INT'>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
   <templateId root='2.16.840.1.113883.10.20.1.29'/><!-- see text of section 0 -->
   <templateId root='2.16.840.1.113883.10.20.1.25'/><!-- see text of section 0 -->
   <id root='' extension=''/>
   <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
   <text><reference value='#xxx'/></text>
   <statusCode code='completed|active|aborted|cancelled'/>
   <effectiveTime>
      <low value=''/>
      <high value=''/>
   </effectiveTime>
   <priorityCode code=''/>
   <approachSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
   <targetSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
   <entryRelationship typeCode='COMP' inversionInd='true'>
      <act classCode='ACT' moodCode=''>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
         <id root='' extension=''/>
      </act>
   </entryRelationship>
   <entryRelationship typeCode='RSON'>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
        <id root='' extension=''/>
```

```
      </act>
   </entryRelationship>
</procedure>
```

2.5.4.11 Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2

The product entry describes a medication or immunization used in a <substanceAdministration> or <supply> act. It adopts the constraints of the ASTM/HL7 Continuity of Care Document.

Standards

Pharmacy	HL7 Pharmacy Domain (Normative)
CCD	ASTM/HL7 Continuity of Care Document

Table 2-36 Product Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	manufacturedProduct[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2']				
	templateId	2..2	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.7.2
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.53
	manufacturedMaterial	1..1	SHALL		
Coded Product Name	Code	0..1	SHOULD	CE	
	code	0..1	SHOULD		See conformance statement below
Product Name Description	originalText	0..1	SHOULD	ED	
	reference/@value	1..1	SHALL		
Medication Brand Name	name	1..1	SHALL		2.16.840.1.113883.3.88.12.80.16 (Medication Brand Name (RxNorm) PHIN VADS link

Specification

1. **SHALL** contain exactly two [2..2] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.7.2".
   b. **SHALL** conform to CCD Representation of a Product template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.53".
2. **SHALL** contain exactly one [1..1] **manufacturedMaterial** to specify the name and strength of the medication.
   a. This manufacturedMaterial **SHOULD** contain zero or one [0..1] **code**, where the **@code SHALL** be selected from one of the CodeSystems in Table 2-37 Controlled Vocabularies for Medications.
      i. **SHOULD** be the code that represents the generic medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen).

ii. **MAY** be selected from ValueSet `Medication Clinical Drug Name Value Set(RxNorm) 2.16.840.1.113883.3.88.12.80.17` **DYNAMIC** (PHIN VADS link).

iii. This code **SHOULD** contain zero or one [0..1] **originalText**.

1. The originalText, if present, **SHALL** contain exactly one [1..1] **reference/@value**.
    a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
2. Note: When the text is supplied from the narrative, the implication is that if you supply the components of a combination medication in an entry, you must also display these in the narrative text, otherwise you would not be able to break the combination medication down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

b. This manufacturedMaterial **SHALL** contain exactly one [1..1] **name**.

i. This name element **SHOULD** contain the brand name of the medication (or active ingredient in the case of subordinate substanceAdministration elements used to record components of a medication).

ii. **MAY** be selected from ValueSet `Medication Brand Name (RxNorm) 2.16.840.1.113883.3.88.12.80.16` **DYNAMIC**.

Table 2-37 Controlled Vocabularies for Medications

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.88	RxNorm	RxNorm
ValueSet: 2.16.840.1.113883.3.88.12.3221.8.7	ValueSet: Medication Clinical Drug Name Value Set (RxNorm)	Rx Norm Value Set PHIN VADS link
2.16.840.1.113883.6.69	NDC	National Drug Codes
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.59	CVX	CDC Vaccine Codes

Figure 2.34 Product Entry Example

```
<manufacturedProduct>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
  <manufacturedMaterial>
    <code code='' displayName='' codeSystem='' codeSystemName=''>
      <originalText><reference value=''/></originalText>
    </code>
    <name></name>
  </manufacturedMaterial>
</manufacturedProduct>
```

2.5.4.12 Simple Observations 1.3.6.1.4.1.19376.1.5.3.1.4.13

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

Standards

CCD ASTM/HL7 Continuity of Care Document

Table 2-38 Simple Observation Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	observation[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.13']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13
	id	1..*	SHALL	II	
	code	1..1	SHALL	CD	
	text	1..*	SHALL	ED	
	reference /@value	1..*	SHALL		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
Result DateTime	effectiveTime	1..1	SHALL	TS or IVL<TS>	
Result Value	value	1..1	SHALL	ANY	
Result Interpretation	interpretationCode	0..*	MAY	CE	
	methodCode	0..1	MAY	SET<CE>	
	targetSiteCode	0..1	MAY	SET<CD>	
	author	0..1	MAY		
	assignedAuthor	1..1	SHALL		
	classCode	1..1	SHALL		2.16.840.1.113883.5.110 (HL7RoleClass) =ASSIGNED
	id	1..1	SHALL	II	

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).

3. **SHALL** contain exactly one [1..1] **templateId** **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.13".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code.**
    a. For Coded Results, **MAY** be selected from ValueSet Lab Test Result Name (LOINC) 2.16.840.1.114222.4.11.1002.
6. **SHALL** contain at least one [1..0] **text.**
7. **SHALL** contain at least one [1..*] **reference/@value**.
    a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
8. **SHALL** contain exactly one [1..1] **statusCode**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
9. **SHALL** contain exactly one [1..1] **effectiveTime**.
    a. **SHOULD** be precise to the day.
10. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="ANY".
11. **MAY** contain zero or more [0..*] **interpretationCode**.
12. **MAY** contain zero or one [0..1] **methodCode**.
13. **MAY** contain zero or one [0..1] **targetSiteCode**.
14. **MAY** contain zero or one [0..1] **author** such that
    a. The person object including **name** and **id** **SHALL** be included when the author of the observation is not an author of the document.
    b. The author, if present, **SHALL** contain exactly one [1..1] **assignedAuthor.**
    c. The author, if present, **SHALL** contain exactly one [1..1] **@classCode**="ASSIGNED" (CodeSystem: HL7 roleClass 2.16.840.1.113883.5.110).
    d. The author, if present, **SHALL** contain exactly one [1..1] **id** such that it **SHOULD** reference the id of the author in the Header.

Figure 2.35 Simple Observation Example

```
<observation classCode='OBS' moodCode='EVN'>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
   <id root='' extension=''/>
   <code code='' displayName='' codeSystem='' codeSystemName=''/>
   <!-- for CDA -->
   <text><reference value='#xxx'/></text>
   <!-- For HL7 Version 3 Messages
   <text>text</text>
  -->
   <statusCode code='completed'/>
   <effectiveTime value=''/>
   <repeatNumber value=''/>
   <value xsi:type='' …/>
   <interpretationCode code='' codeSystem='' codeSystemName=''/>
   <methodCode code='' codeSystem='' codeSystemName=''/>
   <targetSiteCode code='' codeSystem='' codeSystemName=''/>
   <author typeCode='AUT'>
      <assignedAuthor classCode='ASSIGNED'><id ... /></assignedAuthor><!-- for CDA -->
   </author>
</observation>
```

2.5.4.13 Social History Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.4

A social history observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD. It defines the patient's occupational, personal (e.g., lifestyle), social and environmental history and health risk factors.

Standards

CCD	ASTM/HL7 Continuity of Care Document

Parent Template

The parent of this template is Simple Observation. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.33.

Table 2-39 Social History Observation Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	observation[templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']				
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	3..3	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13.4
	@root	1..1	SHALL		2.16.840.1.113883.10.20.1.33
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13
	id	1..*	SHALL	II	
Social History Type	code	---	SHALL	CD	Further constrained for each required social history observation in this Implementation guide. See below.
	value	---	SHALL	CD	Further constrained for each required social history observation in this Implementation guide. See below.
Social History Description	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly three [3..3] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.13.4".

b. **SHALL** conform to IHE Simple Observation template and contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.13".
c. **SHALL** conform to CCD Social History Observation Template and contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.33".

4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code/@code.** (See specific Social History Further Constraints for observation specific codes).
    a. The code **SHOULD** contain zero or one [0..1] **originalText.**
        i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
            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).
6. **SHALL** contain exactly one [1..1] **value/@value.** (See specific Social History Further Constraints for observation specific codes).
7. **SHALL** contain exactly one [1..1] **statusCode**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

2.5.4.13.1 Social History Further Constraints

The Social History Observation Further Constraints provides the conformance statements and required value sets for three specific Social History observations: Occupation History, Industry History, and Smoking Status.

2.5.4.13.1.1 Occupation History

Table 2-40 Occupation History Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
Occupation	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)=21843-8
	value	1..1	SHALL	CD	
	code	1..1	SHALL		2.16.840.1.114222.4.11.6036 (Census Occupation Codes) PHIN VADS link
Occupation Description	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed

Specification

1. **SHALL** contain exactly one [1..1] **code/@code**="21843-8" Usual Occupation Hx (CodeSystem: LOINC 2.16.840.1.113883.6.1).
2. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD" to record the occupation of the patient, where the **@code SHALL** be selected from ValueSet Census Occupation Codes 2.16.840.1.114222.4.11.6036 **DYNAMIC.**

a. **SHOULD** contain zero or one [0..1] **originalText.**

i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.

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).

3. **SHALL** contain exactly one [1..1] **statusCode**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

Figure 2.36 Occupation History Example

```
<observation classCode="OBS" moodCode="EVN">
< !-- templateId for PCC simple observation, CCD social history observation, PCC social history
observation -->
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
<templateId root="2.16.840.1.113883.10.20.1.33"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"/>
<code  codeSystem="2.16.840.1.113883.6.1"
           codeSystemName="LOINC"
           code="21843-8"
           displayName="Usual Occupation Hx"/>
<statusCode code="completed"/>
<value xsi:type="CD"
           codeSystem="2.16.840.1.113883.6.240"
           codeSystemName="Census Occupation Codes"
           code="402"
           displayName="Cook, Restaurant">
<originalText>cook</originalText>
</value>
</observation>
```

2.5.4.13.1.2 Industry History

Table 2-41 Industry History Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
Industry	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)=21844-6
	value	1..1	SHALL	CD	
	code	1..1	SHALL		2.16.840.1.114222.4.11.6037 (Census Industry Codes) PHIN VADS link
Industry Description	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus)=completed

Specification

1. **SHALL** contain exactly one [1..1] **code/@code**="21844-6" Usual Industry Hx (CodeSystem: LOINC 2.16.840.1.113883.6.1).
2. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD" to record the industry of the patient, where the **@code SHALL** be selected from ValueSet Census Industry Codes 2.16.840.1.114222.4.11.6037 **DYNAMIC.**

a. **SHOULD** contain zero or one [0..1] **originalText.**

i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
    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).

3. **SHALL** contain exactly one [1..1] **statusCode**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

Figure 2.37 Industry History Example

```
<observation classCode="OBS" moodCode="EVN">
< !-- templateId for PCC simple observation, CCD social history observation, PCC social history
  observation -->
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
<templateId root="2.16.840.1.113883.10.20.1.33"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"/>
    <code   codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC"
            code="21844-6"
            displayName="Usual Industry Hx"/>
    <statusCode code="completed"/>
    <value xsi:type="CD"
            codeSystem="2.16.840.1.113883.6.310"
            codeSystemName="Census Industry Codes"
            code="xxx"
            displayName="yyy">
      <originalText>Oil and Gas</originalText>
   </value>
</observation>
```

2.5.4.13.1.3 Smoking Status

Table 2-42 Smoking Status Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
Smoking Status	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)= 72166-2
	value	1..1	SHALL	CD	
	code	1..1	SHALL		2.16.840.1.114222.4.11.6027 (Smoking Status) PHIN VADS link
Smoking Status Description	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed

Specification

1. **SHALL** contain exactly one [1..1] **code/@code**="72166-2" Smoking Status (CodeSystem: LOINC 2.16.840.1.113883.6.1).
2. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD" to record the patient's smoking status, where the **@code SHALL** be selected from ValueSet Smoking Status 2.16.840.1.114222.4.11.6027 **DYNAMIC**.
    a. **SHOULD** contain zero or one [0..1] **originalText**.

i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
    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).

3. **SHALL** contain exactly one [1..1] **statusCode**="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14).

Table 2-43 Smoking Status Value Set

Value Set: Smoking Status Value Set 2.16.840.1.114222.4.11.6027 **DYNAMIC**	
PHIN VADS link	
Code System:	SNOMEDCT 2.16.840.1.113883.6.96
LOINC:	72166-2 Tobacco smoking status
Description:	Smoking status of patient
Code	**Meaning**
449868002	Current every day smoker
428041000124106	Current some day smoker
8517006	Former smoker
266919005	Never smoker
77176002	Smoker, current status unknown
266927001	Unknown if ever smoked
428071000124103	Current Heavy tobacco smoker
428061000124105	Current Light tobacco smoker

Figure 2.38 Smoking Status Example

```
<observation classCode="OBS" moodCode="EVN">
< !-- templateId for PCC simple observation, CCD social history observation, PCC social history
observation -->
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
<templateId root="2.16.840.1.113883.10.20.1.33"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"/>
   <code   codeSystem="2.16.840.1.113883.6.1"
           codeSystemName="LOINC"
           code="72166-2"
           displayName="Smoking Status"/>
   <statusCode code="completed"/>
   <value xsi:type="CD"
           codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT"
           code="449868002"
           displayName="Current every day smoker">
   <originalText>Patient smokes every day</originalText>
</value>
</observation>
```

2.5.4.14 TNM Clinical Stage Information Entry 1.3.6.1.4.1.19376.1.7.3.1.4.14.2

TNM Clinical Stage Information entry describes detailed site-specific information on the progression of disease for the cancer/tumor as defined by AJCC and recorded by the ambulatory healthcare provider (physician).

Standards

CCD	ASTM/HL7 Continuity of Care Document
NAACCR	North American Association of Central Cancer Registries Volume II: Data Standards and Data Dictionary, Record
AJCC	American Joint Committee on Cancer TNM Staging Manual

Table 2-44 TNM Entry Constraints Overview

Name	XPath	Card.	Verb	Data Type	Fixed Value
	observation[templateId/@root = '1.3.6.1.4.1.19376.1.7.3.1.4.14.2']				
	observation	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood)=EVN
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.7.3.1.4.14.2
	code	1..1	SHALL	CD	2.16.840.1.113883.6.96 (SNOMEDCT)=106248000
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus)=completed
TNM Clinical Stage Group	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.9 (NAACCR TNM Clinical Stage Group) AJCC Website link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
TNM Clinical Stage Descriptor	qualifier	1..1	SHALL	CD	
	name	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)=21909-7
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.10 (NAACCR TNM Clinical Stage Descriptor) PHIN VADS link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
TNM Edition Number	qualifier	1..1	SHALL	CD	
	name	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)=21917-0

	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.5 (NAACCR TNM Edition Number) PHIN VADS link
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
Provider who Recorded Stage Information	Participant	1..1	SHALL		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.90 (HL7 Participation Type)=PPRF
	participantRole	1..1	SHALL		
	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC)=21910-5
	playingEntity	1..1	SHALL		
	code	1..1	SHALL	CE	2.16.840.1.113883.3.520.4.4 (NAACCR TNM Clinical Staged By) PHIN VADS link
	entryRelationship	0..3	SHOULD		
	@typeCode	1..1	SHALL		2.16.840.1.113883.5.1002 (HL7ActRelationshipType)=COMP
	@inversionInd	1..1	SHALL		false
TNM Clinical T	observation	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood)=EVN
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13
	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 21905-5
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus)=completed
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.6 (Table 2-50 NAACCR TNM Clinical Tumor Value Set)
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
TNM Clinical N	observation	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass)=OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood)=EVN
	templateId	1..1	SHALL	SET<II>	

	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13
	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 21906-3
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.7 (NAACCR TNM Clinical Node Value Set)
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		
TNM Clinical M	observation	1..1	SHALL		
	@classCode	1..1	SHALL		2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL	SET<II>	
	@root	1..1	SHALL		1.3.6.1.4.1.19376.1.5.3.1.4.13
	code	1..1	SHALL	CD	2.16.840.1.113883.6.1 (LOINC) = 21907-1
	statusCode	1..1	SHALL	CS	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	
	code	0..1	SHOULD		2.16.840.1.113883.3.520.4.8 (NAACCR TNM Clinical Metastasis Value)
	originalText	0..1	SHOULD	ED	
	reference/@value	0..1	SHOULD		

Specification

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
3. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.4.14.2".
4. **SHALL** contain exactly one [1..1] **code="**106248000" TNM classification of malignant tumor before any treatment (CodeSystem: SNOMEDCT 2.16.840.1.113883.6.96).
5. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD", which records the TNM Clinical Stage Group, which is a detailed site-specific code for the clinical stage group as defined by AJCC and recorded by the ambulatory healthcare provider (physician).

a. This value **SHOULD** contain zero or one [0..1] **code**, such that
    i. If uncoded, **SHALL** be a string value describing the TNM Clinical Stage Group of the tumor/cancer.
    ii. If coded, **SHALL** be selected from ValueSet `NAACCR TNM Clinical Stage Group 2.16.840.1.113883.3.520.4.9` **DYNAMIC.**
b. This value **SHOULD** contain zero or one [0..1] **originalText**.
    i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
        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).

7. **SHALL** contain exactly one [1..1] **qualifier** that provides TNM Clinical Stage Descriptor information, indicating the AJCC clinical stage prefix/suffix recorded by the ambulatory healthcare provider (physician). AJCC stage descriptors identify special cases that require separate analysis.
    a. This qualifier **SHALL** contain exactly one [1..1] **name**="21909-7" Descriptor.clinical Cancer (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) .
    b. This qualifier **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD".
        i. This value **SHOULD** contain zero or one [0..1] **code**, such that
            1. If uncoded, **SHALL** be a string value describing the AJCC clinical stage prefix/suffix.
            2. If coded, **SHALL** be selected from ValueSet `NAACCR TNM Clinical Stage Descriptor 2.16.840.1.113883.3.520.4.10` **DYNAMIC.**
            3. This value **SHOULD** contain zero or one [0..1] **originalText**.
                a. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.
                    i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).
8. **SHALL** contain exactly one [1..1] **qualifier** that provides TNM Edition Number information, indicating the edition number of the AJCC Staging Manual, such that
    a. This qualifier **SHALL** contain exactly one [1..1] **name**="21917-0" Version TNM Classification (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) .
    b. This qualifier **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD".
    c. This value **SHOULD** contain zero or one [0..1] **code** such that
        i. If uncoded, **SHALL** be a string value describing the TNM Edition number of the AJCC Staging Manual.
        ii. It **SHALL** be selected from ValueSet `NAACCR TNM Edition Number 2.16.840.1.113883.3.520.4.5` **DYNAMIC.**
        iii. This value **SHOULD** contain zero or one [0..1] **originalText**.
            1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value**.

a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

9. **SHALL** contain exactly one [1..1] **participant** to specify the person who recorded the AJCC staging elements and stage group in the patient's medical record, such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="PPRF" Primary Performer (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90).
    b. **SHALL** contain exactly one [1..1] **participantRole**.
        i. This participantRole **SHALL** contain exactly one [1..1] **code="**21910-5" Stager.clinical Cancer (CodeSystem: LOINC 2.16.840.1.113883.6.1).
        ii. This participantRole **SHALL** contain exactly one [1..1] **playingEntity.**
            1. **SHALL** contain exactly one [1..1] **code** that identifies the person who recorded the staging elements, and **SHALL** be selected from (ValueSet: NAACCR TNM Clinical Staged By 2.16.840.1.113883.3.520.4.4 **DYNAMIC**).
10. **SHOULD** contain zero to three [0..3] **entryRelationship** providing information on the TNM Clinical Stage.
    a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
    b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="false" false .
    c. Each of the three <entryRelationship> elements **SHALL** contain exactly one [1..1] **Simple Observation** (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13) that specifies the TNM Clinical Tumor, TNM Clinical Nodes, and TNM Clinical Metastases, each of which is a component of the TNM Stage Group, such that it
        i. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6).
        ii. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
        iii. **SHALL** contain exactly one [1..1] **templateId** such that it **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.13".
        iv. **SHALL** contain exactly one [1..1] **@code="**21905-5|21906-3|21907-1" Primary tumor.clinical |Regional lymph nodes.clinical||Distant metastases.clinical (Code System: LOINC 2.16.840.1.113883.6.1) to indicate the component of TNM Stage Group represented in the Observation such that
            1. **@code='**21905-5' **SHALL** be used to indicate the TNM Clinical T.
            2. **@code='**21906-3' **SHALL** be used to indicate the TNM Clinical N.

3. `@code='21907-1'` **SHALL** be used to indicate the TNM Clinical M.

v. **SHALL** contain exactly one [1..1] `statusCode="completed"` Completed (CodeSystem: `ActStatus 2.16.840.1.113883.5.14`).

vi. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"`.

1. This value **SHOULD** contain zero or one [0..1] `code`, appropriate to the coded observation according to Table 2-45 TNM LOINC Codes and SHALL be selected from the appropriate value set as indicated in Table 2-45.
2. This value **SHOULD** contain zero or one [0..1] `originalText`.
   a. The originalText, if present, **SHOULD** contain zero or one [0..1] `reference/@value`.
      i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1).

Table 2-45 TNM LOINC Codes

LOINC Code	Display Name	Value Set	Description
21905-5	TNM Clinical T	Table 2-50 NAACCR TNM Clinical Tumor Value Set 2.16.840.1.113883.3.520.4.6	A detailed site-specific code for the clinical tumor (T) as defined by AJCC and recorded by the physician.
21906-3	TNM Clinical N	Table 2-51 NAACCR TNM Clinical Node Value Set 2.16.840.1.113883.3.520.4.7	A detailed site-specific code for the clinical nodes (N) as defined by AJCC and recorded by the physician.
21907-1	TNM Clinical M	Table 2-52 NAACCR TNM Clinical Metastasis Value 2.16.840.1.113883.3.520.4.8	A detailed site-specific staging code for the clinical metastases (M) as defined by AJCC and recorded by the physician.

Table 2-46 TNM Stage Group Value Set

Note: The AJCC Staging Manual TNM system is proprietary and its definitions cannot be included in other documents without permission.

Value Set: NAACCR TNM Stage Group 2.16.840.1.113883.3.520.4.9 **DYNAMIC**	
Code System:	TNM 5. Edition: 2.16.840.1.113883.15.8 - tnm5 TNM 6. Edition: 2.16.840.1.113883.15.7 - tnm6 TNM 7. Edition: 2.16.840.1.113883.15.6 - tnm7
SNOMEDCT:	106248000
Description:	Detailed site-specific code for the clinical stage group as defined by AJCC and recorded by the ambulatory healthcare provider (physician).
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
0	Site specific descriptions prevent listing of text equivalents.
0a	“

0is	“
I	“
IA	“
IA1	“
IA2	“
IB	“
IB1	“
IB2	“
IC	“
II	“
IIA	“
IIA1	“
IIA2	“
IIB	“
IIC	“
III	“
IIIA	“
IIIB	“
IIIC	“
IS	“
IV	“
IVA	“
IVB	“
IVC	“

Table 2-47 NAACCR TNM Clinical Staged By Value Set

Value Set: NAACCR TNM Clinical Staged By 2.16.840.1.113883.3.520.4.4 **DYNAMIC**	
PHINVADS link to Clinical Staged by	
Code System:	NAACCR TNM Clinical Staged By 2.16.840.1.113883.3.520.3.4
LOINC:	21910-5 Stager.clinical Cancer
Description:	Identifies the person who recorded the pathologic AJCC staging elements and the stage group in the patient's medical record.
Code	**Meaning**
0	Not Staged
1	Managing physician
2	Pathologist
3	Pathologist and managing physician
4	Cancer Committee chair, cancer liaison physician, or registry physician advisor
5	Cancer registrar
6	Cancer registrar and physician
7	Staging assigned at another facility
8	Case is not eligible for staging

9	Unknown; not stated in patient's record

Table 2-48 NAACCR TNM Clinical Stage Descriptor Value Set

Value Set: NAACCR TNM Clinical Stage Descriptor 2.16.840.1.113883.3.520.4.10 **DYNAMIC**	
PHIN VADS link to TNM Clinical Stage Descriptor	
Code System:	NAACCR TNM Clinical Stage Descriptor 2.16.840.1.113883.3.520.3.10
LOINC:	21909-7 Descriptor.clinical Cancer
Description:	Identify special cases that need separate data analysis.
Code	**Meaning**
0	None
1	E (Extranodal, lymphomas only)
2	S (Spleen, lymphomas only)
3	M (Multiple primary tumors in a single site)
5	E & S (Extranodal and spleen, lymphomas only)
9	Unknown; not stated in patient's record

Table 2-49 TNM Edition Value Set

Value Set: NAACCR TNM Edition Number 2.16.840.1.113883.3.520.4.5 **DYNAMIC**	
PHIN VADS link	
Code System:	NAACCR TNM Edition Number 2.16.840.1.113883.3.520.3.5
LOINC:	21917-0 Version TNM Classification
Description:	A code that indicates the Edition of the AJCC Staging Manual used to stage the case
Code	**Meaning**
5	AJCC Staging Manual, 5th Edition
6	AJCC Staging Manual, 6th Edition
7	AJCC Staging Manual, 7th Edition

Table 2-50 NAACCR TNM Clinical Tumor Value Set

The AJCC Staging Manual TNM system is propriety and its definitions cannot be included in documents or electronic vocabulary systems without permission.

Value Set: NAACCR TNM Clinical Tumor 2.16.840.1.113883.3.520.4.6 **DYNAMIC**	
AJCC Website link	
Code System:	NAACCR TNM Clinical Tumor 2.16.840.1.113883.3.520.3.6
LOINC:	21905-5 Primary tumor.clinical
Description:	Detailed site-specific codes for the clinical tumor (T) as defined by AJCC and recorded by the physician.
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
Ta	Site specific descriptions prevent listing of text equivalents.
Tis	"
T0	"
T1	"

T1mic	“
T1a	“
T1a1	“
T1a2	“
T1b	“
T1b1	“
T1b2	“
T1c	“
T1d	“
T2	“
T2a	“
T2a1	“
T2a2	“
T2b	“
T2c	“
T2d	“
T3	“
T3a	“
T3b	“
T3c	“
T3d	“
T4	“
T4a	“
T4b	“
T4c	“
T4d	“
T4e	“
Tx	“

Table 2-51 NAACCR TNM Clinical Node Value Set

The AJCC Staging Manual TNM system is propriety and its definitions cannot be included in documents or electronic vocabulary systems without permission.

Value Set: NAACCR TNM Clinical Node 2.16.840.1.113883.3.520.4.7 **DYNAMIC**	
AJCC Website link	
Code System:	NAACCR TNM Clinical Node 2.16.840.1.113883.3.520.3.7
LOINC:	21906-3 Regional lymph nodes.clinical
Description:	Detailed site-specific codes for the clinical tumor (N) as defined by AJCC and recorded by the physician.
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
N0	Site specific descriptions prevent listing of text equivalents.
N1	“
N1mi	“

N1a	“
N1b	“
N1b1	“
N1b2	“
N1b3	“
N1b4	“
N1c	“
N2	“
N2a	“
N2b	“
N2c	“
N3	“
N3a	“
N3b	“
N3c	“
N	“

Table 2-52 NAACCR TNM Clinical Metastasis Value

The AJCC Staging Manual TNM system is propriety and its definitions cannot be included in documents or electronic vocabulary systems without permission.

Value Set: NAACCR TNM Clinical Metastasis 2.16.840.1.113883.3.520.4.8 **DYNAMIC**	
AJCC Website link	
Code System:	NAACCR TNM Clinical Metastasis 2.16.840.1.113883.3.520.3.8
LOINC:	21906-3 Distant metastases.clinical
Description:	Detailed site-specific codes for the clinical tumor (M) as defined by AJCC and recorded by the physician.
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
M0	Site specific descriptions prevent listing of text equivalents.
M1	“
M1a	“
M1b	“
M1c	“
M1d	“
M1e	“
Mx	“

Figure 2.39 TNM Clinical Stage Entry Example Diagnosis

```
<entryRelationship typeCode="SUBJ" inversionInd="true">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.7.3.1.4.14.2"/>
        <code code="106248000" displayName="  TNM classification of malignant tumor before any
treatment" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>

<!-- Narrative TNM Clinical Stage -->
      <text> Stage 0 TisN0M0 </text>
      <statusCode code="completed"/>
```

```
      <value xsi:type="CD" code="0" codeSystem="2.16.840.1.113883.3.520.3.9"
codeSystemName="NAACCR TNM Clinical Stage Group" displayName="In Situ">

<!--TNM Clinical Stage Descriptor Observation -->
      <qualifier>
         <name code="21909-7" displayName="TNM Clinical Stage Descriptor"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
      <value xsi:type="CD" code="0" codeSystem="2.16.840.1.113883.3.520.3.10"
   codeSystemName="NAACCR TNM Clinical Stage Descriptor" displayName="None"/>
      </qualifier>

<!--AJCC TNM Edition Number.-->
      <qualifier>
         <name code="21917-0" displayName="TNM Edition Number"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
      <value xsi:type="CD" code="7" codeSystem="2.16.840.1.113883.3.520.3.5"
   codeSystemName="NAACCR TNM Edition Number" displayName="7th Edition"/>
         </qualifier>
         </value>
         <participant typeCode="PPRF">
         <participantRole>
            <code code="21910-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Stager.clinical Cancer"/>
         <playingEntity nullFlavor="NA">
         <code xsi:type="CE" code="1" codeSystem="2.16.840.1.113883.3.520.3.4"
codeSystemName="TNM Clinical Staged By" displayName="Managing Physician"/>
      </playingEntity>
      </participantRole>
      </participant>

      <entryRelationship typeCode="COMP">

<!-- 6.3.4.62 TNM Clinical Tumor Observation-->
      <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
      <code code="21905-5" displayName="TNM Clinical T" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
      <statusCode code="completed"/>
      <value xsi:type="CD" code="Tis" codeSystem="2.16.840.1.113883.3.520.3.6"
codeSystemName="NAACCR TNM Clinical Tumor" displayName="In Situ"/>
      </observation>
      </entryRelationship>

<!--6.3.4.63 TNM Clinical Nodes Observation -->
      <entryRelationship typeCode="COMP">
         <observation classCode="OBS" moodCode="EVN">
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
         <code code="21906-3" displayName="TNM Clinical N" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
            <statusCode code="completed"/>
            <value xsi:type="CD" code="N0" codeSystem="2.16.840.1.113883.3.520.3.7"
codeSystemName="NAACCR TNM Clinical Nodes" displayName="None"/>
            </observation>
         </entryRelationship>

<!--6.3.4.64 TNM Clinical Metastases Observation-->
         <entryRelationship typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
            <code code="21907-1" displayName="TNM Clinical M" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
            <statusCode code="completed"/>
            <value xsi:type="CD" codeSystem="2.16.840.1.113883.3.520.3.8"
codeSystemName="NAACCR TNM Clinical Metastases" code="M0" displayName="None"/>
            </observation>
         </entryRelationship>
        </observation>
      </entryRelationship>
```

Appendix A: Namespaces and Vocabularies

The following Namespaces and Vocabularies (Code Systems) are referenced in this document. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/.

Namespaces

Namespace OID	Namespace	Description
2.16.840.1.113883.5	HL7	This is the root OID for HL7 v3 code systems
1.3.6.1.4.1.19376.1.5.3.1	IHE PCC Template Identifiers	This is the root OID for all IHE PCC Templates.
1.3.6.1.4.1.19376.1.7.3	IHE QRPH Template Identifiers	This is the root OID for all IHE QRPH Templates.
1.3.6.1.4.1.19376.1.5.3.4	IHE Extensions to CDA Release 2.0	Namespace OID used for IHE Extensions to CDA Release 2.0
2.16.840.1.113883.3.520	NAACCR	This is the root OID for North American Association of Central Cancer Registries
2.16.840.1.113883.3.221	PHDSC	This is the root OID for Public Health Data Standards Consortium

Code Systems

Code System OID	Code System Name	Minimum Standard (version)
2.16.840.1.113883.5.1	HL7 V3 Administrative Gender	HL7 V3
2.16.840.1.113883.6.238	CDC Race and Ethnicity	1.1
2.16.840.1.113883.6.238	HL7 V3 Ethnicity	HL7 V3
2.16.840.1.113883.5.2	HL7 V3 Marital Status	HL7 V3
2.16.840.1.113883.6.240	U.S. Census Occupation Code	2010
2.16.840.1.113883.6.310	U.S. Census Industry Code	2010
2.16.840.1.113883.6.43.1	International Classification of Diseases for Oncology (ICD-O-3)	Third Edition (ICD-O-3) Updates 2011
2.16.840.1.113883.3.520.3.14	NAACCR Behavior Code	NAACCR Standards for Cancer Registries, Volume II: Data Standards and Data Dictionary, Sixteenth Edition ("NAACCR Vol II, Sixteenth Edition")
2.16.840.1.113883.3.520.3.3	NAACCR Diagnostic Confirmation	NAACCR Vol II, Sixteenth Edition
2.16.840.1.113883.3.520.3.1	NAACCR Laterality at Diagnosis	NAACCR Vol II, Sixteenth Edition
2.16.840.1.113883.15.6	AJCC Cancer Staging Manual	7th Edition
2.16.840.1.113883.3.520.3.10	NAACCR TNM Clinical Stage Descriptor	NAACCR Vol II, Sixteenth Edition
2.16.840.1.113883.3.520.3.4	NAACCR TNM Clinical Staged By	NAACCR Vol II, Sixteenth Edition
2.16.840.1.113883.6.103	International Classification of Diseases	International Classification of Diseases, Ninth Revision, Clinical Modification, Version 29, FY 2012 (Effective Oct 2011)

Code System OID	Code System Name	Minimum Standard (version)
2.16.840.1.113883.6.3	International Classification of Diseases	2011 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
2.16.840.1.113883.6.12	American Medical Association's Current Procedure Terminology	4th Edition (CPT-4) 2011
2.16.840.1.113883.6.88	RxNorm	July 2012 release – 07/02/2012
2.16.840.1.113883.6.1	Logical Observation Identifiers Names and Codes (LOINC)	LOINC 2.40 Released: 2012-06-30
2.16.840.1.113883.6.96	Systematized Nomenclature of Medicine--Clinical Terms (SNOMED CT)	20120131 (Jan 31st, 2012)
2.16.840.1.113883.4.6	National Plan and Provider Enumeration System (NPPES) National Provider Identifier	Not applicable
2.16.840.1.113883.4.1	United States Social Security Administration (SSA)	Not applicable
2.16.840.1.113883.6.101	National Uniform Claim Committee for Provider Types (NUCC)	Version 12, 1/12
2.16.840.1.113883.6.92	FIPS 5-2 (State)	05/28/1987
2.16.840.1.113883.6.231	US Postal Codes	July 2012

Appendix B: NAACCR Data Element and CDA Element Relationship Table

The following table provides the data elements, template ID, CDA document location (XPath mapping), vocabulary constraints, and optionality for the Ambulatory Healthcare Provider Cancer Event Report. Appendix A contains a list of namespaces and vocabulary/value sets.

Data Elements Cross Reference

DATA ELEMENTS CROSS REFERENCE	
Column	**Definition**
NAACCR ID Number (1)	Data Item number reference assigned to data elements by the North American Association of Central Cancer Registries (NAACCR) and used by hospital, state, provincial and national cancer registries in North America. NAACCR ID Number can be used to find data element definition in NAACCR Standards for Cancer Registries, Volume II: Data Standards and Data Dictionary, Sixteenth Edition
Data Element (2)	This is the concept that may be present or a formal data element name corresponding to a standard representation of this concept.
Opt (Optionality) (6)	Indicates optionality of the data element.
templateID (3)	OID for the templateID
Source XPATH Mapping (4)	XPATH of the data element for the Source Document

Ambulatory Healthcare Provider Cancer Event Report — Data Elements

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
2110	Date Case Report Exported	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/effectiveTime/@value
2230	Patient Last Name	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/family
2270	Patient Name Suffix	**SHOULD**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/suffix
2240	Patient First Name	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/given[1]
2250	Patient Middle Name	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/given[2]
2390	Patient Maiden Name	**SHOULD**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/family[@qualifier='BR']
2280	Patient Name Alias	**SHOULD**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/name/family[@qualifier='CL']

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
2350, 1810, 1820, 1830	Patient Address (Street Address, City, State, Zip Code, Country)	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/addr/*
	Address History	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/addr/useablePeriod/*
	Address Use	**SHOULD**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/addr/@use
	Patient Telephone	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/telecom/@value
220	Patient Sex/Gender	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode/@*
240	Patient Date of Birth	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/birthTime/@value
2300	Patient Medical Record Number	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/id[not(@root= '2.16.840.1.113883.4.1')]/@extension
2320	Patient Social Security Number	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/id[@root='2.16.840.1.113883.4.1']/@extension
160, 161,162, 163, 164	Patient Race	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/raceCode/@*
160, 161,162, 163, 164	sdtc:race (raceCode extension)	**MAY**	2.16.840.1.113883.10.20.22.1.1 [HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1]	ClinicalDocument/recordTarget/patientRole/patient/sdtc:raceCode
190	Patient Ethnicity	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode/@*
250	Patient Birth Place	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.1.14.1	ClinicalDocument/recordTarget/patientRole/patient/birthplace/place/addr/*
1502	Patient Marital Status	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/recordTarget/patientRole/patient/maritalStatusCode/@*
2460, 2470, 2480, 2490, 2500	Physician Name	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/*
2465, 2475, 2485, 2495, 2505	Physician ID (NPI)	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/id[@root='2.16.840.1.113883.4.6']/@extension

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Physician Address (Street Address, City, State, Zip Code, Country)	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/addr/*
	Physician email	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom
	Physician Specialty	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/code/@*
540	Provider Organization ID	**SHALL**	2.16.840.1.113883.10.20.3 [General Header Constraints for CDA R2]	ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/*
2410	Provider Referred From	**SHOULD**	1.3.6.1.4.1.19376.1.4.1.3.1 [Encompassing Encounter]	ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant/assignedEntity/representedOrganization/*
2415, 2460, 2470, 2480, 2490, 2500	Provider Referred From ID (NPI)	**SHOULD**	1.3.6.1.4.1.19376.1.4.1.3.1 [Encompassing Encounter]	ClinicalDocument/componentOf/encompassingEncounter/encounterParticipant/assignedEntity/id[@root='2.16.840.1.113883.4.6']/@extension
	Coded Social History Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]
	Social History Narrative	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/text/*
270	Occupation	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [Social History Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'] and code[@code='21843-8']]/value/@*
280	Industry	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [Social History Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'] and code[@code='21844-6']]/value/@*
	Smoking Status	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [Social History Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'] and code[@code='72166-2']]/value/@*
	Payers Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7']]
630	Payer Type	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.17 [Coverage Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7']]/entry/act[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.17']]/entryRelationship/act/code/@*

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Cancer Diagnosis Section	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.3.14.1	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]
	Cancer Diagnosis Entry	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]
390	Diagnosis Date	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/effectiveTime/low/@value
522	Histologic type	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryR/’.elationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/value/@*
523	Behavior	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/value/qualifier[name[@code="31206-6"]]/value/@*
490	Diagnostic confirmation	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/value/qualifier[name[@code="21861-0"]]/value/@*
400	Primary Site	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/targetSiteCode/@*
410	Laterality	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.1 [Cancer Diagnosis Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/targetSiteCode/qualifier/value/@*
	TNM Clinical Stage Entry	**SHOULD**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation/entryRelationship/observation/templateId/@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.2'
	Stage Group Narrative	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/entryRelationship/observation/text

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
970	TNM Clinical Stage Group	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/entryRelationship/observation/value/@*
980	TNM Clinical Stage Descriptor	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/entryRelationship/observation/value/qualifier[name[@code="21909-7"]]/value/@*
1060	TNM Edition Number	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/entryRelationship/observation/value/qualifier[name[@code="21917-0"]]/value/@*
990	Provider who recorded stage information	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.4.14.1']]/entryRelationship/observation/participant/participantRole/playingEntity/code/@*
940	TNM Clinical T	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation/entryRelationship/observation/entryRelationship/observation[code[@code='21905-5']]/value/@*
950	TNM Clinical N	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation/entryRelationship/observation/entryRelationship/observation[code[@code='21906-3']]/value/@*
960	TNM Clinical M	**SHALL**	1.3.6.1.4.1.19376.1.7.3.1.4.14.2 [TNM Stage Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.3.14.1']]/entry/act/entryRelationship/observation/entryRelationship/observation/entryRelationship/observation[code[@code='21907-1']]/value/@*
	Active Problems Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.6	ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']
	Start and Stop date of problem	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.6	ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']/entry/act/effectiveTime
3110 - 3164	Problem Code	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.5.2 [Problem Concern Entry]	ClinicalDocument/component/structuredBody/component/section[title='Active Problems Section']/entry/act/entryRelationship/observation/value/@*
	Progress Note Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7']]

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Progress Notes Narrative	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.7']]/text
	Coded Results Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.28	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]
	Procedure Entry	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/procedure
	Procedure Type	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/procedure/code/@*
	Procedure DateTime	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/procedure/effectiveTime/*
	Result Value	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/code/@*
	Result Text	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/text
	Result DateTime	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/effectiveTime/@value
	Facility	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/author/assignedAuthor/representedOrganization/name
	Facility ID	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.13 [Simple Observation]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/entry/observation/author/assignedAuthor/representedOrganization/id
	Procedures Section	**SHALL**	2.16.840.1.113883.10.20.1.12	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]
	Procedure Activity Entry	**SHALL**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure
670, 690	Procedure Type	**SHALL**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure/code/@*
	Body Site of procedure	**SHALL**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure/targetSiteCode/@*
1200,1210	Procedure DateTime	**SHALL**	2.16.840.1.113883.10.20.1.29	ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.1.12']]/entry/procedure/effectiveTime/*

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Medications Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]
700, 710,720	Medications Entry (Chemotherapy, Hormone Therapy, Immunotherapy)	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration
1220, 1230,1240	Start Date	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/effectiveTime[1]/low
	Stop Date	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/effectiveTime[1]/high
	Frequency	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/effectiveTime[2]/period/@*
	Route	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/routeCode/@*
	Dose	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/doseQuantity/@*
	Site	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/approachSiteCode
	Rate	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/rateQuantity
	Consumable	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable
	Product Entry	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct
	Medication Brand Name	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/name
	Strength	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/originalText

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Coded product name	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.19']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/@*
	Medications Administered Section (medications that are administered during the encounter) Chemotherapy, Hormone Therapy, Immunotherapy	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.21	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]
700, 710,720	Medications Entry (Chemotherapy, Hormone Therapy, Immunotherapy)	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration
1220, 1230,1240	Medication Start Date	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/effectiveTime[1]/low
	Medication Stop Date	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/effectiveTime[1]/high
	Administration Timing (Frequency)	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/effectiveTime[2]/period/@*
	Route	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/routeCode/@*
	Dose	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/doseQuantity/@*
	Site of medication administration	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/approachSiteCode
	Rate	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/rateQuantity
	Consumable	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable
	Product Entry	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct

NAACCR ID	Data Element	Opt	templateID	XPATH Mapping
	Product	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Medications]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/name
	Strength	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/originalText
	Code	**SHOULD**	1.3.6.1.4.1.19376.1.5.3.1.4.7.2 [Product Entry]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.21']]/entry/substanceAdministration/consumable/manufacturedProduct/manufacturedMaterial/code/@*
	Care Plan Section	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.3.31	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]
	Observation Requests	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1']]
	Medication Entry	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.7	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.7']]
	Immunization Entry	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.12	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.12']]
	Procedure Entry	**MAY**	1.3.6.1.4.1.19376.1.5.3.1.4.19	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.19']]
	Encounters Entry	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.14	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry/encounter
2420, 2425, 2460, 2470, 2480, 2490, 2500	Provider Referred To	**SHALL**	1.3.6.1.4.1.19376.1.5.3.1.4.14 [Encounters]	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.31']]/entry/encounter/performer/assignedEntity/assignedPerson/name/*

Appendix C: 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: CDA Release 2 – Continuity of Care Document (CCD) (http://www.hl7.org/index.cfm)

HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 5, for more information about use of TemplateIDs.

IHE QRPH Technical Framework Supplement – Physician Reporting to a Public Health Repository - Cancer Registry (QRPH–PRPH-Ca), copyright IHE International, Inc. (http://www.ihe.net/Technical_Framework/)

IHE Patient Care Coordination Technical Framework, Volume 2 (PCC TF-2), copyright IHE International, Inc. (http://www.ihe.net/Technical_Framework/)

IHE Patient Care Coordination Technical Framework Supplement – CDA Content Modules, copyright IHE International, Inc. (http://www.ihe.net/Technical_Framework/)

IHE Cardiology Technical Framework Supplement – Cardiac Imaging Report Content (CARD-CIRC), copyright IHE International, Inc. (http://www.ihe.net/Technical_Framework/)

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

Appendix D: Acronyms

AJCC	American Joint Commission on Cancer
BR	Business Rule
BRM	Biological Response Modifier
CCD	Continuity of Care Document
CCR	Central Cancer Registry
CDA	Clinical Document Architecture
CDA R2	Clinical Document Architecture, Release 2.0
CDC	Centers for Disease Control and Prevention
CIRC	Cardiac Imaging Report Content
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	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-O-3	International Classification of Diseases for Oncology, Third Edition
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
PCC	Patient Care Coordination
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

Appendix E: 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 case 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.

Continuity of Care Document (CCD): "The Continuity of Care Document (CCD) is a joint effort of HL7 International and ASTM. CCD fosters interoperability of clinical data by allowing physicians to send electronic medical information to other providers without loss of meaning and enabling improvement of patient care. CCD is an implementation guide for sharing Continuity of Care Record (CCR) patient summary data using the HL7 Version 3 Clinical Document Architecture (CDA), Release 2. CCD establishes a rich set of templates representing the typical sections of a summary record, and expresses these templates as constraints on CDA. These same templates for vital signs, family history, plan of care, and so on can then be reused

in other CDA document types, establishing interoperability across a wide range of clinical use cases."

Source: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6.

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.

Continuity of Care Record: [See Continuity of Care Document]

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). The structured part relies on coding systems (such as from SNOMED and LOINC) to represent concepts." Source: 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:

- share information relevant to quality improvement,
- improve the liaison between the primary care system and clinical research and
- 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.