Australian Government
Australian Digital Health Agency

Core Level One Clinical Document

Structured Content Specification

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Approved for external use

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Document Information

Key Information

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Product Version History

Product version	Date	Release comments
1.0	11 Feb 2013	Initial version to enable sharing birth detail documents.
1.1	24 Jul 2018	This version of the specification formerly known as Structured Content Free Document introduces changes to the design to allow for documents other than birth details.

Related Documents

Name	Version/Release Date
Participation Data Specification	Version 3.3, Issued 30 January 2017
Core Level One Clinical Document CDA Implementation Guide	Version 1.1, To be published

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Table of Contents

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1 Introduction

This document is a structured content specification (SCS) for clinical documents that contain the content of the document as either encapsulated data or narrative, but not as structured data. Such documents are sometimes referred to as structured content free documents.

Appendix B, *Specification Guide for Use* explains the data type constraints applied to data elements defined in this SCS. It also provides important information on how to read and use the SCS and is therefore an essential compendium for a better understanding of the SCS.

We value your questions and comments about this document. Please direct your questions or feedback to *help@digitalhealth.gov.au*.

1.1 Document Purpose

This document describes the structured content of documents that contain structured context information where clinical content is contained in narrative or as encapsulated data only, and are to be exchanged between care providers using Australian digital health systems.

The content within this document provides reviewers (software development teams, architects, designers, clinicians and informatics researchers) with the necessary information (or references to information held outside this document) to evaluate and assess the clinical suitability of the specification.

It is also a key input to the *Core Level One Clinical Document CDA Implementation Guide [DH2018f]*, which describes how to implement Agency-compliant documents that have no structured content using the *HL7 Clinical Document Architecture [HL7CDAR2]*.

1.2 Intended Audience

This document is aimed at software development teams, architects, designers, clinicians and informatics researchers who are responsible for the delivery of clinical applications, infrastructure components and messaging interfaces, and also for those who wish to evaluate the clinical suitability of the Agency-endorsed specifications.

1.3 Document Scope

This document specifies the essential data groups, data elements, and the constraints that should be applied to them when creating a structured document free of structured content for exchange.

This is not a guide to the implementation of any specific messaging standard.

This document is not to be used as a guide to presentation (or rendering) of the data. It contains no information as to how the data described by it should be displayed and no such guidance should be inferred from this document.

1.4 Known Issues

Known issues with this document are described in Appendix A, *Known Issues*.

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2 Clinical Document Structured Document

2.1 Purpose

To allow for the sharing of clinical documents with no atomic clinical content, such as an observation or other clinical entry.

2.2 Use

Use to share clinical documents that contain context information (such as the author and subject of care) as structured data, and contain the clinical content as encapsulated data or as section narrative.

- Support the provision of a clinical document that conforms to Level 1A as defined by the Clinical Documents Common Conformance Profile.
- Support the provision of a clinical document that conforms to Level 1B as defined by the Clinical Documents Common Conformance Profile.

2.3 CLINICAL DOCUMENT

Identification

Label	CLINICAL DOCUMENT
Metadata Type	Structured Document
Identifier	SD-16888
OID	1.2.36.1.2001.1001.101.100.16888

Definition

Definition	Clinical document containing structured context information, such as author, and containing clinical content as encapsulated data or as section narrative.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

Items below with a grey background are data components that are included in the relevant detailed clinical model specification, but whose use is discouraged in this particular scenario.

Items below with a clear background are data components whose use is encouraged in this particular scenario.

CLINICAL DOCUMENT			
CONTEXT			
	SUBJECT OF CARE		1..1
	DOCUMENT AUTHOR		1..1
	ENCOUNTER		0..1
		DateTime Health Event Started	0..1
		DateTime Health Event Ended	0..1
		HEALTHCARE FACILITY	0..1
	Document Instance Identifier		1..1
	RELATED INFORMATION		0..0

		Document Type		1..1
		Document Title		0..1
		PARTICIPANT		0..*
CONTENT				
		SECTION		1..1
			ENCAPSULATED DATA	0..*
			Encapsulated Data Item	1..1
			INFORMATION PROVIDER	0..0
			SUBJECT	0..0
			Encapsulated Data Instance Identifier	0..0
			RELATED INFORMATION	0..0
			Detailed Clinical Model Identifier	0..0
		Section Instance Identifier		0..0
		RELATED INFORMATION		0..0
		Section Type		0..0

2.4 SUBJECT OF CARE

Identification

Label	SUBJECT OF CARE
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Person who receives care services.
Definition Source	Australian Digital Health Agency
Synonymous Names	Patient Individual
Scope	The person who is the focus of the document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [DH2017a]*. Further constraints on this data group that apply to this reuse of it are listed below. Obligation and occurrence constraints: • Participation Period is **PROHIBITED**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • Relationship to Subject of Care is **PROHIBITED**. • EMPLOYMENT DETAIL is **PROHIBITED**. • DEMOGRAPHIC DATA is **ESSENTIAL**. • Sex is **ESSENTIAL**. • DATE OF BIRTH DETAIL is **ESSENTIAL**. • Indigenous Status is **ESSENTIAL**. • Qualifications is **PROHIBITED**. Other constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject of Care”. • Role **SHALL** have an implementation-specific value equivalent to “Patient”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.

	Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	CLINICAL DOCUMENT	1..1

2.5 DOCUMENT AUTHOR

Identification

Label	DOCUMENT AUTHOR
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Composer of the document.
Definition Source	Australian Digital Health Agency
Synonymous Names	Author
Notes	The date, or date and time, that the authoring of the document was completed is recorded in the *Participation Period* of the *Author*. This may be a care provider, the subject of care, a subject of care's representative, a healthcare provider or a device.

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [DH2017a]*. Further constraints on this data group that apply to this reuse of it are listed below. Obligation and occurrence constraints: • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or a DEVICE. **DOCUMENT AUTHOR as a PERSON** Additional obligation and occurrence constraints when the document author is a person (PERSON OR ORGANISATION OR DEVICE is instantiated as a PERSON): • Participation Period is **ESSENTIAL**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. Other constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Document Author”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. **DOCUMENT AUTHOR as a DEVICE** Additional obligation and occurrence constraints when the document author is a device (PERSON OR ORGANISATION OR DEVICE is instantiated as a DEVICE): • Participation Period is **ESSENTIAL**.

	• LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • ENTITLEMENT is **PROHIBITED**. • Qualifications is **PROHIBITED**. Other constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Document Author”. • Role **SHALL** have an implementation-specific value equivalent to “Not applicable”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a DEVICE. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	1..1

2.6 ENCOUNTER

Identification

Label	ENCOUNTER
Metadata Type	Data Group
Identifier	DG-16057
OID	1.2.36.1.2001.1001.101.102.16057

Definition

Definition	Encounter between a subject of care and a health system.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	0..1

Children

Data Type	Name	Occurrences
	DateTime Health Event Started	0..1
	DateTime Health Event Ended	0..1
	HEALTHCARE FACILITY	0..1

2.7 DateTime Health Event Started

Identification

Label	DateTime Health Event Started
Metadata Type	Data Element
Identifier	DE-15507
OID	1.2.36.1.2001.1001.101.103.15507

Definition

Definition	Date, and optionally time, that the health event to which the document relates was started.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ENCOUNTER	0..1

2.8 DateTime Health Event Ended

Identification

Label	DateTime Health Event Ended
Metadata Type	Data Element
Identifier	DE-15510
OID	1.2.36.1.2001.1001.101.103.15510

Definition

Definition	Date, and optionally time, that the health event to which the document relates was completed.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ENCOUNTER	0..1

2.9 HEALTHCARE FACILITY

Identification

Label	HEALTHCARE FACILITY
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Healthcare organisation or facility involved in, or associated with, the delivery of services to the subject of care.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [DH2017a]*. Further constraints on this data group that apply to this reuse of it are listed below. Obligation and occurrence constraints: • Participation Period is **PROHIBITED**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • ADDRESS is **ESSENTIAL**. • ENTITLEMENT is **PROHIBITED**. • Qualifications is **PROHIBITED**. Other additional constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Facility”. • Role **SHOULD** have a value representing the type of Healthcare Facility e.g. Hospital, Clinic. Role **MAY** have an implementation-specific null flavour. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as an ORGANISATION. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ENCOUNTER	0..1

2.10 Document Instance Identifier

Identification

Label	Document Instance Identifier
Metadata Type	Data Element
Identifier	DE-20101
OID	1.2.36.1.2001.1001.101.103.20101

Definition

Definition	Globally unique identifier for each instance of a *Clinical Document* document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Context	A document can have multiple instances as it passes through its life cycle of creation, revisions before it is first sent, and revised versions thereafter. The value of this `data element` enables systems to identify all instances of a document uniquely, thus enabling efficient storage, query and audit trail of information about a subject of care.
Context Source	Australian Digital Health Agency
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	1..1

2.11 Document Type

Identification

Label	Document Type
Metadata Type	Data Element
Identifier	DE-10335
OID	1.2.36.1.2001.1001.101.103.10335

Definition

Definition	Type of document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be publicly registered. Examples of publicly registered values include the Agency and LOINC document types.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	1..1

2.12 Document Title

Identification

Label	Document Title
Metadata Type	Data Element
Identifier	DE-16966
OID	1.2.36.1.2001.1001.101.103.16966

Definition

Definition	Title of the document.
Definition Source	Australian Digital Health Agency
Synonymous Names	Document Name
Notes	This `data element` is only used when the title of the document is distinct from the name of the document type.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	0..1

2.13 PARTICIPANT

Identification

Label	PARTICIPANT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Party involved in, or associated with, the provision of services to the subject of care.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [DH2017a]*. Further constraints on this data group that apply to this reuse of it are listed below. Obligation and occurrence constraints: • Participation Period is **PROHIBITED**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • DEMOGRAPHIC DATA is **PROHIBITED**. Other constraints: • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or an ORGANISATION. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	0..*

2.14 SECTION

Identification

Label	SECTION
Metadata Type	Section
Identifier	S-16886
OID	1.2.36.1.2001.1001.101.101.16886

Definition

Definition	Section with minimal or no structured content.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	CLINICAL DOCUMENT	1..1

Children

Data Type	Name	Occurrences
	ENCAPSULATED DATA	0..*
	Section Instance Identifier	0..0
	RELATED INFORMATION	0..0
	Section Type	0..0

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3 Encapsulated Data Detailed Clinical Model

This chapter describes a reuse of version 1.1 of the *Encapsulated Data* Detailed Clinical Model.

3.1 Purpose

To hold an item of encapsulated data.

3.2 ENCAPSULATED DATA

Identification

Label	ENCAPSULATED DATA
Metadata Type	Data Group
Identifier	DG-16883
OID	1.2.36.1.2001.1001.101.102.16883

Definition

Definition	Container for an item of encapsulated data.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Local attachment containing clinical content such as a PDF of a report.
Scope Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SECTION	0..*

Children

Data Type	Name	Occurrences
	Encapsulated Data Item	1..1
	INFORMATION PROVIDER	0..0
	SUBJECT	0..0
	Encapsulated Data Instance Identifier	0..0
	RELATED INFORMATION	0..0
	Detailed Clinical Model Identifier	0..0

3.3 Encapsulated Data Item

Identification

Label	Encapsulated Data Item
Metadata Type	Data Element
Identifier	DE-16884
OID	1.2.36.1.2001.1001.101.103.16884

Definition

Definition	Item of encapsulated data.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is used to represent the clinical document contents as encapsulated data, for example, a PDF of a clinical document.
Data Type	EncapsulatedData

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	ENCAPSULATED DATA	1..1

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4 UML Class Diagrams

The following figure represents the data hierarchy using a UML 2.0 class diagram. The diagram displays data groups, sections, structured documents and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes; data groups, sections and structured documents are displayed as classes; their label names are represented as association role names. Association role names are only displayed if they differ from the associated class name. When a data element has a choice of data types, the data type of the attribute that represents it is an abstract interface class generalised from the individual data types. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

If a data element's label differs from its name, the label is the attribute name and the name is a stereotype of the attribute. If a data group's or section's label differs from its name, the label is the class name and the name is a stereotype of the class.

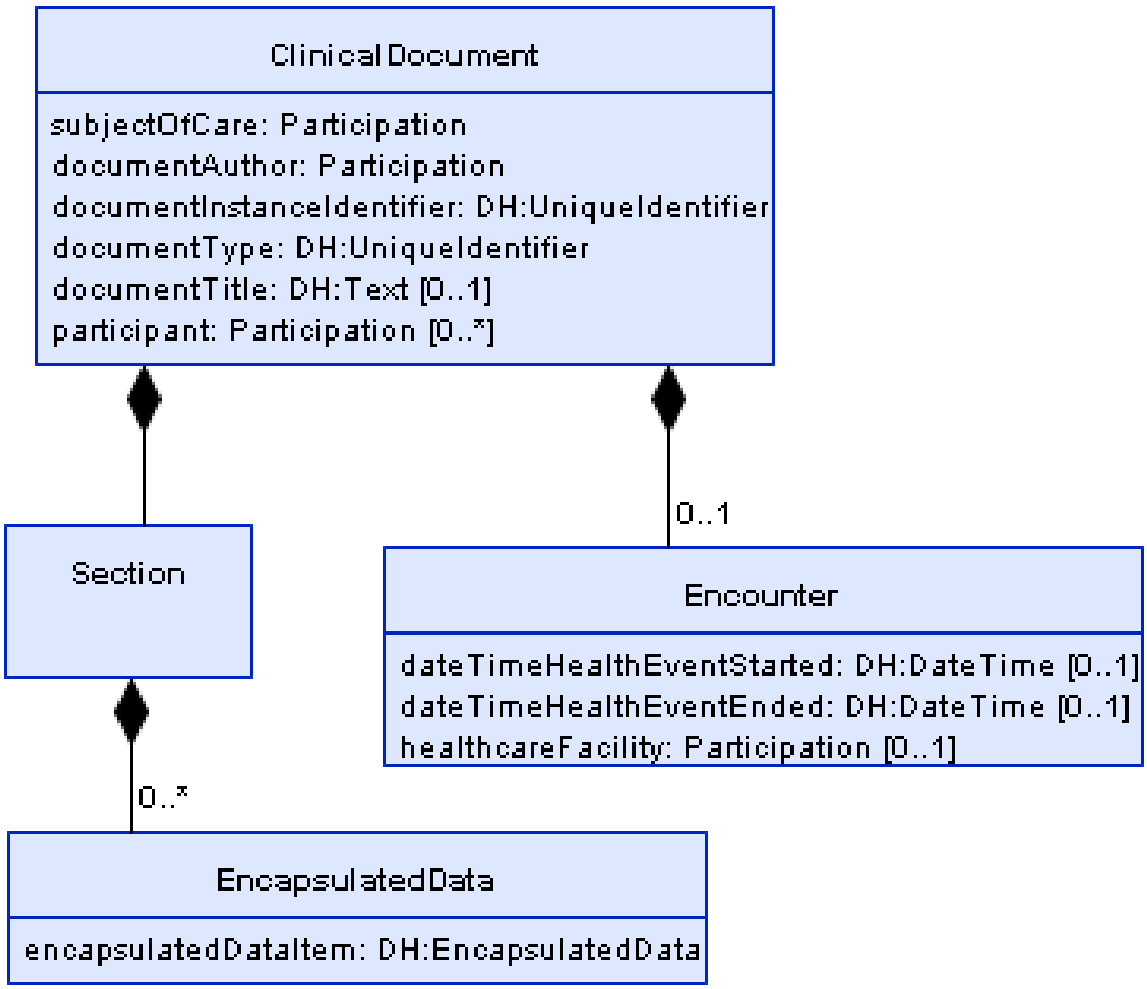

Figure 4.1. Clinical Document

Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. We are working on solutions to these issues and encourage comments to help us develop these solutions.

Reference	Description
Links to external resources	Certain combinations of web browsers and PDF readers have problems opening URL links (usually found in reference sections) that span more than one line.
Level 1 document	Limited inclusion of structured data in the CONTENT of the clinical document is intentional. This restriction is in place to emulate a Level 1 document. The typical level represented in CONTENT is Level 3.
Alignment with the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard	The concepts as modelled in this specification, and in particular participation, are not fully consistent with HL7 FHIR resources. Work is underway to address alignment to HL7 FHIR and is expected to result in adjustment to the structure of this model.
Gender	The model of participation referenced by this specification includes a data component for sex, but not a data component for gender. The preferred Australian Government approach is to collect and use gender information. Work is underway to address alignment with the government guidelines on sex and gender in Agency information models.

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Appendix B. Specification Guide for Use

B.1 Overview

The participation data specification, each detailed clinical model (DCM) and each structured content specification (SCS) is designed on a shared basis for data interpretation. Each specifies rigorous business and technical definitions of data that systems may need to share. Each is intended to be a logical specification of the data to be persisted within or communicated between systems. They are also the foundation for the compliance, conformance, and declaration process. Our CDA implementation guides are guides to the implementation of HL7 CDA R2 messages based upon these DCMs and SCSs.

The participation data specification specifies data components that enable a recipient of a document to identify participations within their own systems. Participations record context-specific information about relationships between participants and healthcare events. As such, participations are only meaningful within the context in which they are used.

Each DCM specifies all of the data components required for any use of a clinical concept; for instance, an entry in a medical record such as a procedure or an imaging test. As such, they are maximal data sets. DCMs are building blocks, which are trimmed to size for use in the construction of SCSs.

Each SCS describes a template of a Structured Document. It specifies the data for a single type of clinical document or information exchange, such as a discharge summary. It is assembled using DCMs that have been constrained to eliminate data components not relevant to the particular context. For example, *Procedure* in a discharge summary uses only some of the data components required by *Procedure* in a specialist report.

B.2 The Structured Content Specification Metamodel

Our metamodel for structured content specifications (see Figure 1) is used to specify the overall structure of a structured content specification. The structure is a tree, so every item in the tree, other than the root node, has a parent node. For an SCS, the root node is a Structured Document. For a DCM, the root node is a Data Group.

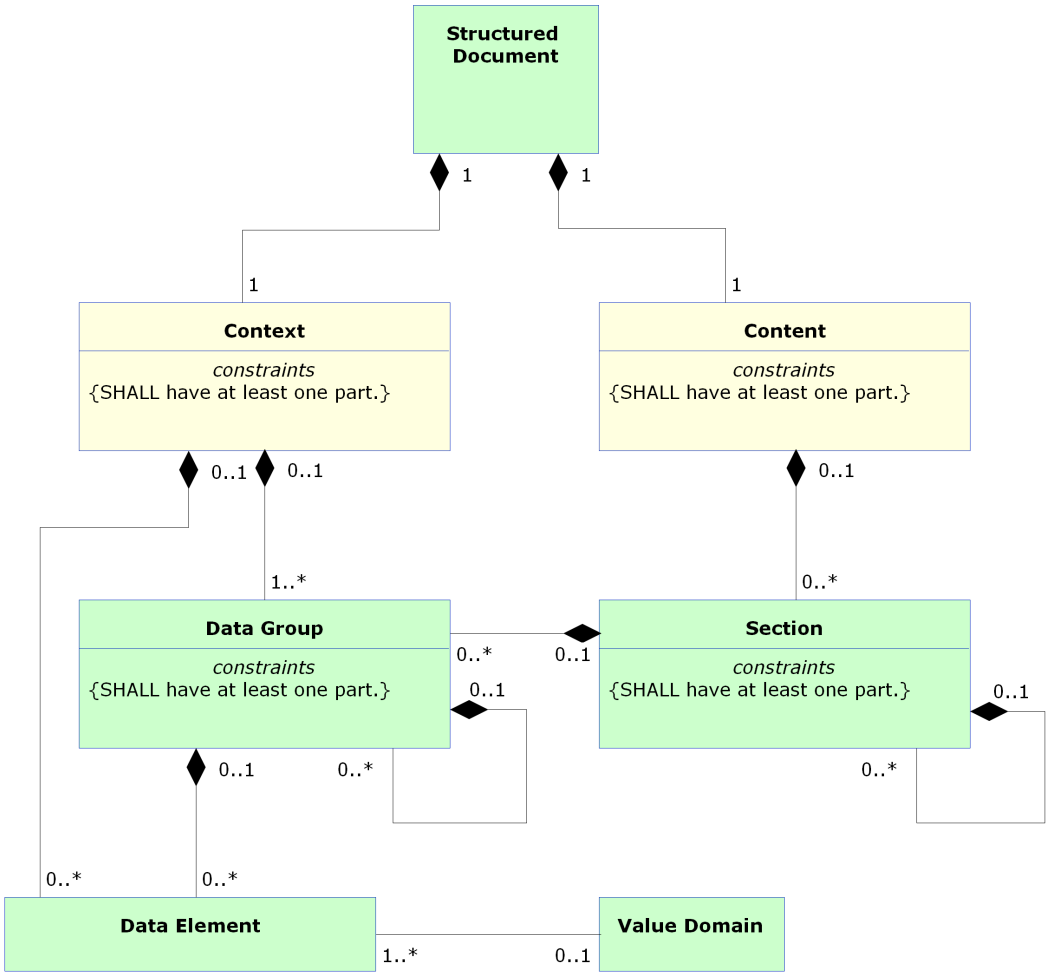

Figure B.1. SCS Metamodel

There are two main items used to organise information within an SCS as follows:

Context: This contains information related to the overall context of the document.

Content: This contains information that changes between different SCSs, but is always structured as shown in Figure 1, and consists of the following data components:

- Section
- Data Group
- Data Element
- Value Domain

These data components are described in more detail below.

Structured Document

A structured document is a collection of health information about a subject of care that is relevant to the ongoing care of that person. They are composed of one or more data groups and data elements that are organised into sections. Ex-

amples of structured documents are *Discharge Summary*, *Shared Health Summary*, and *Advance Care Directive Custodian Record*.

Context

The purpose of the context is to identify and classify the document and to provide subjects of care and involved healthcare providers with the information related to the relevant healthcare events.

Content

Content contains a collection of personal information and health information pertinent to a subject of care that is derived from the healthcare event described in the document. The detail is organised into one or more data groups, which are optionally grouped into sections.

Section

A section is composed of data groups, other sections, or both. It is an organising container that cues the reader about expected content. A section organises information in a manner suitable for the primary purpose for which it is collected and provides a way to navigate through the data components within the document, thereby enabling more efficient querying. It is recommended that the section support safe reuse for secondary purposes, e.g. clinical coding or inclusion in a summarised form in an electronic health record. A section is context-specific to the document in which it resides.

Data Group

Each data group is used to represent one concept. A data group consists of other data groups, data elements, or both. Some data groups are reused across DCMs.

Every instance of a data group **SHALL** have at least one child data component instantiated.

Participation

Participation is a special case of a data group that is based on a data group template, which is reused throughout the DCMs and SCSs. Participations are an amalgam of the Actors (see below) operating within a defined healthcare domain and the Roles they are playing within that domain.

A Participant has been defined to align with the concepts of the Agency's *Interoperability Framework [NEHT2007b]*. It equates to an *Entity* that is related to the action described in an SCS as an *Actor*. A Participant can be a human, an organisation, or an IT system.

Choice

Choice represents a selection, to be made at run-time, of a single member from a set of data groups, where the set is defined at design-time, i.e. one and only one member of the set is chosen for each instance of the choice.

For example, at design-time a healthcare provider provides a service, but it is not until run-time that a decision can be made as to whether the provider is a person or an organisation. Hence, when a healthcare provider *Participant* is instantiated, it will contain either an instance of the *Person* data group or an instance of the *Organisation* data group.

Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. For example, *DateTime of Observation* and *Observation Note*. Data elements are bound to data types (see Data Types Legend). Some data elements are reused in different data groups.

While all data elements are constrained by their data type, some data elements are further constrained by value domains (see Value Domain below).

Value Domain

A value domain constrains the permissible values for a data element. The values are often a subset of values based on a generic data type.

Value domains are reusable items, therefore the same value domain can be referred to by different data elements in different contexts. Value domains are often specified with reference to a *reference set*. A reference set is a constrained list of SNOMED CT-AU concepts that are appropriate to a particular context or use. Since many of these reference sets have been developed specifically for the context in which they appear, it is recommended that an assessment of fitness for purpose be undertaken before using any of the reference sets in another context.

Value domains constrain either by specifying a lower or upper bound (or both) on the range of permissible values or by specifying a finite set of prescribed values. Such a set of prescribed values can be specified directly within the definition of the data element, or in a separate but associated specification, or else by reference to one or more vocabulary or terminology reference sets. The table below provides some examples of value domains.

Table 1: Value Domain Examples

<table>
<tr><th>Data Element</th><th>Data Type</th><th>Example of Value Domain</th></tr>
<tr><td>Sex</td><td>CodedText</td><td>Standards Australia AS 4846 (2006) – Health Care Provider Identification [SA2006a] and Standards Australia AS 5017 (2006) – Health Care Client Identification [SA2006b] derive their values from METeOR 287316, which includes values such as:
<table>
<tr><th>Value</th><th>Meaning</th></tr>
<tr><td>1</td><td>Male</td></tr>
<tr><td>2</td><td>Female</td></tr>
<tr><td>3</td><td>Intersex or Indeterminate</td></tr>
<tr><td>9</td><td>Not Stated/Inadequately Described</td></tr>
</table></td></tr>
<tr><td>Diagnosis</td><td>CodeableText</td><td>A SNOMED CT-AU reference set that references concepts such as “Bronchitis” (Concept ID: 32398004).</td></tr>
<tr><td>Therapeutic Good Identification</td><td>CodeableText</td><td>An AMT reference set that references concepts such as “Ibuprofen Blue (Herron) (ibuprofen 200 mg) tablet: film-coated, 1 tablet” (Concept ID: 54363011000036107).</td></tr>
<tr><td>Individual Pathology Test Result Name</td><td>CodeableText</td><td>A LOINC subset that references concepts such as “Cholesterol [Moles/volume] in Serum or Plasma” (ID: 14647-2).</td></tr>
</table>

B.3 Icon Legend

These legends describe all icons that are used in the Agency's DCMs and SCSs.

Metadata Types Legend

The following table explains each of the icons used to represent the metadata types within DCMs and SCSs.

Table 2: Metadata Types Legend

Icon	Metadata Types
	Structured Document
	Section
	Data Group
	Participation
	Choice

Data Types Legend

The following table explains each of the icons used to represent the data types bound to each data element in the SCSs. These data types are a profile of the **ISO 21090-2011** data types as specified in *Data Types in NEHTA Specifications: A Profile of the ISO 21090 Specification [NEHT2010c]*.

Table 3: Data Types Legend

Icon	Data type	Explanation
	Any (ISO 21090: ANY)	Use of this icon indicates that instances of the data element can be of any concrete data type. There are no limitations on the data type of the data element. The values that can be required will vary considerably depending on the context. This is an abstract data type that is the basis for all data types and **SHOULD NOT** be used in an actual implementation.
	Boolean (ISO 21090: BL)	A data type, sometimes called the logical data type, having one of the two values: *true* and *false*. Many systems represent true as *non-zero* (often 1, or -1) and false as *zero*. **Usage/Examples** • An actual value entered by a user might be “yes” or could be chosen by a mouse click on an icon such as ☑.

CodeableText

(ISO 21090: CD)

Coded text *with* exceptions; supports various ways of holding text, both free text and coded text.

Often used to support compliance for early adopters of the structured content specifications.

While it is recommended that the values in this data type come from the bound value domain, it allows other value domains to also be used (with or without translations to the bound value domain) or free text alternatives. This is useful when it is not possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) and when there are competing code sets in existence. Note that within exchange specifications or message profiles this data type **MAY** be constrained to mandate compliance with the bound value domain.

Usage/Examples

- The Australian Institute of Health and Welfare (AIHW) defines a data element concept *Episode of admitted patient care-separation mode* (the status at separation of a subject of care and the place to which they are released). An early adopter could have a similar concept (coded or otherwise) that maps to this data element but does not strictly comply with the AIHW values.
- A SNOMED CT-AU coded/complex expression that embodies single or multiple concepts. The SNOMED CT-AU concepts behind these CodeableText data elements are specified in the structured content specification value domains.

CodedText

(ISO 21090: CD)

Coded text *without* exceptions; text with code mappings. Values in this data type **SHALL** come from the bound value domain, with no exceptions.

Often used for reference sets with only a small number of applicable values, e.g. Gender and Document Status.

Usage/Examples

Standards Australia AS 5017 (2006) – Health Care Client Identification [SA2006b] specifies the following value domain representing a type of address:

Value	Meaning
1	Business
2	Mailing or Postal
3	Temporary Accommodation
4	Residential (permanent)
9	Not Stated/Unknown/Inadequately Described

DateTime

(ISO 21090: TS)

A single date, optionally with a time of day.

Has the ability to indicate a level of precision, but not whether the date or time is estimated. Cannot represent a time alone.

String representations of known dates **SHALL** conform to the format within the **ISO 21090-2011** standard without the use of extensions, i.e. YYYY[MM[DD[HH[MM[SS[.U[U[U[U]]]]]]]]][+|-ZZzz].

Usage/Examples

- Partial dates: 2008, 20081001.
- To indicate 1:20 pm on May the 31st, 1999 for a time zone that is 10 hours ahead of Coordinated Universal Time (UTC): 19990531132000+1000.

	Duration (ISO 21090: PQ.TIME)	The period of time during which something continues. Consists of a value and a unit that represents the time value, e.g. hours, months. Compound durations are not allowed, e.g. 10 days 3 weeks 5 hours. **Usage/Examples** • 3 hours • 6 months • 1 year
	EncapsulatedData (ISO 21090: ED)	Data that is primarily intended for human interpretation or for further machine processing outside the scope of this specification. This includes unformatted or formatted written language, multimedia data, or structured information as defined by a different standard (e.g. XML signatures). **Usage/Examples** • JPEG images • HTML documents • [RFC1521] MIME types
	Integer (ISO 21090: INT)	The mathematical data type comprising the exact integral values. **Usage/Examples** • 1 • -50 • 125
	Link (ISO 21090: TEL)	A general link, reference or pointer to an object, data or application that exists logically or is stored electronically in a computer system. **Usage/Examples** • URL (Uniform Resource Locator) – the World Wide Web address of a site on the internet, such as the URL for the Google internet search engine – *http://www.google.com*. • An absolute or relative path within a file or directory structure – e.g. in the Windows operating system, the “link” or absolute path to a particular letter could be *C:\Documents and Settings\GuestUser\MyDocuments\letter.doc*
	Quantity (ISO 21090: PQ)	A magnitude value with a unit of measurement. This is used for recording many real world measurements and observations. As the default unit of measure is 1, even counts of items can be recorded with *Quantity*. **Usage/Examples** • 100 centimetres • 25.5 grams • 3 per month

QuantityRange

(ISO 21090: IVL)

A range of *Quantity* values.

It may be identified using a combination of an optional minimum *Quantity* and an optional maximum *Quantity* (i.e. lower and upper bounds).

This is typically used for defining the valid range of values for a particular measurement or observation. Unbounded quantity ranges can be identified by not including a minimum or a maximum *Quantity* value.

Usage/Examples

- -20 to 100 Celsius
- 30-50 mg
- >10 kg
- 2-3 hours

QuantityRatio

(ISO 21090: RTO)

A relative magnitude of two *Quantity* values.

Usually recorded as numerator and denominator.

Usage/Examples

- 25 mg / 500 ml
- 200 mmol per litre

Real

(ISO 21090: REAL)

A computational approximation to the standard mathematical concept of real numbers.

These are often called floating-point numbers.

Usage/Examples

- 1.075
- -325.1
- 3.14157

Text

(ISO 21090: ST)

A character string (with optional language) containing any combination of alpha, numeric, or symbols from the Unicode character set. Also referred to as *free text*.

Usage/Examples

"The patient is a 37 year old man who was referred for cardiac evaluation after complaining of occasional palpitations, racing heart beats and occasional dizziness."

TimeInterval

(ISO 21090:IVL)

An interval in time.

It is identified using a combination of an optional start *DateTime*, an optional end *DateTime*, and an optional *Duration*.

Usage/Examples

- 20080101+1000 - 20081231+1000
- 200801010130+1000 - 200801011800+1000
- 200801010130+1000, duration=16.5 hours

	UniqueIdentifier (ISO 21090: II)	A unique value used to identify a physical or virtual object or concept. In using this data type, the attributes of the UniqueIdentifier data type **SHOULD** be populated from the identifiers as defined in *AS 4846 (2006) – Health Care Provider Identification [SA2006a]* and *AS 5017 (2006) – Health Care Client Identification [SA2006b]* as follows: • *root*: a globally unique object identifier that identifies the combination of geographic area, issuer and type. If no such globally unique object identifier exists, it **SHALL** be created. • *extension*: a unique identifier within the scope of the root that is directly equivalent to the identifier designation element. • *identifierName*: a human readable name for the namespace represented by the root that is populated with the issuer or identifier type values, or a concatenation of both, as appropriate. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used for that purpose. • *identifierScope*: the geographic span or coverage that applies to or constrains the identifier. It is directly equivalent to the geographic area element. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used as such. Also, the following constraints apply on the UniqueIdentifier data type: 1) The *root* attribute **SHALL** be used. 2) For an Entity Identifier, the *root* attribute **SHALL** be an OID that consists of a node in a hierarchically assigned namespace, formally defined using the ITU-T's ASN.1 standard. 3) For an Entity Identifier, the *root* attribute **SHALL NOT** be a UUID. **Usage/Examples** Australian health identifiers (e.g. IHI, HPI-I and HPI-O) and patient hospital medical record numbers are examples of identifiers that may be carried by data elements of this data type.

Keywords Legend

Where used in this document and in DCMs and SCSs, the keywords **SHALL, SHOULD, MAY, SHALL NOT** and **SHOULD NOT** are to be interpreted as described in *Key Words for Use in RFCs to Indicate Requirement Levels [RFC2119]*. Our specifications use the terms **SHALL** in place of “MUST” and **SHALL NOT** in place of “MUST NOT”. The key word definitions in RFC 2119, adjusted to remove the key words not used in the Agency specifications, are presented in the following table.

Table 4: Keywords Legend

Keyword	Definition
SHALL	This word means that the statement is an absolute requirement of the specification.
SHOULD	This word means that there may exist valid reasons in particular circumstances to ignore a particular data component, but the full implications must be understood and carefully weighed before choosing a different course.

MAY	This word means that a data component is truly optional. One implementer may choose to include the data component because a particular implementation requires it, or because the implementer determines that it enhances the implementation, while another implementer may omit the same data component. An implementation that does not include a particular option shall be prepared to interoperate with another implementation that does include the option, perhaps with reduced functionality. In the same vein, an implementation that does include a particular option shall be prepared to interoperate with another implementation that does not include the option (except of course, for the feature the option provides).
SHALL NOT	This phrase means that the statement is an absolute prohibition of the specification.
SHOULD NOT	This phrase means that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

Obligation Legend

In DCMs and SCSs obligations on a data component specify whether or not it **SHALL** be populated in the logical record architecture of a message. We intend that all data components that are not **PROHIBITED** will be implemented.

Obligations in statements about values specify whether or not certain values are permitted.

Implementation guides specify the rules and formats for implementing and populating data components in specific messaging formats.

The following table defines the obligations.

Table 5: Obligations Legend

Keyword	Interpretation
ESSENTIAL	Indicates that the data component is considered a mandatory item of information and **SHALL** be populated. **Usage/Examples:** The Participant data component for a Subject of Care **SHALL** include an Entity Identifier data component in order to hold the IHI.
OPTIONAL	Indicates that the data component is not considered a mandatory item of information and **MAY** be populated. **Usage/Examples:** Such data components will be implemented, only inclusion and population are optional. This is only needed when a DCM incorrectly asserts that a data component is **ESSENTIAL**. It will be used with a note stating that the DCM needs revision.
PROHIBITED	On a data component this indicates that the data component is considered a forbidden item of information and **SHALL NOT** be included. In a statement about values this indicates that the use of the specified values is considered forbidden and they **SHALL NOT** be used. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be populated.

CONDITIONAL	Indicates that a data component is considered **ESSENTIAL** only on satisfaction of a given condition. Individual data components specify the obligation of the data component when the condition is not met. When a condition is met, the data component is considered to be **ESSENTIAL** and **SHALL** be populated. When a condition is not met, the data component may be considered **PROHIBITED**, or the data component may be considered **OPTIONAL**. **Usage/Examples:** Within a Pathology Result Report, the *Specimen Detail* `data group` is **ESSENTIAL** if the requested test is to be performed on a specimen; otherwise it **SHALL NOT** be included.

Obligations follow the usual scope rules: where **ESSENTIAL** child data components are contained within **OPTIONAL** parent data components, the child data components **SHALL NOT** be included when the parent is not included.

B.4 Exceptional Values

Occasionally a data element will have an exceptional value: an abnormal value (i.e. the value cannot be described using the expected set of values) or an absent value (i.e. no value is provided). Some abnormal values are only relevant to data elements of certain data types (e.g. positive infinity is relevant to numbers but not Booleans).

Unless otherwise specified, all data elements are permitted to have exceptional values. Constraints on the use of exceptional values are contained in the Exceptional Values row of the Usage section, except for instances of Participation, when they are in the Conditions of Use row. The most common statements constraining exceptional values are:

- Absent values are **PROHIBITED**.
- Abnormal values are **PROHIBITED**.

The commonly used implementation specifications ISO 21090 and HL7 CDA R2 use *nullFlavor* to manage abnormal and absent values.

The following table provides a classification of nullFlavor values as abnormal or absent.

Table 6: Classification of ISO 21090 nullFlavor values as absent or abnormal

Level	Code	Term	Abnormal	Absent
1	NI	No information		Absent
2	INV	Invalid	Abnormal	
3	OTH	Other	Abnormal	
4	PINF	Positive infinity	Abnormal	
4	NINF	Negative infinity	Abnormal	
3	UNC	Unencoded	Abnormal	
3	DER	Derived	Abnormal	
2	UNK	Unknown		Absent
3	ASKU	Asked but unknown		Absent
4	NAV	Temporarily unavailable		Absent
3	NASK	Not asked		Absent
3	QS	Sufficient quantity	Abnormal	
3	TRC	Trace	Abnormal	
2	MSK	Masked		Absent

Level	Code	Term	Abnormal	Absent
2	NA	Not applicable		Absent

B.5 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each section, data group and data element within the Agency's DCMs and SCSs, and identifies when each part is applicable.

Chapter Name

Each section, data group, data element, value domain or choice has its own eponymous chapter. The chapter name is used in all data hierarchies.

Identification Section Legend

The following table illustrates the layout of the Identification section and describes the various parts of the section.

Table 7: Identification Section Legend

Label	A suggested display name for the data component.
Metadata Type	The type of the data component, e.g. section, data group or data element.
Identifier	An Agency-assigned internal identifier of the data component. Note that if one data component is used twice (e.g. *Therapeutic Good Identification* is used in both *Medication Instruction* and *Medication Action*), both uses of the data component will have the same identifier. A data component identifier identifies a data component, not a **use** of a data component.
OID	An object identifier equivalent to the data component identifier.
External Identifier	An identifier of the concept represented by the data component that is assigned by an organisation other than the Agency.

Definition Section Legend

The following table illustrates the layout of the Definition section and describes the various parts of the section.

Table 8: Definition Section Legend

Definition	The meaning, description or explanation of the data component. For data groups used in a particular context, the definition **MAY** be a refinement of the generic data group definition.
Definition Source	The authoritative source for the Definition statement.
Synonymous Names	A list of any names the data component may also be known as. Implementers may prefer to use synonymous names to refer to the data component in specific contexts.
Scope	Situations in which the data component may be used, including the Scope circumstances where specified data are required or recommended.

	For example, Medication Instruction (data group) has a scope that includes all prescribable therapeutic goods, both medicines and non-medicines. This item is not relevant to data elements or value domains.
Scope Source	The authoritative source for the Scope statement.
Context	The environment in which the data component is meaningful, i.e. the circumstance, purpose and perspective under which this data component is defined or used. For example, Street Name has a context of Address. This item is applicable only to data elements.
Assumptions	Suppositions and notions used in defining the data component.
Assumptions Source	The authoritative source for the Assumptions statement.
Notes	Informative text that further describes the data component, or assists in the understanding of how the data component can be used.
Data Type	The data type (or data types) of the data element, e.g. DateTime or Text. The valid data types are specified in the Data Types Legend. This item is applicable only to data elements.
Value Domain	The name of the Value Domain used to define the range of values of the data element, or a statement describing what values to use in the absence of a defined value domain for the related data element. The statement is: In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated. This item is applicable only to data elements with data type CodedText or CodeableText.

Data Hierarchy

The top-level data components (a Structured Document in an SCS or Data Groups in a DCM) contain a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one data component in another. Each entry contains at least three occupied cells. The left-most cell contains an icon to indicate the entry's data type. The next cell to the right contains the label of the data component (if the label is different from the name, the name is displayed in brackets after the label). The next cell to the right contains the multiplicity range for the data component.

If a row is not shaded, this indicates that the data component **SHOULD** be used. Where the minimum multiplicity is zero, this does not mean that it is optional to support the data component in the clinical information system, rather it means that the clinical information system has the capability to record that data component but that it may not populate it in a particular clinical document instance.

If a row is shaded grey, this indicates that the data component **SHOULD NOT** be used. This will be because analysis of requirements either did not find reasons to use it or found reasons to not use it.

If the text in a row is in a ~~strike through~~ font and the multiplicity is 0..0, this indicates that the data component **SHALL NOT** be used. This will be because analysis of requirements found reasons to prohibit the use of it.

Sample SCS Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

Items below with a grey background are data components that are included in the relevant detailed clinical model specification, but whose use is discouraged in this particular scenario.

Items below with a clear background are data components whose use is encouraged in this particular scenario.

SPECIALIST LETTER			
CONTEXT			
	SUBJECT OF CARE		1..1
	DOCUMENT AUTHOR		1..1
	ENCOUNTER		1..1
		DateTime Subject of Care Seen (DateTime Health Event Started)	1..1
		DateTime Health Event Ended	0..0
		HEALTHCARE FACILITY	0..0
	Document Instance Identifier		0..1
	RELATED INFORMATION		0..0
	Document Type		1..1
CONTENT			
	RESPONSE DETAILS		1..1
		Diagnosis (PROBLEM/DIAGNOSIS)	0..*
		Diagnosis Name (Problem/Diagnosis Identification)	1..1
		Clinical Description	0..0
and more			

Value Domain Section Legend

The following table illustrates the layout of the Value Domain section and describes the various parts of the section.

Table 9: Value Domain Section Legend

Source	The name of the terminology or vocabulary from which the value domain's permissible values are sourced, e.g. SNOMED CT-AU, LOINC.
Version Number	Version number of the value domain source.
Permissible Values	A specification of the permissible values in the value domain. This may be a list of codes. (Each code is typically presented as a triple with code values, text equivalent, and description) for example: 1, Registered No result yet available. This may be a conformance statement (e.g. "The permissible values are the members of the following seven AMT reference sets: ...").

Usage Section Legend

The following table illustrates the layout of the Usage section and describes the various parts of the section.

Table 10: Usage Section Legend

Examples	Sample values for the data element, with or without notes about sample values. Where a data element has an associated value domain, examples representative of that domain are used where possible. Where the value domain is yet to be determined, indicative examples are provided. Implementation guides may contain specific examples of how data elements may be populated and how they relate to each other. This item is applicable only to data elements.
Conditions of Use	Prerequisites, provisos or restrictions for use of the data component.
Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate or wrong uses of the data component.
Default Value	A common denomination, or at least a usable denomination, from the Value Domain where available or applicable, typically assigned at the creation of an instance of the data component.
Exceptional Values	A statement of limitations on the use of exceptional values, see Exceptional Values. Unless otherwise specified, all data elements are permitted to have exceptional values. The most common statements constraining exceptional values are: • Abnormal values are **PROHIBITED**. • Absent values are **PROHIBITED**. This item is applicable only to data elements.

Relationships Section Legend

The Relationships section specifies the cardinality between parent and child data components.

The following table illustrates the layout of the Parent relationships table. Note that the occurrences in the relationships described by this table are from the parent to the child data component, i.e. from the data component listed in the table to the data component described by the section.

Table 11: Parent Legend

Data Type	Name	Occurrences (child within parent)
The icon illustrating the metadata type or data type.	Parent Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

The following table illustrates the layout of the Children relationships table.

Table 12: Children Legend

Data Type	Name	Occurrences
The icon illustrating the metadata type or data type.	Child Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

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