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Pharmaceutical Benefits Report Structured Content Specification Version 1.1.1

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Document Information

Key information

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1.0	30 Apr 2012	Limited Release - For Consultation.
1.0	19 Jun 2012	Limited Release - For Consultation.
1.1.1	15 Sep 2014	Initial public release. Publication version. This version of the specification includes typographical, stylistic, and editorial corrections. Changes to the Data Hierarchy in this specification are to explicitly identify technical identifiers. A detailed list of changes can be provided upon request.

Related documents

Name	Version/Release Date
NEHTA Acronyms, Abbreviations & Glossary of Terms	Version 1.2, Issued 25 May 2005
Participation Data Specification	Version 3.2, Issued 20 July 2011
Medicare Repositories Detailed Clinical Model Specification	Version 1.1, To be published
Personally controlled electronic health record system: Glossary of Terms	Issued 2014

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Table of Contents

1 Introduction

This document is a Structured Content Specification (SCS) for a Pharmaceutical Benefits Report.

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

NEHTA values your questions and comments about this document. Please direct your questions or feedback to *help@nehta.gov.au*.

1.1 Document Purpose

This document describes the structured content of Pharmaceutical Benefits Report documents that are added to the personally controlled electronic health record (PCEHR) system.

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 *NEHTA Pharmaceutical Benefits Report CDA Implementation Guide [NEHT2014b]*, which describes how to implement NEHTA-compliant Pharmaceutical Benefits Reports 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. It is also intended for those who wish to evaluate the clinical suitability of NEHTA-endorsed specifications.

1.3 Document Scope

This document specifies the essential clinical data groups and elements to be captured in a Pharmaceutical Benefits Report exchange and the constraints that should be applied. Its scope is aligned to the document *Concept of Operations: Relating to the introduction of a Personally Controlled Electronic Health Record System [DHA2011b]*.

This is not a guide to implementing 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 information should be inferred.

1.4 Known Issues

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

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2 Pharmaceutical Benefits Report Structured Document

2.1 Purpose

To record information about pharmaceutical items prescribed and dispensed to an individual that were partially or fully funded under the Pharmaceutical Benefit Schedule (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS).

2.2 Use

Use to display or share, in the PCEHR system and related applications, information about pharmaceutical items prescribed and dispensed to an individual.

2.3 PHARMACEUTICAL BENEFITS REPORT

Identification

Label	PHARMACEUTICAL BENEFITS REPORT
Metadata Type	Structured Document
Identifier	SD-16650
OID	1.2.36.1.2001.1001.101.100.16650

Definition

Definition	Information about pharmaceutical items prescribed and dispensed to an individual that were partially or fully funded under the Pharmaceutical Benefits Scheme (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS).
Definition Source	NEHTA
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. It is typically expected that such identifiers will be generated internally by systems and not displayed to users since they usually have no clinical significance.

Items below whose background is grey and whose text is struck through are data components that are included in the relevant Detailed Clinical Model Specification, but whose use is prohibited in this particular scenario.

		PHARMACEUTICAL BENEFITS REPORT	
CONTEXT			
		SUBJECT OF CARE	1..1
		DOCUMENT AUTHOR	1..1
		~~ENCOUNTER~~	~~0..0~~
		Document Instance Identifier	1..1
		~~RELATED INFORMATION~~	~~0..0~~
		Document Type	1..1
CONTENT			
		PHARMACEUTICAL BENEFIT ITEMS	1..1

			PHARMACEUTICAL BENEFIT ITEM		1..*
				PBS/RPBS Item Code	1..1
				PBS/RPBS Manufacturer Code	0..1
				Brand (Pharmaceutical Item Brand)	1..1
				Item Generic Name (Pharmaceutical Item Generic Name)	1..1
				Item Form and Strength (Pharmaceutical Item Form and Strength)	1..1
				Date of Supply	1..1
				Date of Prescribing	1..1
				Quantity	1..1
				Number of Repeats	1..1
				~~INFORMATION PROVIDER~~	~~0..0~~
				~~SUBJECT~~	~~0..0~~
				Pharmaceutical Benefit Item Instance Identifier	1..1
				~~RELATED INFORMATION~~	~~0..0~~
				Detailed Clinical Model Identifier	1..1
			~~Pharmaceutical Benefit Items Instance Identifier~~		~~0..0~~
			~~RELATED INFORMATION~~		~~0..0~~
			Section Type		1..1

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 healthcare services.
Definition Source	NEHTA
Synonymous Names	Patient Individual
Scope	The person who is the focus of this document.
Scope Source	NEHTA

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*. Additional obligation and occurrence constraints: • Participation Period is **PROHIBITED**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • DEMOGRAPHIC DATA is **ESSENTIAL**. • Sex is **ESSENTIAL**. • DATE OF BIRTH DETAIL is **ESSENTIAL**. • Relationship to Subject of Care is **PROHIBITED**. • EMPLOYMENT DETAIL is **PROHIBITED**. • Qualifications is **PROHIBITED**. Other additional constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject of Care”. • Role **SHALL** have an implementation-specific value equivalent to “Patient”.

	• The value of one Entity Identifier **SHALL** be an Australian Individual Healthcare Identifier (IHI). • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. • Indigenous Status **SHOULD** have a value.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	PHARMACEUTICAL BENEFITS REPORT	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	NEHTA
Synonymous Names	Author
Notes	The date the document is authored (DateTime Authored) is contained in the *Participation Period* of the *Document Author*.

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*. Additional obligation and occurrence constraints: • Participation Period is **ESSENTIAL**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • ADDRESS is **PROHIBITED**. • ELECTRONIC COMMUNICATION DETAIL is **PROHIBITED**. • ENTITLEMENT is **PROHIBITED**. • Qualifications is **PROHIBITED**. Other additional constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Document Author”. • Role **SHALL** have an implementation-specific value equivalent to “Not Applicable”. • The value of one Entity Identifier **SHALL** be a PCEHR Assigned Identifier for Device (PAI-D). • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a DEVICE.

Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	PHARMACEUTICAL BENEFITS REPORT	1..1

2.6 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	A globally unique identifier for each instance of a *Pharmaceutical Benefits Report* document.
Definition Source	NEHTA
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 after it is first sent. 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	NEHTA
Notes	This `data element` is intended for machine or system use only and hence need not be displayed on documents.
Data Type	UniqueIdentifier

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFITS REPORT	1..1

2.7 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	NEHTA
Synonymous Names	
Notes	A document's type is identified by a unique identifier, not by a name.
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.100.16650
Default Value Conditions of Use	The value of this item is fixed and **SHALL** be the default value.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFITS REPORT	1..1

2.8 PHARMACEUTICAL BENEFIT ITEMS

Identification

Label	PHARMACEUTICAL BENEFIT ITEMS
Metadata Type	Section
Identifier	S-16649
OID	1.2.36.1.2001.1001.101.101.16649

Definition

Definition	Information about pharmaceutical items prescribed and dispensed to an individual that were partially or fully funded under the Pharmaceutical Benefit Schedule (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS).
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFITS REPORT	1..1

Children

Data Type	Name	Occurrences
	PHARMACEUTICAL BENEFIT ITEM	1..*
	~~Pharmaceutical Benefit Items Instance Identifier~~	~~0..0~~
	~~RELATED INFORMATION~~	~~0..0~~
	Section Type	1..1

2.9 Section Type

Identification

Label	Section Type
Metadata Type	Data Element
Identifier	DE-16693
OID	1.2.36.1.2001.1001.101.103.16693

Definition

Definition	NEHTA OID for type of Section.
Definition Source	NEHTA
Synonymous Names	
Notes	A section's type is identified by a unique identifier, not by a name.
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.101.16649
Default Value Conditions of Use	The value of this item is fixed and **SHALL** be the default value.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	PHARMACEUTICAL BENEFIT ITEMS	1..1

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3 Pharmaceutical Benefit Item Detailed Clinical Model

This chapter describes a reuse of version 1.1 of the *Pharmaceutical Benefit Item* Detailed Clinical Model (DCM).

See *Medicare Repositories Detailed Clinical Model Specification [NEHT2014ad]* for more information.

3.1 Purpose

To record information about pharmaceutical items prescribed and dispensed to an individual that were partially or fully funded under the Pharmaceutical Benefit Schedule (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS).

3.2 Use

Use to display or share, in the PCEHR system and related applications, information about pharmaceutical items prescribed and dispensed to an individual.

3.3 PHARMACEUTICAL BENEFIT ITEM

Identification

Label	PHARMACEUTICAL BENEFIT ITEM
Metadata Type	Data Group
Identifier	DG-16674
OID	1.2.36.1.2001.1001.101.102.16674

Definition

Definition	Information about pharmaceutical items prescribed and dispensed to an individual that were partially or fully funded under the Pharmaceutical Benefits Scheme (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS).
Definition Source	NEHTA
Synonymous Names	
Notes	This is the pharmaceutical item for which funding was claimed and not necessarily the actual pharmaceutical item that was supplied.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEMS	1..*

Children

Data Type	Name	Occurrences
	PBS/RPBS Item Code	1..1
	PBS/RPBS Manufacturer Code	0..1
	Brand (Pharmaceutical Item Brand)	1..1
	Item Generic Name (Pharmaceutical Item Generic Name)	1..1
	Item Form and Strength (Pharmaceutical Item Form and Strength)	1..1
	Date of Supply	1..1
	Date of Prescribing	1..1

Data Type	Name	Occurrences
	Quantity	1..1
	Number of Repeats	1..1
	~~INFORMATION PROVIDER~~	~~0..0~~
	~~SUBJECT~~	~~0..0~~
	Pharmaceutical Benefit Item Instance Identifier	1..1
	~~RELATED INFORMATION~~	~~0..0~~
	Detailed Clinical Model Identifier	1..1

3.4 PBS/RPBS Item Code

Identification

Label	PBS/RPBS Item Code
Metadata Type	Data Element
Identifier	DE-16062
OID	1.2.36.1.2001.1001.101.103.16062

Definition

Definition	Administrative code and short description of the pharmaceutical item supplied.
Definition Source	NEHTA
Synonymous Names	
Notes	This element is to be used to assist with claims processing. This would typically be used for the PBS Scheduled Item Code, which is a Department of Health allocated detailed code that specifies a medication use together with its funding.
Data Type	CodedText
Value Domain	PBS/RPBS Item Code Values

Usage

Examples	1) 1746X (paracetamol 500 mg tablet, 100) 2) 4657D (bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage)

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.5 PBS/RPBS Item Code Values

Identification

Label	PBS/RPBS Item Code Values
Metadata Type	Value Domain
Identifier	VD-16645
OID	1.2.36.1.2001.1001.101.104.16645

Definition

Definition	The set of item codes (and associated short descriptions) contained in the PBS Schedule list.
Definition Source	NEHTA
Notes	The codes recommended for PBS Schedule item code by the Department of Health are available from http://www.pbs.gov.au/pbs/home (accessed 20 June 2014).

Value Domain

Source	Department of Health, PBS Schedule item code.

Usage

Conditions of Use	Values **SHALL** be codes recommended for PBS Schedule item code by the Department of Health.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	PBS/RPBS Item Code	1..1

3.6 PBS/RPBS Manufacturer Code

Identification

Label	PBS/RPBS Manufacturer Code
Metadata Type	Data Element
Identifier	DE-16675
OID	1.2.36.1.2001.1001.101.103.16675

Definition

Definition	The PBS-assigned administrative code identifying the manufacturer of the pharmaceutical item supplied.
Definition Source	NEHTA
Synonymous Names	
Notes	This element is used to assist with claims processing.
Data Type	CodedText
Value Domain	PBS/RPBS Manufacturer Code Values

Usage

Examples	1) SW (sanofi-aventis Australia) 2) MH (Molnlycke Health Care)

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	0..1

3.7 PBS/RPBS Manufacturer Code Values

Identification

Label	PBS/RPBS Manufacturer Code Values
Metadata Type	Value Domain
Identifier	VD-16647
OID	1.2.36.1.2001.1001.101.104.16647

Definition

Definition	The set of values derived from the PBS manufacturer code.
Definition Source	NEHTA
Notes	The codes recommended for PBS manufacturer code by the Department of Health are available from http://www.pbs.gov.au/pbs/home (accessed 20 June 2014).

Value Domain

Source	Department of Health, PBS manufacturer code.

Usage

Conditions of Use	Values **SHALL** be codes recommended for PBS manufacturer code by the Department of Health.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PBS/RPBS Manufacturer Code	1..1

3.8 Pharmaceutical Item Brand

Identification

Label	Brand
Metadata Type	Data Element
Identifier	DE-16703
OID	1.2.36.1.2001.1001.101.103.16703

Definition

Definition	The brand of the pharmaceutical item supplied.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1) Amoxil (Trade Product of Medicinal Product Amoxycillin)

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.9 Pharmaceutical Item Generic Name

Identification

Label	Item Generic Name
Metadata Type	Data Element
Identifier	DE-16676
OID	1.2.36.1.2001.1001.101.103.16676

Definition

Definition	The generic name of the item supplied.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1) Amoxycillin

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.10 Pharmaceutical Item Form and Strength

Identification

Label	Item Form and Strength
Metadata Type	Data Element
Identifier	DE-16677
OID	1.2.36.1.2001.1001.101.103.16677

Definition

Definition	The form and strength of the item supplied.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1) Capsules 500mg

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.11 Date of Supply

Identification

Label	Date of Supply
Metadata Type	Data Element
Identifier	DE-16678
OID	1.2.36.1.2001.1001.101.103.16678

Definition

Definition	The recorded date the pharmaceutical item was supplied.
Definition Source	NEHTA
Synonymous Names	
Notes	This is essentially the date of dispense. The PBS system does not record the date the item was actually collected by patient.
Data Type	DateTime

Usage

Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a date or time (or both).

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.12 Date of Prescribing

Identification

Label	Date of Prescribing
Metadata Type	Data Element
Identifier	DE-16679
OID	1.2.36.1.2001.1001.101.103.16679

Definition

Definition	The date the pharmaceutical item was prescribed.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a date or time (or both).

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.13 Quantity

Identification

Label	Quantity
Metadata Type	Data Element
Identifier	DE-10145
OID	1.2.36.1.2001.1001.101.103.10145

Definition

Definition	The number of doses or the physical amount of the therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Data Type	Quantity

Usage

Examples	1) 20 capsules

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.14 Number of Repeats

Identification

Label	Number of Repeats
Metadata Type	Data Element
Identifier	DE-10169
OID	1.2.36.1.2001.1001.101.103.10169

Definition

Definition	The number of repeats of the prescription that have been authorised by the prescriber for a given medication.
Definition Source	NEHTA
Synonymous Names	
Data Type	Integer

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.15 Pharmaceutical Benefit Item Instance Identifier

Identification

Label	Pharmaceutical Benefit Item Instance Identifier
Metadata Type	Data Element
Identifier	DE-16747
OID	1.2.36.1.2001.1001.101.103.16747

Definition

Definition	A globally unique identifier for each instance of a *Pharmaceutical Benefit Item* administration entry.
Definition Source	NEHTA
Synonymous Names	
Notes	This `data element` is intended for machine or system use only and hence need not be displayed on documents.
Data Type	UniqueIdentifier

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

3.16 Detailed Clinical Model Identifier

Identification

Label	Detailed Clinical Model Identifier
Metadata Type	Data Element
Identifier	DE-16693
OID	1.2.36.1.2001.1001.101.103.16693

Definition

Definition	The NEHTA OID for the concept represented by this Detailed Clinical Model.
Definition Source	NEHTA
Synonymous Names	
Notes	This `data element` is intended for machine or system use only and hence need not be displayed on documents.
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16674
Default Value Conditions of Use	The value of this item is fixed and **SHALL** be the default value.

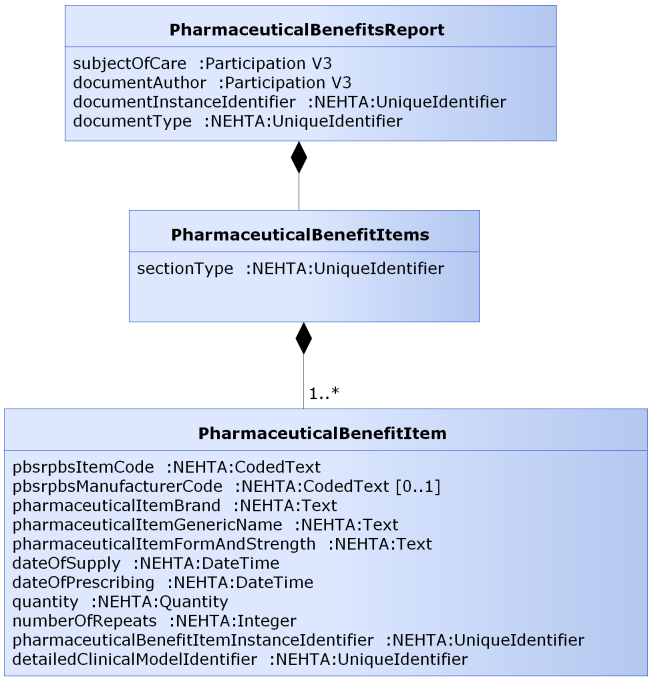
Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PHARMACEUTICAL BENEFIT ITEM	1..1

4 UML Class Diagrams

The following figures present the data hierarchy using UML 2.0 class diagrams. The diagrams display 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 labels are represented as association role names. Association role names are only displayed if they differ from the associated class name. The diagrams show the data hierarchy excluding the details of participation. The default multiplicity is 1..1.



UML class diagram of the Pharmaceutical Benefits Report data hierarchy

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Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. NEHTA is working on solutions to these issues, and we encourage comments to further assist with the development of these solutions.

Reference	Description
Link to external resources	If a link (usually in references section) spans several lines, certain combinations of PDF reader and web browser have problems opening it.
No requirements	There is no written statement of requirements for this document. It was constructed using the Detailed Clinical Model for Pharmaceutical Benefit Item. Consequently *Subject of Care* and *Document Author* data components could be better understood and described in the given Medicare context. Other components such as *Dispenser* and *Prescriber* might need to be included.
Data Model	This Structured Content Specification does not make use of AMT codes. AMT codes are the standard representation of medications. When Medicare supplies AMT codes, the data model will have to be changed.
Subject of Care	This specification does not prohibit use in *Subject of Care* of any of the demographic information permitted by the *Participation* v3.2 data specification. That includes date of death. Some of the demographic data items may be prohibited in future versions of this specification.
Pharmaceutical Benefit Items Instance Identifier	*Pharmaceutical Benefit Items Instance Identifier* is currently constrained out to allow compatibility with the implemented model.
Department of Health	This specification references the Department of Health. However this name could change during the life of the specification.

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Appendix B. Specification Guide for Use

B.1 Overview

Each Detailed Clinical Model (DCM) and Structured Content Specification (SCS) is designed to be a shared basis for data interpretation. It specifies rigorous business and technical definitions of data which systems may need to share. It is intended to be a logical specification of the data to be persisted within or communicated between systems. It is also the foundation for conformance, compliance and accreditation testing of implemented systems. NEHTA's CDA implementation guides are guides to the implementation of HL7 CDA R2 messages based upon these DCMs and SCSs.

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 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

The NEHTA Structured Content Specification Metamodel (see Figure 1) is used to specify the overall structure of a Structured Content Specification.

A DCM can be regarded as a data group with no parent.

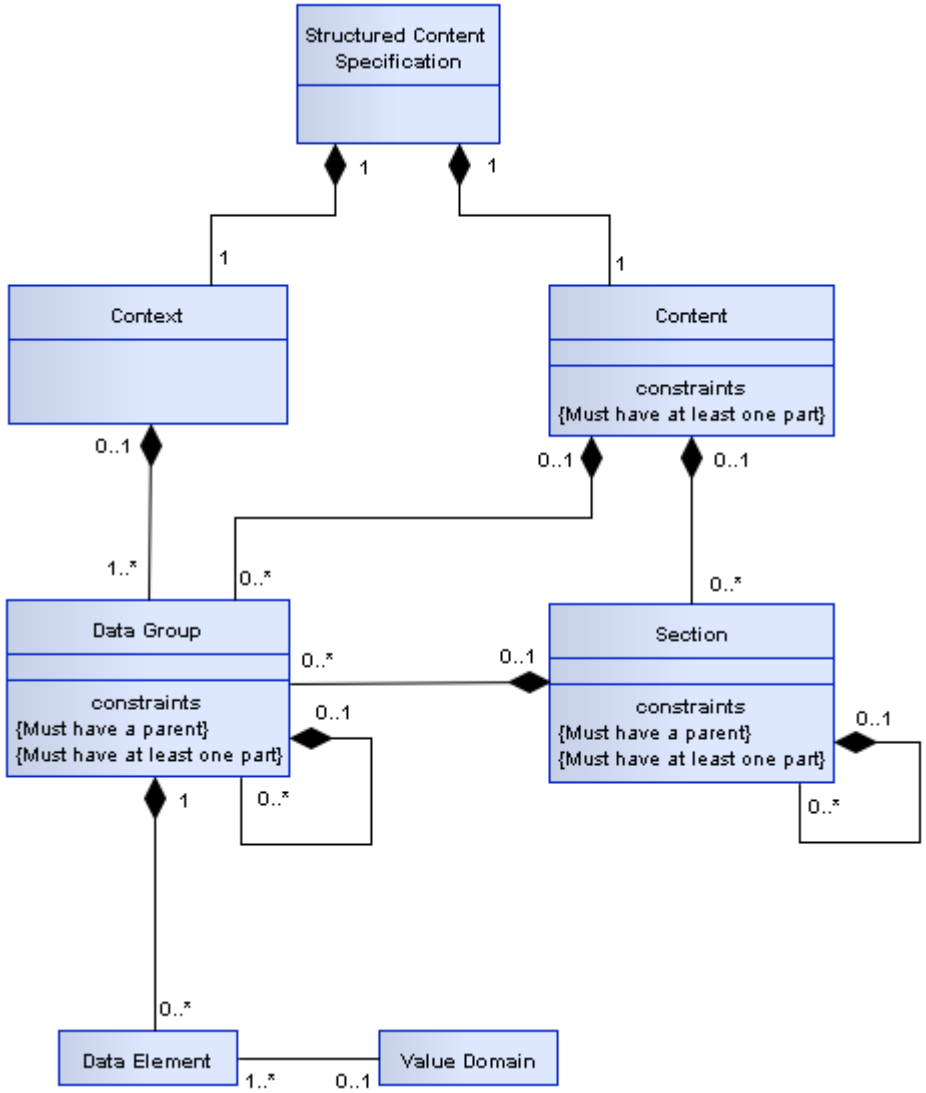

Figure 1: SCS Metamodel

There are two main components 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, and consists of the following components:

- Section
- Data Group
- Data Element
- Value Domain

These components are described in more detail below.

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 which 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 other sections, data groups, or both. It is an organising container that gives the reader a clue as to the expected content. The primary purpose of a section is to organise information in a manner that is suitable for the primary purpose for which it is collected, and to provide 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 or 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 NEHTA 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.

[NEHT2011v] defines the full Participation specification.

Choice

Choice represents a decision to be made at run-time between a disjunctive mandatory set of data groups 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.

Whilst 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 components and therefore, the same value domain can be referred to by different data elements in different contexts. Value domains are often specified as a reference set. A reference set (or a subset) is a constrained list of SNOMED CT-AU, AMT or LOINC concepts that are appropriate to a particular context. It is noted that 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 by either specifying a lower or upper bound (or both) on the range of permissible values or else 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/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>[SA2006a] and [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 which references concepts such as ‘Bronchitis’ (Concept ID: 32398004).</td></tr>
<tr><td>Therapeutic Good Identification</td><td>CodeableText</td><td>An AMT reference set which 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 which 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 within the various NEHTA information specifications.

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 [NEHT2010c].

Table 3: Data Types Legend

Icon	Data type	Explanation
	Boolean (ISO 21090: BL)	A primitive data type, sometimes called the logical data type, having one of 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; a flexible data type to support various ways of holding text, both free text and coded text. Commonly 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 in recognition that it may not be possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) or that there may be 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** • AIHW Separation Mode specifies the status at separation of a person from an organisation. An early adopter **MAY** 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 components 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

[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)

Used for specifying a single date or time (or both). Has the ability to indicate a level of precision, but not whether the date or time is estimated. String representations of known dates **SHALL** conform to the nonextended format within the **ISO 21090-2011** standard, 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 which is 5 hours behind Coordinated Universal Time (UTC): 19990531132000-0500.

Duration

(ISO 21090: PQ.TIME)

The period of time during which something continues. Consists of a value and a unit which 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

Any

(ISO 21090: ANY)

Represents a data element where the data type to be used is conditional on another data component. The values that can be required will vary considerably depending on the context. Note that this is an abstract data type that is the basis for all data types and **SHOULD NOT** be used in an actual implementation.

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 (according to [NEHT2010c]). **Usage/Examples** • 1 • -50 • 125
 Link (ISO 21090: TEL)	This is 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)	Used for recording many real world measurements and observations. Includes the magnitude value and the units. **Usage/Examples** • 100 centimetres • 25.5 grams
 QuantityRatio (ISO 21090: RTO)	The relative magnitudes of two *Quantity* values (usually expressed as a quotient). **Usage/Examples** • 25 mg/500 ml • 200 mmol per litre
 QuantityRange (ISO 21090: IVL)	Two *Quantity* values that define the minimum and maximum values, 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 defined by not including a minimum and/or a maximum quantity value. **Usage/Examples** • -20 to 100 Celsius • 30-50 mg • >10 kg

	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)	Character strings (with optional language). Unless otherwise constrained by an implementation, can be any combination of alpha, numeric or symbols from the Unicode character set. This is sometimes 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:TS)	An interval in time, with (optionally) a start date/time and (optionally) an end date/time and/or a duration/width. **Usage/Examples** • 01/01/2008 – 31/12/2008 • 1:30 a.m. – 6:00 p.m., duration/width = 16.5 hours

 UniqueIdentifier (ISO 21090: II)	A general unique value 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) [SA2006a] and AS 5017 (2006) [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. 4) The *extension* attribute **SHALL** be used. **Usage/Examples** IHIs, HPI-Is, HPI-Os and patient hospital medical record numbers are examples of identifiers that **MAY** be carried by 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 [RFC2119].

The following table defines these keywords.

Table 4: Keywords Legend

Keyword	Interpretation
SHALL	This word, or the term ‘required’, means that the statement is an absolute requirement of the specification.
SHOULD	This word, or the adjective ‘recommended’, means that there **MAY** exist valid reasons in particular circumstances to ignore a particular component, but the full implications **SHALL** be understood and carefully weighed before choosing a different course.

MAY	This word, or the adjective 'optional', means that a component is truly optional. One implementer may choose to include the component because a particular implementation requires it, or because the implementer determines that it enhances the implementation, while another implementer may omit the same 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, or the phrase 'not recommended' 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

Obligation in DCMs or SCSs specifies whether or not a data component **SHALL** be populated in the logical record architecture of a message. NEHTA intends that all data components will be implemented.

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 component of information and **SHALL** be populated. **Usage/Examples:** The Participant 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 component of information and **MAY** be populated. **Usage/Examples:** 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	Indicates that the data component is considered a forbidden component of information and **SHALL NOT** be populated. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be completed.

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 as **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 populated.

Where **ESSENTIAL** child data components are contained within **OPTIONAL** parent data components, the child data components only need to be populated when the parent is populated.

B.4 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each section, data group and data element within NEHTA's information model specifications and identifies when each part is applicable.

Data Hierarchy

The top-level component contains a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one 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 and description of the 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.

The right-hand side of the data hierarchy may contain one or more columns under the heading "Core Requirement". Each column contains information for one document exchange scenario. A cell that is empty indicates that the data component on that row is **OPTIONAL** to implement. That is, software that creates documents made in conformance with this specification **MAY** exclude the data component; and software that reads documents made in conformance with this specification **MAY** ignore the data component. All other components **SHALL** be implemented.

In an SCS, a component may be prohibited, that is, it occurs in the referenced DCM but it **SHALL NOT** be included in documents created according to the SCS. This is represented by a multiplicity range of 0..0. The text of the entry is also in a ~~strike-through~~ font and it has a grey background.

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 6: Identification Section Legend

Label	A suggested display name for the component. (Source NEHTA.)
Metadata Type	The type of the component, e.g. section, data group or data element. (Source NEHTA.)
Identifier	A NEHTA assigned internal identifier of the concept represented by the component. (Source NEHTA.)
OID	An object identifier that uniquely identifies the concept represented by the data component. (Source NEHTA.)
External Identifier	An identifier of the concept represented by the data component that is assigned by an organisation other than NEHTA. (Source NEHTA.)

Definition Section Legend

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

Table 7: Definition Section Legend

Definition	The meaning, description or explanation of the data component. (Source NEHTA.) 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. (Source NEHTA.) Implementers **MAY** prefer to use synonymous names to refer to the component in specific contexts.
Scope	Situations in which the data component may be used, i.e. the extent and capacity within which this data component may be used, including the circumstances under which the collection of specified data is required or recommended. For example, Medication Instruction (data group) has a scope which includes all prescribable therapeutic goods, both medicines and non-medicines. This attribute is not relevant to data elements or value domains. (Source NEHTA.)
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. (Source NEHTA.)
Assumptions	Suppositions and notions used in defining the data component. (Source NEHTA.)
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. (Source NEHTA.)
Notes Source	The authoritative source for the Notes statement.
Data Type	The data type of the data element, e.g. DateTime or Text. (Source NEHTA.) The data type is applicable only to data elements. The valid data types are specified in the Data Types Legend.

Value Domain	The name and identifier of the terminologies, code sets and classifications to define the data element value range, or a statement describing what values to use in the absence of a defined value domain for the related data element. 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. (Source NEHTA.) The Value Domain is applicable only to CodedText and CodeableText data elements.

Value Domain Section Legend

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

Table 8: 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	List of permissible values in the value domain.

Usage Section Legend

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

Table 9: Usage Section Legend

Examples	One or more demonstrations of the data that is catered for by the data element. (Source NEHTA.) 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, an indicative example is provided. Implementation guides **MAY** contain specific examples for how data elements **SHALL** be populated and how they relate to each other. The Value Domain is applicable only to CodedText and CodeableText data elements.
Conditions of Use	Prerequisites, provisos or restrictions for use of the component. (Source NEHTA.)
Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate or wrong uses of the component. (Source NEHTA.)
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 component. (Source NEHTA.)

Relationships Section Legend

The Relationships section specifies the cardinality and conditionality between parent and child data components. Note that if no components in either table have any conditions, then the condition column will be omitted for that table.

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

Table 10: Parent Legend

Data Type	Name	Occurrences (child within parent)	Condition
The icon illustrating the metadata type or data type.	Parent Component Name	The minimum and maximum number of instances of the component described on this page that **SHALL** occur.	The conditions that **SHALL** be met to include the data element. Only applicable for elements with a conditional obligation.

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

Table 11: Children Legend

Data Type	Name	Occurrences	Condition
The icon illustrating the metadata type or data type.	Child Component Name	The minimum and maximum number of instances of the component described on this page that **SHALL** occur.	The conditions that **SHALL** be met to include this child data element. Only applicable for elements with a conditional obligation.

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