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Australian Digital Health Agency

Medication Instruction and Action Detailed Clinical Model Specification Version 2.4

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Document Information

Key Information

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Product Version History

Product version	Date	Release comments
1.0	22 Aug 2006	Initial NEHTA release.
2.0	26 Aug 2011	New version created in accordance with the archetype from NEHTA Clinical Knowledge Manager[1].
2.1	22 Dec 2011	This version of the specification is published to support the Structured Content Specifications published (at the end of 2011) that use the versions of the DCMs included in this specification. Changes to the DCMs, included in this specification, are primarily to support the Consolidated View in the PCEHR.
2.2	4 Sep 2013	This version of the specification (and the included DCMs) is published to support the PCEHR Prescription Record and PCEHR Dispense Record Structured Content Specifications.
2.3	18 Dec 2015	This specification is published to support the Structured Content Specifications published in the first half of 2015 that use the versions of DCMs included in this specification. Changes to the DCMs included in this specification are primarily to support the Shared Health Summary and Event Summary in the PCEHR.
2.4	5 Aug 2016	This version of the specification is published to support the Service Referral structured content specification. It includes rebranding for the Australian Digital Health Agency.

Related Documents

Name	Version/Release Date
Australian Medicines Terminology v3 Model - Editorial Rules v2.0	Version 2.0, Issued 8 July 2014
Participation Data Specification	Version 3.2, Issued 20 July 2011

Included Detailed Clinical Models

This specification contains the following detailed clinical models:

- Medication Instruction, version 3.4
- Medication Action, version 4.2

[1] http://dcm.nehta.org.au/ckm

- Exclusion Statement - Medications, version 1.4

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1 Introduction

1.1 Purpose and Scope

This detailed clinical model (DCM) specification forms part of a suite of data specifications that the Australian Digital Health Agency (the Agency) is developing for the Australian health informatics community. The suite comprises specifications for a range of health topics (represented as data groups), which are considered to be the most critical to support the work programme given to the Agency and to realise the benefits derived from Level 4 (semantic) interoperability[1] in the Australian healthcare setting.

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

1.2 Intended Audience

This document is intended to be read by jurisdictional information and communication technology (ICT) managers, clinicians involved in clinical information system specifications, software architects and developers, and implementers of clinical information systems in various healthcare settings.

This is a technical document; the audience should be familiar with the language of health data specification and also have some familiarity with health information standards and specifications. Definitions and examples are provided to clarify relevant terminology, usage, and intent.

1.3 Background

One area of priority for us is the identification of digital health data to be communicated and its structure. We are addressing this through data specifications, which detail the data elements (logically grouped) and their associated value domains.

Data specifications need to be independent of messaging formats. They are concerned with providing an information framework in which to achieve semantic interoperability.

Data specifications have been developed based on priorities identified by jurisdictions and clinicians, incorporating clinical examples of use to enhance utility and adoption. These specifications are intended to:

- suit the Australian model for a shared electronic health record;
- define collections of related information, e.g. event summaries, data groups, data elements;
- be human readable (with information enhanced by the hierarchical structure);
- provide a set of clinical terminologies specific to the requirements of the Australian healthcare system; and
- allow for expansion and extension as electronic systems mature.

While the My Health Record system is referred to in these documents, implementation within the system is not dealt with here.

1.4 Terminology

Our National Clinical Terminology Service (NCTS) is defining a national approach to clinical terminology. Consistent and accurate articulation and interpretation of clinical terms is critical to the process of safe exchange.

[1] Level 4 interoperability is described in *The Value Of Health Care Information Exchange And Interoperability [WALJ2005a]*.

We recommend the SNOMED CT as the preferred clinical terminology for Australia and this has been endorsed by the Australian, state and territory governments. SNOMED CT is considered to be the most comprehensive multilingual health terminology in the world. It is owned, maintained and distributed by the International Health Terminology Standards Development Organisation (IHTSDO).

Our NCTS is the Australian National Release Centre for SNOMED CT and is also responsible for managing, developing and distributing national clinical terminologies, such as SNOMED CT Australian Release (SNOMED CT-AU), the Australian Medicines Terminology (AMT), and related tools and services.

SNOMED CT-AU provides local variations and customisation of terms relevant to the Australian healthcare community. It includes the international resources, along with all Australian-developed terminology for implementation in Australian clinical information technology systems. The AMT provides a consistent approach to the identification and naming of medicines, and supports medicines management and activity across the Australian healthcare domain. The AMT is now included within SNOMED CT-AU, with even closer integration planned for the future.

Reference sets listed as value domains within this document have been developed taking into account data element and data group definitions, as well as how they align with and complement the SNOMED CT concept model.

SNOMED CT-AU has been available for software developers to use in their Australian products since 1 July 2006. It is updated monthly and is freely available under a dual licensing arrangement – namely the SNOMED CT Affiliate License and Australian National Terminology License.

For further information regarding terminology and the development of reference sets, please visit http://-www.healthterminologies.gov.au. Email *help@digitalhealth.gov.au* with questions or feedback.

2 Medication Instruction Detailed Clinical Model

This chapter describes version 3.4 of the *Medication Instruction* Detailed Clinical Model.

2.1 Purpose

To record the intent to use or to continue to use a medicine, vaccine, or other therapeutic good, including instructions on use, dispensing, and administration, where necessary.

2.2 Use

Use for recording instructions to dispense, administer or use a medicine, vaccine or other therapeutic good. This medication instruction can be used in many circumstances including: a record in a progress note; an item in a medication list, prescription or drug chart (to be dispensed or administered); or in a summary document such as a discharge summary or a referral for care. The instruction may be complex and involve more than one activity, such as in the case of a Prednisolone reducing dose regimen, or multiple medications as components of the same order. This would include a written order by a physician, dentist, nurse practitioner, or other designated health professional for a medication to be dispensed and administered to a patient.

This instruction will generally apply to things that can be prescribed or are available 'over the counter'.

Use for orders for vaccinations or other therapeutic goods. These may be presented differently in different applications but require the same structure.

Use for the consistent representation of an item in a medication list comprising the medicines that clinicians collectively expect the individual to be taking.

The information recorded may separate dose, route and timing to achieve a computable and shareable specification but also allows for narrative instructions for orders like "Frusemide 40mg two tablets in the morning and one at lunch" to ensure compatibility with existing systems. To achieve a structured statement for such compound orders, two items are required: "Frusemide 40mg two tablets in the morning" and "Frusemide 40mg one tablet at lunch". The instruction will usually include information about the timing and dose (which may be structured) and in some settings will include the route of administration. The amount of the medicines will usually be given in terms of a number and a dose unit but may be a textual statement to ensure compatibility with existing systems and also coverage of all scenarios.

Use to represent a prescription item for a medicine, vaccine or other therapeutic good within a document such as an electronic prescription or a medication chart.

The content is potentially complex. Where the content is reusable in other contexts, especially the paired *Medication Action* (for recording dispensing, administration etc.) the content has been specified in reusable data groups. For example: the *AMOUNT OF MEDICATION* data group contains detail about medication dose; the *TIMING* data group contains detail about structured dose timing; the *MEDICATION ADMINISTRATION* data group contains structure around administration for both the order and the action; and the *CHEMICAL DESCRIPTION OF MEDICATION* data group describes the specific ingredients within a medicine. All of these data groups together are required to make up the total maximal dataset for a reusable medication instruction.

2.3 Misuse

Not to be used to record administration, use or dispensing. (For those use *Medication Action*.)

Not to be used to record ordering of blood products, implants or major devices such as pacemakers and defibrillators, etc.

2.4 UML Class Diagrams

The following figures represent the data hierarchy using UML 2.0 class diagrams. The diagrams display data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes; data groups 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 diagrams show the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

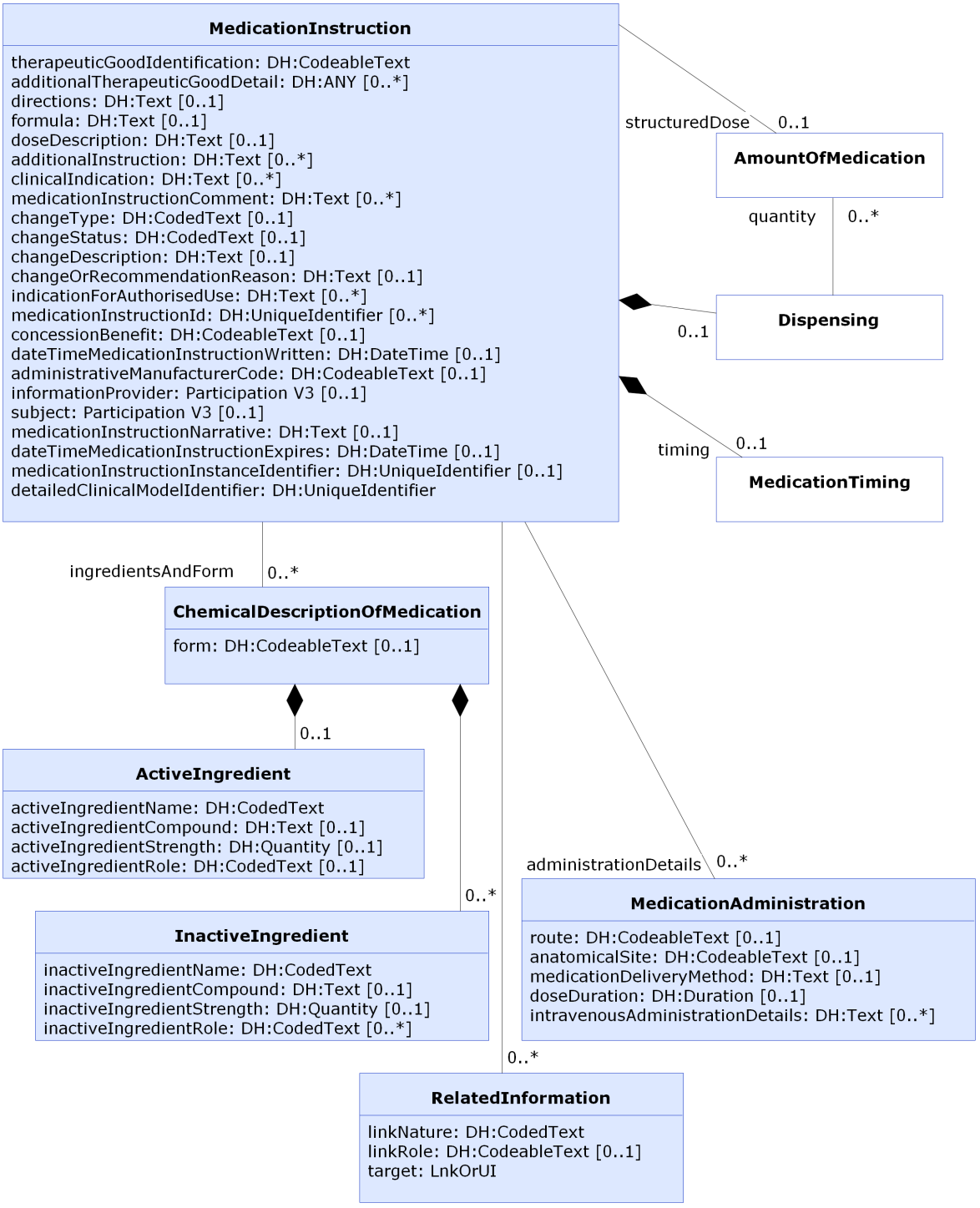

Figure 2.1. Medication Instruction part 1

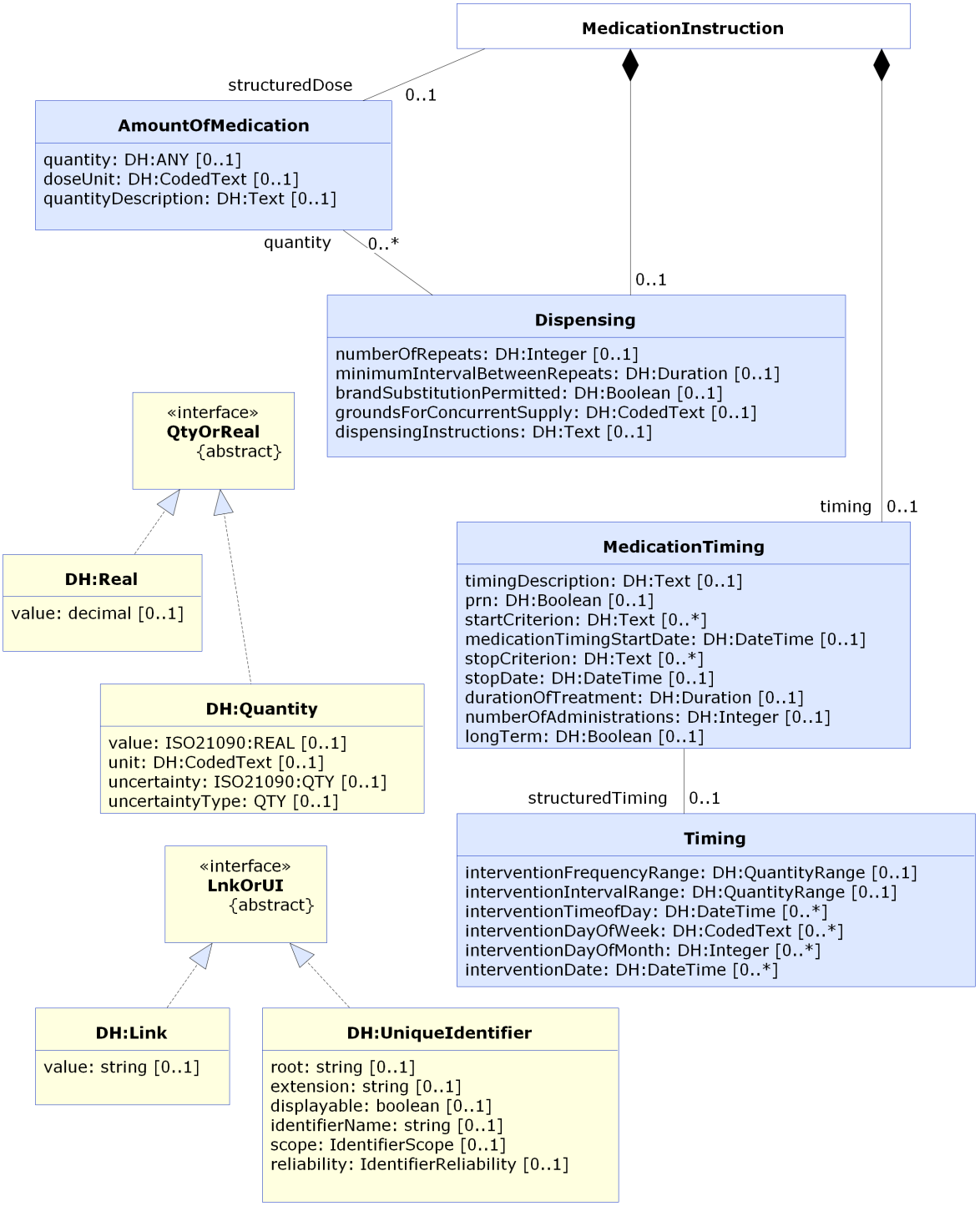

Figure 2.2. Medication Instruction part 2

2.5 MEDICATION INSTRUCTION

Identification

Label	MEDICATION INSTRUCTION
Metadata Type	Data Group
Identifier	DG-16211
OID	1.2.36.1.2001.1001.101.102.16211

Definition

Definition	Details of a medicine, vaccine or other therapeutic good with instructions for use.
Definition Source	Australian Digital Health Agency
Synonymous Names	Prescribed Item

Usage

Misuse	Recording stock on hand of a therapeutic good. *Medication Instruction* **SHALL NOT** be used to record administration of a medication.

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.

MEDICATION INSTRUCTION					
	Therapeutic Good Identification				1..1
	Additional Therapeutic Good Detail				0..*
	Directions				0..1
	Formula				0..1
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)				0..*
		ACTIVE INGREDIENT			0..1
			Name (Active Ingredient Name)		1..1

				Compound (Active Ingredient Compound)	0..1
				Strength (Active Ingredient Strength)	0..1
				Role (Active Ingredient Role)	0..1
			Form		0..1
			INACTIVE INGREDIENT		0..*
				Name (Inactive Ingredient Name)	1..1
				Compound (Inactive Ingredient Compound)	0..1
				Strength (Inactive Ingredient Strength)	0..1
				Role (Inactive Ingredient Role)	0..*
		Dose Description			0..1
		Structured Dose (AMOUNT OF MEDICATION)			0..1
			Quantity		0..1
			Dose Unit		0..1
			Quantity Description		0..1
		Timing (MEDICATION TIMING)			0..1
			Timing Description		0..1
			Structured Timing (TIMING)		0..1
				Intervention Frequency Range	0..1
				Intervention Interval Range	0..1
				Intervention Time of Day	0..*
				Intervention Day of Week	0..*
				Intervention Day of Month	0..*
				Intervention Date	0..*
			PRN		0..1
			Start Criterion		0..*

			Medication Timing Start Date	0..1
			Stop Criterion	0..*
			Stop Date	0..1
			Duration of Treatment	0..1
			Number of Administrations	0..1
			Long-Term	0..1
		Additional Instruction		0..*
		Clinical Indication		0..*
		Administration Details (MEDICATION ADMINISTRATION)		0..*
			Route	0..1
			Anatomical Site	0..1
			Medication Delivery Method	0..1
			Dose Duration	0..1
			Intravenous Administration Details	0..*
		Medication Instruction Comment		0..*
		DISPENSING		0..1
			Quantity (AMOUNT OF MEDICATION)	0..*
			Quantity	0..1
			Dose Unit	0..1
			Quantity Description	0..1
			Number of Repeats	0..1
			Minimum Interval Between Repeats	0..1
			Brand Substitution Permitted	0..1
			Grounds for Concurrent Supply	0..1
			Dispensing Instructions	0..1

		Change Type	0..1
		Change Status	0..1
		Change Description	0..1
		Change or Recommendation Reason	0..1
		Indication for Authorised Use	0..*
		Medication Instruction ID	0..*
		Concession Benefit	0..1
		DateTime Medication Instruction Written	0..1
		Administrative Manufacturer Code	0..1
		INFORMATION PROVIDER	0..1
		SUBJECT	0..1
		Medication Instruction Narrative	0..1
		DateTime Medication Instruction Expires	0..1
		Medication Instruction Instance Identifier	0..1
		RELATED INFORMATION	0..*
		Link Nature	1..1
		Link Role	0..1
		Target	1..1
		Detailed Clinical Model Identifier	1..1

2.6 Therapeutic Good Identification

Identification

Label	Therapeutic Good Identification
Metadata Type	Data Element
Identifier	DE-10194
OID	1.2.36.1.2001.1001.101.103.10194

Definition

Definition	The medicine, vaccine or other therapeutic good being ordered for, administered to or used by the subject.
Definition Source	Australian Digital Health Agency
Synonymous Names	Item Name
Context	This includes medications and medical devices. It includes drugs, appliances, dressings, and reagents.
Context Source	Australian Digital Health Agency
Notes	Identifies a therapeutic good, which is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the *Therapeutic Goods Act 1989*). Therapeutic use means use in or in connection with: • preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or • influencing, inhibiting or modifying a physiological process; or • testing the susceptibility of persons to a disease or ailment; or • influencing, controlling or preventing conception; or • testing for pregnancy; or • replacement or modification of parts of the anatomy. From the *Therapeutic Goods Act 1989* [TGA1989a]. The formal definition of a therapeutic good is given in Section 3 of the *Therapeutic Goods Act 1989*.
Data Type	CodeableText
Value Domain	Medicines Terminology

Usage

Conditions of Use	Where the therapeutic good can be identified by an Australian Medicines Terminology (AMT) concept, the value of this data element **SHALL** be the AMT ConceptID and Preferred Term. For details see Medicines Terminology. For items without an AMT code (including some extemporaneous preparations), a text description is suitable. For a medication, this **SHALL** include the name of the medication

	(brand name or generic name equivalent), the strength and, where appropriate, the dose form.
Conditions of Use Source	Australian Digital Health Agency
Examples	Some examples of AMT ConceptIDs and their AMT Preferred Terms are: 1) 23641011000036102 |*paracetamol 500 mg + codeine phosphate 30 mg tablet*| 2) 28329011000036108 |*paracetamol 500 mg + codeine phosphate 30 mg tablet, 20*| 3) 13362011000036106 |*Panadeine Forte tablet: uncoated, 20*| 4) 6647011000036101 |*Panadeine Forte tablet: uncoated*| 5) 20138011000036107 |*Panadeine Forte tablet: uncoated, 20, blister pack*| 6) 51295011000036108 |*bandage compression 10 cm x 3.5 m bandage: high stretch*| 7) 48667011000036100 |*Eloflex (2480) 10 cm x 3.5 m bandage: high stretch*| 8) 926706011000036104 |*Engerix-B Paediatric 10 microgram/0.5 mL injection: suspension, 0.5 mL syringe*|
Misuse	Detailing the formula of a compounded (extemporaneous) medication.
Exceptional Values	Absent values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION INSTRUCTION	1..1

2.7 Medicines Terminology

Identification

Label	Medicines Terminology
Metadata Type	Value Domain
Identifier	VD-16115
OID	1.2.36.1.2001.1001.101.104.16115

Definition

Definition	A set of values used to refer to medicines and other therapeutic goods.
Definition Source	Australian Digital Health Agency
Notes	An explanation of AMT concepts can be found in *Australian Medicines Terminology v3 Model - Editorial Rules v2.0 [NEHT2014ag]*.

Value Domain

Source	Australian Medicines Terminology
Permissible Values	The permissible values are the members of the following seven AMT reference sets: • 929360061000036106 |*Medicinal product reference set*| • 929360081000036101 |*Medicinal product pack reference set*| • 929360071000036103 |*Medicinal product unit of use reference set*| • 929360021000036102 |*Trade product reference set*| • 929360041000036105 |*Trade product pack reference set*| • 929360031000036100 |*Trade product unit of use reference set*| • 929360051000036108 |*Containered trade product pack reference set*|

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Therapeutic Good Identification	1..1

2.8 Additional Therapeutic Good Detail

Identification

Label	Additional Therapeutic Good Detail
Metadata Type	Data Element
Identifier	DE-16769
OID	1.2.36.1.2001.1001.101.103.16769

Definition

Definition	An item of information about a therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Any

Usage

Conditions of Use	This **SHALL NOT** contradict the value of the *Therapeutic Good Identification* `data element`.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Any.

Relationships

Parents

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

2.9 Directions

Identification

Label	Directions
Metadata Type	Data Element
Identifier	DE-16429
OID	1.2.36.1.2001.1001.101.103.16429

Definition

Definition	A complete narrative description of how much, when and how to use the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	It is essential that when the *Directions* `data element` is used together with structured information components such as *Ingredients and Form* and *Structured Dose* in clinical records or prescriptions, the contents of *Directions* not contradict the contents of these structured information components.
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)
	MEDICATION INSTRUCTION	0..1

2.10 Formula

Identification

Label	Formula
Metadata Type	Data Element
Identifier	DE-16272
OID	1.2.36.1.2001.1001.101.103.16272

Definition

Definition	The recipe for compounding a medicine.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Salicylic Acid 2% in White Soft Paraffin to 100g: Salicylic Acid 2g White Soft Paraffin to 100g
Misuse	Describing off-the-shelf medications.

Relationships

Parents

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

2.11 CHEMICAL DESCRIPTION OF MEDICATION

Identification

Label	Ingredients and Form
Metadata Type	Data Group
Identifier	DG-16408
OID	1.2.36.1.2001.1001.101.102.16408

Definition

Definition	Detailed information about the ingredient(s) including form and strength.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	ACTIVE INGREDIENT	0..1
	Form	0..1
	INACTIVE INGREDIENT	0..*

2.12 ACTIVE INGREDIENT

Identification

Label	ACTIVE INGREDIENT
Metadata Type	Data Group
Identifier	DG-10132
OID	1.2.36.1.2001.1001.101.102.10132

Definition

Definition	Information about an ingredient that is active.
Definition Source	Australian Digital Health Agency
Synonymous Names	Active Pharmaceutical Ingredient Active Pharmaceutical Constituent
Notes	The substance in the medication formulation that is pharmaceutically active and is responsible for the medication's therapeutic effect defined by its identifying name and the strength per dose unit.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..1

Children

Data Type	Name	Occurrences
	Name (Active Ingredient Name)	1..1
	Compound (Active Ingredient Compound)	0..1
	Strength (Active Ingredient Strength)	0..1
	Role (Active Ingredient Role)	0..1

2.13 Active Ingredient Name

Identification

Label	Name
Metadata Type	Data Element
Identifier	DE-10195
OID	1.2.36.1.2001.1001.101.103.10195

Definition

Definition	The name of the chemical or medication.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The identifying name of the active ingredient in the formulated medication.
Data Type	CodedText
Value Domain	*Not specified.* 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[1] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ACTIVE INGREDIENT	1..1

[1] http://www.hl7.org/oid/index.cfm

2.14 Active Ingredient Compound

Identification

Label	Compound
Metadata Type	Data Element
Identifier	DE-16409
OID	1.2.36.1.2001.1001.101.103.16409

Definition

Definition	The detailed chemical name of the compound that is an active ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	ACTIVE INGREDIENT	0..1

2.15 Active Ingredient Strength

Identification

Label	Strength
Metadata Type	Data Element
Identifier	DE-16410
OID	1.2.36.1.2001.1001.101.103.16410

Definition

Definition	The amount or concentration of this ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

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

Relationships

Parents

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

2.16 Active Ingredient Role

Identification

Label	Role
Metadata Type	Data Element
Identifier	DE-16412
OID	1.2.36.1.2001.1001.101.103.16412

Definition

Definition	The role of the ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[2] 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.

Usage

Examples	1) Therapeutic: The chemical has a known and desired effect that is positive. 2) Toxic: This chemical is toxic and has no therapeutic effect. 3) Adjuvant: The chemical is active but aids the therapeutic effect of another ingredient. 4) Other: The chemical has another active role.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

[2] http://www.hl7.org/oid/index.cfm

2.17 Form

Identification

Label	Form
Metadata Type	Data Element
Identifier	DE-10186
OID	1.2.36.1.2001.1001.101.103.10186

Definition

Definition	The formulation or presentation of the overall substance.
Definition Source	Australian Digital Health Agency
Synonymous Names	Manufactured Form Dose Form
Notes	*Form* is used to specify a characteristic of a product as it is manufactured or formulated for dispensing. The form the medication takes when actually administered may vary somewhat from the manufactured form. Tablets may be soluble. Such tablets may or may not be actually dissolved into a solution prior to administration. Similarly with powders and liquids. If it is critical for the care of the patient to differentiate the manufactured form from the administered form, then this should be done via correct labelling and patient instructions. See *Subject of Care Instructions* and *Cautionary Advice*.
Data Type	CodeableText
Value Domain	Medication Form Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Oral drops 4) Effervescent powder

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..1

2.18 Medication Form Reference Set

Identification

Label	Medication Form Reference Set
Metadata Type	Value Domain
Identifier	VD-16618
OID	1.2.36.1.2001.1001.101.104.16618
External Identifier	SNOMED CT-AU Concept Id: 32570621000036105

Definition

Definition	The set of values for the medication form.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.19 INACTIVE INGREDIENT

Identification

Label	INACTIVE INGREDIENT
Metadata Type	Data Group
Identifier	DG-16413
OID	1.2.36.1.2001.1001.101.102.16413

Definition

Definition	Ingredients in the substance that are not active.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..*

Children

Data Type	Name	Occurrences
	Name (Inactive Ingredient Name)	1..1
	Compound (Inactive Ingredient Compound)	0..1
	Strength (Inactive Ingredient Strength)	0..1
	Role (Inactive Ingredient Role)	0..*

2.20 Inactive Ingredient Name

Identification

Label	Name
Metadata Type	Data Element
Identifier	DE-16415
OID	1.2.36.1.2001.1001.101.103.16415

Definition

Definition	The name of the inactive substance.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[3] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	INACTIVE INGREDIENT	1..1

[3] http://www.hl7.org/oid/index.cfm

2.21 Inactive Ingredient Compound

Identification

Label	Compound
Metadata Type	Data Element
Identifier	DE-16416
OID	1.2.36.1.2001.1001.101.103.16416

Definition

Definition	The detailed chemical name of the compound that is an inactive ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	INACTIVE INGREDIENT	0..1

2.22 Inactive Ingredient Strength

Identification

Label	Strength
Metadata Type	Data Element
Identifier	DE-16417
OID	1.2.36.1.2001.1001.101.103.16417

Definition

Definition	The amount or concentration of this ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

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

Relationships

Parents

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

2.23 Inactive Ingredient Role

Identification

Label	Role
Metadata Type	Data Element
Identifier	DE-16419
OID	1.2.36.1.2001.1001.101.103.16419

Definition

Definition	The role of the ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[4] 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.

Usage

Examples	1) Additive: Inert additive. 2) Diluent: Inert diluent. 3) Propellant: Inert propellant. 4) Preservative: The ingredient is present to prolong the life of the substance. 5) Colouring: The ingredient is used to colour the substance.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

[4] http://www.hl7.org/oid/index.cfm

Relationships

Parents

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

2.24 Dose Description

Identification

Label	Dose Description
Metadata Type	Data Element
Identifier	DE-16430
OID	1.2.36.1.2001.1001.101.103.16430

Definition

Definition	The amount and units of the medicine, vaccine or other therapeutic good to be used or administered at one time.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Conditions of Use	If this *Dose Description* `data element` is used together with the *Structured Dose* information component, its contents **SHALL NOT** contradict the contents of the structured information component.
Conditions of Use Source	Australian Digital Health Agency
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)
	MEDICATION INSTRUCTION	0..1

2.25 AMOUNT OF MEDICATION

Identification

Label	Structured Dose
Metadata Type	Data Group
Identifier	DG-16423
OID	1.2.36.1.2001.1001.101.102.16423

Definition

Definition	Structured information on dose with dose unit.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Quantity	0..1
	Dose Unit	0..1
	Quantity Description	0..1

2.26 Quantity

Identification

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

Definition

Definition	The quantity, number or proportion.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The number of doses or physical amount of the therapeutic good.
Data Type	Real Quantity

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Dose (AMOUNT OF MEDICATION)	0..1

2.27 Dose Unit

Identification

Label	Dose Unit
Metadata Type	Data Element
Identifier	DE-16524
OID	1.2.36.1.2001.1001.101.103.16524

Definition

Definition	The dose unit of this amount.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Sachet 4) mg 5) mL
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Dose (AMOUNT OF MEDICATION)	0..1

2.28 Dose Unit Reference Set

Identification

Label	Dose Unit Reference Set
Metadata Type	Value Domain
Identifier	VD-16523
OID	1.2.36.1.2001.1001.101.104.16523
External Identifier	SNOMED CT-AU Concept Id: 32570641000036102

Definition

Definition	The set of values for dose unit.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Dose Unit	1..1

2.29 Quantity Description

Identification

Label	Quantity Description
Metadata Type	Data Element
Identifier	DE-16525
OID	1.2.36.1.2001.1001.101.103.16525

Definition

Definition	Free text description of the amount which may consist of the quantity and dose unit.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	Structured Dose (AMOUNT OF MEDICATION)	0..1

2.30 MEDICATION TIMING

Identification

Label	Timing
Metadata Type	Data Group
Identifier	DG-16766
OID	1.2.36.1.2001.1001.101.102.16766

Definition

Definition	Details of the timing of the use or administration of the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Timing Description	0..1
	Structured Timing (TIMING)	0..1
	PRN	0..1
	Start Criterion	0..*
	Medication Timing Start Date	0..1
	Stop Criterion	0..*
	Stop Date	0..1
	Duration of Treatment	0..1
	Number of Administrations	0..1

Data Type	Name	Occurrences
	Long-Term	0..1

2.31 Timing Description

Identification

Label	Timing Description
Metadata Type	Data Element
Identifier	DE-16432
OID	1.2.36.1.2001.1001.101.103.16432

Definition

Definition	The timing of the doses, which may include frequency and details such as relationship to food.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Conditions of Use	If *Timing Description* is used together with the *Structured Timing* information component, the contents of both **SHALL** be semantically equivalent.
Conditions of Use Source	Australian Digital Health Agency
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)
	Timing (MEDICATION TIMING)	0..1

2.32 TIMING

Identification

Label	Structured Timing
Metadata Type	Data Group
Identifier	DG-16431
OID	1.2.36.1.2001.1001.101.102.16431

Definition

Definition	Structured details of the timing of the use or administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Timing (MEDICATION TIMING)	0..1

Children

Data Type	Name	Occurrences
	Intervention Frequency Range	0..1
	Intervention Interval Range	0..1
	Intervention Time of Day	0..*
	Intervention Day of Week	0..*
	Intervention Day of Month	0..*
	Intervention Date	0..*

2.33 Intervention Frequency Range

Identification

Label	Intervention Frequency Range
Metadata Type	Data Element
Identifier	DE-16547
OID	1.2.36.1.2001.1001.101.103.16547

Definition

Definition	Frequency, expressed as the number of times per time period, that the intervention takes place.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Includes details of variable upper and lower frequency e.g. 3-4 times a day.
Data Type	QuantityRange

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Timing (TIMING)	0..1

2.34 Intervention Interval Range

Identification

Label	Intervention Interval Range
Metadata Type	Data Element
Identifier	DE-16548
OID	1.2.36.1.2001.1001.101.103.16548

Definition

Definition	Length of time between doses or interventions.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Includes details of variable upper and lower intervals e.g. 2-3 hours.
Data Type	QuantityRange

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Timing (TIMING)	0..1

2.35 Intervention Time of Day

Identification

Label	Intervention Time of Day
Metadata Type	Data Element
Identifier	DE-16549
OID	1.2.36.1.2001.1001.101.103.16549

Definition

Definition	Specific time during the day when the intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Conditions of Use	This **SHALL NOT** contain a date component.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a time.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Timing (TIMING)	0..*

2.36 Intervention Day of Week

Identification

Label	Intervention Day of Week
Metadata Type	Data Element
Identifier	DE-16551
OID	1.2.36.1.2001.1001.101.103.16551

Definition

Definition	Day of the week when the intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[5] 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.

Usage

Examples	1) Monday 2) Wednesday 3) Friday 4) Sunday
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Structured Timing (TIMING)	0..*

[5] http://www.hl7.org/oid/index.cfm

2.37 Intervention Day of Month

Identification

Label	Intervention Day of Month
Metadata Type	Data Element
Identifier	DE-16552
OID	1.2.36.1.2001.1001.101.103.16552

Definition

Definition	Day of the month when the intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	If it is required to give a dose on the 2nd day of each month, then the value is 2.
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)
	Structured Timing (TIMING)	0..*

2.38 Intervention Date

Identification

Label	Intervention Date
Metadata Type	Data Element
Identifier	DE-16553
OID	1.2.36.1.2001.1001.101.103.16553

Definition

Definition	Date intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Conditions of Use	This **SHALL NOT** contain a time component.
Conditions of Use Source	Australian Digital Health Agency
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)
	Structured Timing (TIMING)	0..*

2.39 PRN

Identification

Label	PRN
Metadata Type	Data Element
Identifier	DE-16433
OID	1.2.36.1.2001.1001.101.103.16433

Definition

Definition	The timing is dependent within limits on the subject's condition or symptoms.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	For example, 4hrly p.r.n. means the medicine can be taken as frequently as every four hours if necessary. "Pro re nata" in Latin means as circumstances arise.
Data Type	Boolean

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Timing (MEDICATION TIMING)	0..1

2.40 Start Criterion

Identification

Label	Start Criterion
Metadata Type	Data Element
Identifier	DE-16434
OID	1.2.36.1.2001.1001.101.103.16434

Definition

Definition	A condition that, when met, requires the start of administration or use.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	Timing (MEDICATION TIMING)	0..*

2.41 Medication Timing Start Date

Identification

Label	Medication Timing Start Date
Metadata Type	Data Element
Identifier	DE-16435
OID	1.2.36.1.2001.1001.101.103.16435

Definition

Definition	Date, and optionally time, to begin using the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
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)
	Timing (MEDICATION TIMING)	0..1

2.42 Stop Criterion

Identification

Label	Stop Criterion
Metadata Type	Data Element
Identifier	DE-16436
OID	1.2.36.1.2001.1001.101.103.16436

Definition

Definition	A condition that, when met, requires the cessation of administration or use.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	Timing (MEDICATION TIMING)	0..*

2.43 Stop Date

Identification

Label	Stop Date
Metadata Type	Data Element
Identifier	DE-16437
OID	1.2.36.1.2001.1001.101.103.16437

Definition

Definition	Date, and optionally time, to stop using the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
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)
	Timing (MEDICATION TIMING)	0..1

2.44 Duration of Treatment

Identification

Label	Duration of Treatment
Metadata Type	Data Element
Identifier	DE-16438
OID	1.2.36.1.2001.1001.101.103.16438

Definition

Definition	The length of time for which the medicine, vaccine or other therapeutic good should be used or administered (from the initial dose to the final dose).
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Duration

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Timing (MEDICATION TIMING)	0..1

2.45 Number of Administrations

Identification

Label	Number of Administrations
Metadata Type	Data Element
Identifier	DE-16439
OID	1.2.36.1.2001.1001.101.103.16439

Definition

Definition	The total number of doses of the medicine, vaccine or other therapeutic good that are to be used or administered (from the initial dose to the final dose).
Definition Source	Australian Digital Health Agency
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)
	Timing (MEDICATION TIMING)	0..1

2.46 Long-Term

Identification

Label	Long-Term
Metadata Type	Data Element
Identifier	DE-16440
OID	1.2.36.1.2001.1001.101.103.16440

Definition

Definition	It is anticipated that the medicine, vaccine or therapeutic good will be represcribed or redispensed over a period of time.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Boolean

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Timing (MEDICATION TIMING)	0..1

2.47 Additional Instruction

Identification

Label	Additional Instruction
Metadata Type	Data Element
Identifier	DE-16441
OID	1.2.36.1.2001.1001.101.103.16441

Definition

Definition	An additional statement on how to use the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION INSTRUCTION	0..*

2.48 Clinical Indication

Identification

Label	Clinical Indication
Metadata Type	Data Element
Identifier	DE-10141
OID	1.2.36.1.2001.1001.101.103.10141

Definition

Definition	Reason for ordering the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	Reason for Prescribing
Notes	The clinical justification (e.g. specific therapeutic effect intended) for this subject's use of the therapeutic good.
Data Type	Text

Usage

Conditions of Use	*Clinical Indication* **SHOULD** be recorded in inpatient discharge summaries.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) Long-term maintenance treatment of bronchospasm and dyspnoea.

Relationships

Parents

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

2.49 MEDICATION ADMINISTRATION

Identification

Label	Administration Details
Metadata Type	Data Group
Identifier	DG-10108
OID	1.2.36.1.2001.1001.101.102.10108

Definition

Definition	Details of the administration of the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Route	0..1
	Anatomical Site	0..1
	Medication Delivery Method	0..1
	Dose Duration	0..1
	Intravenous Administration Details	0..*

2.50 Route

Identification

Label	Route
Metadata Type	Data Element
Identifier	DE-10147
OID	1.2.36.1.2001.1001.101.103.10147

Definition

Definition	The route by which the medication is administered.
Definition Source	Australian Digital Health Agency
Synonymous Names	Route of Administration
Notes	It is used to describe the path or channel by which the substance or agent is introduced or gains access into a patient's body. This includes the route by which medication is administered. Use “Unknown” only for retrospective data collection.
Data Type	CodeableText
Value Domain	Route of Administration Reference Set

Usage

Examples	1) Oral route 2) Subcutaneous route 3) Epidural route 4) Rectal route 5) Otic route

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration Details (MEDICATION ADMINISTRATION)	0..1

2.51 Route of Administration Reference Set

Identification

Label	Route of Administration Reference Set
Metadata Type	Value Domain
Identifier	VD-10147
OID	1.2.36.1.2001.1001.101.104.10147
External Identifier	SNOMED CT-AU Concept Id: 32570601000036100

Definition

Definition	A list of all possible routes of administration of medication.
Definition Source	Australian Digital Health Agency
Notes	Set of allowable values to describe the way through which a medication is administered.

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
001011001	Route	1..1

2.52 Anatomical Site

Identification

Label	Anatomical Site
Metadata Type	Data Element
Identifier	DE-10156
OID	1.2.36.1.2001.1001.101.103.10156

Definition

Definition	Description of the site of administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Location on or in the body where the substance or agent entered, or the therapeutic good was administered.
Data Type	CodeableText
Value Domain	Anatomical Location Name Values

Usage

Examples	1) Entire left thigh 2) Upper arm part 3) Entire left renal artery

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration Details (MEDICATION ADMINISTRATION)	0..1

2.53 Anatomical Location Name Values

Identification

Label	Anatomical Location Name Values
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105 |*Body structure foundation reference set*|

Definition

Definition	The set of values for named anatomical locations.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Anatomical Site	1..1

2.54 Medication Delivery Method

Identification

Label	Medication Delivery Method
Metadata Type	Data Element
Identifier	DE-16470
OID	1.2.36.1.2001.1001.101.103.16470

Definition

Definition	Method by which medication is delivered to the subject.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Delivery via nebuliser or spacer. 2) Delivery via syringe pump.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration Details (MEDICATION ADMINISTRATION)	0..1

2.55 Dose Duration

Identification

Label	Dose Duration
Metadata Type	Data Element
Identifier	DE-16471
OID	1.2.36.1.2001.1001.101.103.16471

Definition

Definition	The length of time over which to administer each dose.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Duration

Usage

Examples	1) An intravenous injection may be administered over a period of 5 minutes.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration Details (MEDICATION ADMINISTRATION)	0..1

2.56 Intravenous Administration Details

Identification

Label	Intravenous Administration Details
Metadata Type	Data Element
Identifier	DE-16634
OID	1.2.36.1.2001.1001.101.105.16634

Definition

Definition	Details of intravenous administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, *Known Issues* for further information.
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)
	Administration Details (MEDICATION ADMINISTRATION)	0..*

2.57 Medication Instruction Comment

Identification

Label	Medication Instruction Comment
Metadata Type	Data Element
Identifier	DE-16044
OID	1.2.36.1.2001.1001.101.103.16044

Definition

Definition	Any additional information that may be needed to ensure the continuity of supply, rationale for current dose and timing, or safe and appropriate use.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Patient requires an administration aid. 2) Portable Pulse Oximeter measurement to be taken by clipping the sensor onto the tip of a finger. 3) Consulted prescriber concerning dose.
Misuse	Use for information that could be recorded as structured data.

Relationships

Parents

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

2.58 DISPENSING

Identification

Label	DISPENSING
Metadata Type	Data Group
Identifier	DG-16442
OID	1.2.36.1.2001.1001.101.102.16442

Definition

Definition	Information for the dispenser.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Quantity (AMOUNT OF MEDICATION)	0..*
	Number of Repeats	0..1
	Minimum Interval Between Repeats	0..1
	Brand Substitution Permitted	0..1
	Grounds for Concurrent Supply	0..1
	Dispensing Instructions	0..1

2.59 AMOUNT OF MEDICATION

Identification

Label	Quantity
Metadata Type	Data Group
Identifier	DG-16423
OID	1.2.36.1.2001.1001.101.102.16423

Definition

Definition	The amount of medicine, vaccine or other therapeutic good to be dispensed.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Quantity	0..1
	Dose Unit	0..1
	Quantity Description	0..1

2.60 Quantity

Identification

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

Definition

Definition	The quantity, number or proportion.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The number of doses or physical amount of the therapeutic good.
Data Type	Real Quantity

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Quantity (AMOUNT OF MEDICATION)	0..1

2.61 Dose Unit

Identification

Label	Dose Unit
Metadata Type	Data Element
Identifier	DE-16524
OID	1.2.36.1.2001.1001.101.103.16524

Definition

Definition	The dose unit of this amount.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Sachet 4) mg 5) mL
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Quantity (AMOUNT OF MEDICATION)	0..1

2.62 Dose Unit Reference Set

Identification

Label	Dose Unit Reference Set
Metadata Type	Value Domain
Identifier	VD-16523
OID	1.2.36.1.2001.1001.101.104.16523
External Identifier	SNOMED CT-AU Concept Id: 32570641000036102

Definition

Definition	The set of values for dose unit.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Dose Unit	1..1

2.63 Quantity Description

Identification

Label	Quantity Description
Metadata Type	Data Element
Identifier	DE-16525
OID	1.2.36.1.2001.1001.101.103.16525

Definition

Definition	Free text description of the amount which may consist of the quantity and dose unit.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	Quantity (AMOUNT OF MEDICATION)	0..1

2.64 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 times the expressed quantity of medicine, vaccine or other therapeutic good may be refilled or redispensed without a new prescription.
Definition Source	Australian Digital Health Agency
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)
	DISPENSING	0..1

2.65 Minimum Interval Between Repeats

Identification

Label	Minimum Interval Between Repeats
Metadata Type	Data Element
Identifier	DE-10164
OID	1.2.36.1.2001.1001.101.103.10164

Definition

Definition	The minimum time between repeat dispensing of the medicine, vaccine or therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is specified by the ordering clinician for a specific reason such as safety or best practice. Where the prescription is for a Schedule 8 medicine and the dispensing of the prescription is authorised to be repeated, the minimum intervals at which it may be dispensed must be written on the prescription by the prescriber. This is different to the PBS rules for claiming subsidies for repeat prescriptions. This may be used for situations where a prescriber wants to limit access – e.g. if there are safety concerns or if the subject is taking greater than the prescribed dose.
Data Type	Duration

Usage

Examples	1) 20 days

Relationships

Parents

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

2.66 Brand Substitution Permitted

Identification

Label	Brand Substitution Permitted
Metadata Type	Data Element
Identifier	DE-10107
OID	1.2.36.1.2001.1001.101.103.10107

Definition

Definition	Indicates whether or not the substitution of a prescribed medicine with a different brand name of the same medicine, vaccine or other therapeutic good, that has been determined as bioequivalent, is allowed when the medication is dispensed or supplied.
Definition Source	Australian Digital Health Agency
Synonymous Names	Allow Substitutions
Notes	PBS prescriptions must not be prepared using a computer prescribing program that contains a default that would result in all prescriptions being indicated as Brand Substitution Not Permitted [DHA2009a].
Data Type	Boolean

Usage

Misuse	Using this data element for therapeutic substitution. Using this data element for medical appliances.
Default Value	true
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Boolean.

Relationships

Parents

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

2.67 Grounds for Concurrent Supply

Identification

Label	Grounds for Concurrent Supply
Metadata Type	Data Element
Identifier	DE-16139
OID	1.2.36.1.2001.1001.101.103.16139

Definition

Definition	Indicates the grounds which authorise a PBS or RPBS subsidy for the concurrent supply of an item specified in a prescription and all of its repeats.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	*Concurrent supply* means supplying an item from a prescription together with all of its repeats at the one time. There are different rules for the concurrent supply of prescribed items, depending upon whether they are subsidised by the PBS or the RPBS. **For PBS prescriptions** (Regulation 24): Generally, a pharmaceutical benefit may not be supplied to the same person more than once in any four clear days (or 20 clear days for items listed in the Schedule with five repeats or more). Under Regulation 24 of the *National Health (Pharmaceutical Benefits) Regulations 1960*, a prescriber can direct that the original and all repeats of a PBS medicine ordered on a prescription be supplied at the one time, provided that the prescriber is satisfied that all of the following circumstances apply: • The maximum quantity or number of units applicable in relation to the pharmaceutical benefit is insufficient for the treatment of the person for whom the prescription is written. • The person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to that person's place of residence. • The person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions. A PBS prescription must be endorsed by the prescriber with “Regulation 24” as certification that all the above conditions apply. An example of where a prescription would need to be endorsed as Regulation 24 for each item would be where a subject taking antihypertensive medicine plans to travel overseas and requires the dispensing of the original and repeats at one time. **For RPBS prescriptions** (Hardship conditions apply): The original and repeat supplies of an item ordered on a prescription may be supplied at the one time if: • the veteran lives a long way from the nearest pharmacy; or

	• the circumstances of the veteran's condition would impose hardship if separate visits for supply of repeats were required. The words “hardship conditions apply” (or “Regulation 24”) written on the prescription will be sufficient authority for a pharmacist to supply the items and repeats at the one time.
Data Type	CodedText
Value Domain	Grounds for Concurrent Supply Values

Usage

Conditions of Use	Only applicable to PBS and RPBS prescriptions. Not applicable to private prescriptions.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.68 Grounds for Concurrent Supply Values

Identification

Label	Grounds for Concurrent Supply Values
Metadata Type	Value Domain
Identifier	VD-16085
OID	1.2.36.1.2001.1001.101.104.16085

Definition

Definition	The set of values of *Grounds of Concurrent Supply*.
Definition Source	Australian Digital Health Agency

Value Domain

Source	Australian Digital Health Agency	
Permissible Values	1, Pursuant to Regulation 24	Supply is in accord with Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960.
	2, Hardship conditions apply	Supply is in accord with the Hardship conditions provision of RPBS prescribing guidelines.
	9, No grounds	There are no grounds for concurrent supply.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Grounds for Concurrent Supply	1..1

2.69 Dispensing Instructions

Identification

Label	Dispensing Instructions
Metadata Type	Data Element
Identifier	DE-10165
OID	1.2.36.1.2001.1001.101.103.10165

Definition

Definition	Additional instructions to the person dispensing the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Information provided by the prescriber to the dispenser in addition to all other Medication data elements relevant to dispensing that provides more detail or guidance about how the medication should be dispensed.
Data Type	Text

Usage

Examples	1) Patient has arthritis of the hands; please supply easy-open bottles.

Relationships

Parents

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

2.70 Change Type

Identification

Label	Change Type
Metadata Type	Data Element
Identifier	DE-16593
OID	1.2.36.1.2001.1001.101.103.16593

Definition

Definition	The way in which this instruction differs from the previous instruction.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Change Type Values

Usage

Examples	1) Prescribed 2) Changed 3) Cancelled
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.71 Change Type Values

Identification

Label	Change Type Values
Metadata Type	Value Domain
Identifier	VD-16592
OID	1.2.36.1.2001.1001.101.104.16592
External Identifier	SNOMED CT-AU Concept Id: 15071000036100 |*Change type reference set*|

Definition

Definition	The set of values for *Change Type*.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Change Type	1..1

2.72 Change Status

Identification

Label	Change Status
Metadata Type	Data Element
Identifier	DE-16595
OID	1.2.36.1.2001.1001.101.103.16595

Definition

Definition	Identifies whether the change has already been made or is a recommendation that has not been made.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Change Status Values

Usage

Examples	1) Change recommended 2) Change made
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.73 Change Status Values

Identification

Label	Change Status Values
Metadata Type	Value Domain
Identifier	VD-16626
OID	1.2.36.1.2001.1001.101.104.16626
External Identifier	SNOMED CT-AU Concept Id: 669181000168104 |*Change status reference set*|

Definition

Definition	The set of values for *Change Status*.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Change Status	1..1

2.74 Change Description

Identification

Label	Change Description
Metadata Type	Data Element
Identifier	DE-10176
OID	1.2.36.1.2001.1001.101.103.10176

Definition

Definition	Description of the change in the subject's medication item information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Correction of prescription error. 2) Cessation of medication. 3) Change of dose. 4) Addition of drug. 5) Substitution of drug.

Relationships

Parents

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

2.75 Change or Recommendation Reason

Identification

Label	Change or Recommendation Reason
Metadata Type	Data Element
Identifier	DE-10177
OID	1.2.36.1.2001.1001.101.103.10177

Definition

Definition	The justification for the stated change in medication.
Definition Source	Australian Digital Health Agency
Synonymous Names	Reason for Alteration Reason for Modification
Notes	Should be completed if a change has been made.
Data Type	Text

Usage

Examples	1) Optimise drug therapy. 2) Intolerable side effect of dizziness.

Relationships

Parents

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

2.76 Indication for Authorised Use

Identification

Label	Indication for Authorised Use
Metadata Type	Data Element
Identifier	DE-16443
OID	1.2.36.1.2001.1001.101.103.16443

Definition

Definition	The specific indication for use that is required by an authorising agency to achieve subsidy for or access to the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Authorising agency could be a national medication scheme, insurance company or other funding agency.
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)
	MEDICATION INSTRUCTION	0..*

2.77 Medication Instruction ID

Identification

Label	Medication Instruction ID
Metadata Type	Data Element
Identifier	DE-16444
OID	1.2.36.1.2001.1001.101.103.16444

Definition

Definition	An identifier used in an external system and associated with this medication instruction.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION INSTRUCTION	0..*

2.78 Concession Benefit

Identification

Label	Concession Benefit
Metadata Type	Data Element
Identifier	DE-16095
OID	1.2.36.1.2001.1001.101.103.16095

Definition

Definition	Indicates the category of subsidy appropriate to the item being prescribed.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This indicates whether the item has been prescribed for a use that attracts a subsidy. Not to be confused with Claim Category.
Data Type	CodeableText
Value Domain	Therapeutic Good Benefit Eligibility Reference Set

Usage

Examples	1) Eligible for PBS subsidy 2) Eligible for Closing the Gap - PBS Co-Payment Measure subsidy 3) Not eligible for a pharmaceutical subsidy

Relationships

Parents

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

2.79 Therapeutic Good Benefit Eligibility Reference Set

Identification

Label	Therapeutic Good Benefit Eligibility Reference Set
Metadata Type	Value Domain
Identifier	VD-16095
OID	1.2.36.1.2001.1001.101.104.16095
External Identifier	SNOMED CT-AU Concept Id: 32570811000036104

Definition

Definition	The set of values of *Concession Benefit*.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Concession Benefit	1..1

2.80 DateTime Medication Instruction Written

Identification

Label	DateTime Medication Instruction Written
Metadata Type	Data Element
Identifier	DE-16770
OID	1.2.36.1.2001.1001.101.103.16770

Definition

Definition	Date, and optionally time, of the completion of the writing of the medication instruction.
Definition Source	Australian Digital Health Agency
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)
	MEDICATION INSTRUCTION	0..1

2.81 Administrative Manufacturer Code

Identification

Label	Administrative Manufacturer Code
Metadata Type	Data Element
Identifier	DE-16648
OID	1.2.36.1.2001.1001.101.103.16648

Definition

Definition	Administrative code of the manufacturer of the therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This element can assist with claims processing. This element is typically used for the PBS Manufacturer's Code, a Department of Health allocated detailed code that specifies the sponsor of the pharmaceutical item supplied.
Data Type	CodeableText
Value Domain	Administrative Manufacturer Code Values

Usage

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

Relationships

Parents

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

2.82 Administrative Manufacturer Code Values

Identification

Label	Administrative 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 of *Administrative Manufacturer Code*.
Definition Source	Australian Digital Health Agency
Notes	If the data element is instantiated as the PBS Manufacturer Code, then the value set Australian PBS Manufacturer Code (OID 1.2.36.1.2001.1005.23) should be used. The set of values appropriate to the type of Administrative Manufacturer Code chosen. For example, if this is instantiated as the PBS Manufacturer Code, then the value set for PBS Manufacturer Code as specified by the Australian Government Department of Human Services (Medicare) should be used.

Value Domain

Source	Department of Health, PBS manufacturer code.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Administrative Manufacturer Code	1..1

2.83 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or 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)
	MEDICATION INSTRUCTION	0..1

2.84 SUBJECT

Identification

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

Definition

Definition	The individual about whom the medication instruction information is being recorded.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • 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)
	MEDICATION INSTRUCTION	0..1

2.85 Medication Instruction Narrative

Identification

Label	Medication Instruction Narrative
Metadata Type	Data Element
Identifier	DE-16596
OID	1.2.36.1.2001.1001.101.103.16596

Definition

Definition	A textual narrative describing what the medication instruction is about.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION INSTRUCTION	0..1

2.86 DateTime Medication Instruction Expires

Identification

Label	DateTime Medication Instruction Expires
Metadata Type	Data Element
Identifier	DE-10104
OID	1.2.36.1.2001.1001.101.103.10104

Definition

Definition	Date, and optionally time, after which the *Medication Instruction* is no longer effective or in force.
Definition Source	Australian Digital Health Agency
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)
	MEDICATION INSTRUCTION	0..1

2.87 Medication Instruction Instance Identifier

Identification

Label	Medication Instruction Instance Identifier
Metadata Type	Data Element
Identifier	DE-16713
OID	1.2.36.1.2001.1001.101.103.16713

Definition

Definition	A globally unique object identifier for each instance of a *Medication Instruction* instruction.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION INSTRUCTION	0..1

2.88 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Medication Instruction*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Link Nature	1..1

Data Type	Name	Occurrences
	Link Role	0..1
	Target	1..1

2.89 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1) is related to 2) is confirmed by or authorised by 3) is related to the same problem or health issue
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.90 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698
External Identifier	LINK_NATURE

Definition

Definition	Set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*. The values are listed here with brief descriptions.

LINK-A0, is related to	The most general category of Link.
LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or supplementary explanatory information.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Nature	1..1

2.91 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1) unspecified link 2) suggests 3) endorses 4) evidence for 5) outcome 6) is documented by 7) excerpts

Relationships

Parents

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

2.92 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699
External Identifier	LINK_ROLE

Definition

Definition	Set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*, together with brief descriptions, are:

LINK-A1, unspecified link	This can be used to say explicitly “there is no semantic information available for this Link”.
LINK-B1, endorses	The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target.
LINK-C3, evidence for	The source describes evidence for the situation (or interpretation) described in the target.
LINK-D1, outcome	The source describes an outcome of the situation (or interpretation) that the target describes.
LINK-E1, documented by	The source is a less formal description of the situation (or interpretation) documented by the target.
LINK-E4, excerpts	The source is an extract (copy) of part or all of the information contained within the target.
LINK-E5, derived from	The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used for *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Role	1..1

2.93 Target

Identification

Label	Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.94 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	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16211
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION INSTRUCTION	1..1

3 Medication Action Detailed Clinical Model

This chapter describes version 4.2 of the *Medication Action* Detailed Clinical Model.

3.1 Purpose

To record activities undertaken with regard to a medicine, vaccine or other therapeutic good, and link to the instruction if appropriate.

3.2 Use

Use to record the planning, issuing of a prescription, dispensing, administration, cessation, suspension, completion of a medicine, vaccine or other therapeutic good. This will usually be in response to a medication order but may be administered immediately without an order at times, thus requiring recording of the administration alone (e.g. in an emergency). Such a record may be made to indicate the administration of a dose, dispensing of a certain quantity or as a record of ceasing a medication. The state of the medication instruction is altered by the action taken, as indicated in the pathway definition.

There is a date and time at which this action took place (as there is for all actions) and use of this detailed clinical model (DCM) indicates that some action has actually occurred.

3.3 Misuse

Not to be used for recording an instruction or order (use *Medication Instruction* DCM).

3.4 UML Class Diagrams

The following figures represent the data hierarchy using UML 2.0 class diagrams. The diagrams display data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes; data groups 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 diagrams show the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

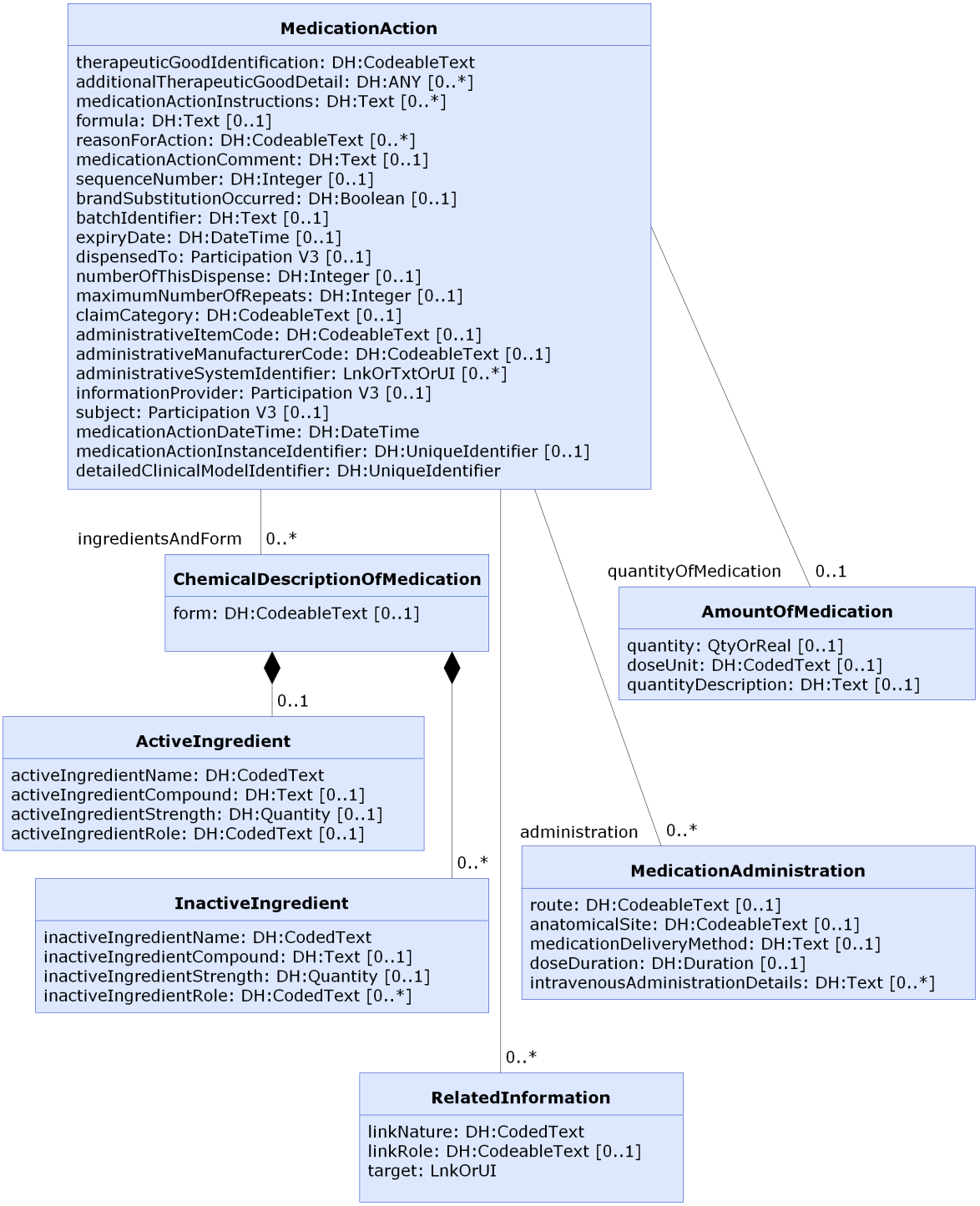

Figure 3.1. Medication Action part 1

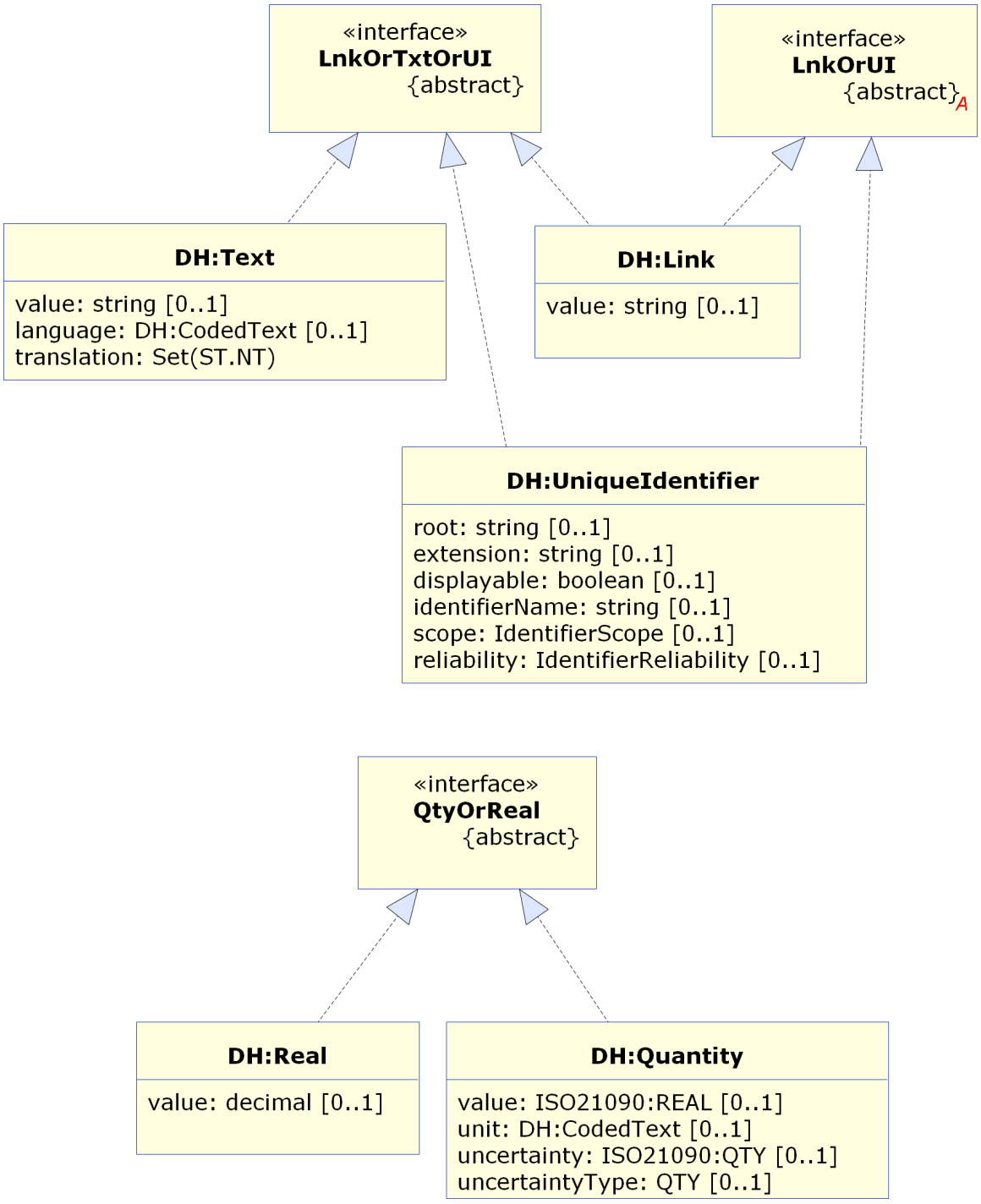

Figure 3.2. Medication Action part 2

3.5 MEDICATION ACTION

Identification

Label	MEDICATION ACTION
Metadata Type	Data Group
Identifier	DG-16210
OID	1.2.36.1.2001.1001.101.102.16210

Definition

Definition	Details of use, administration, dispensing or other care step relating to a medicine, vaccine or other therapeutic good which may arise from an instruction from a clinician.
Definition Source	Australian Digital Health Agency
Synonymous Names	Medication Item
Scope	The specification of each constituent data element is the same, regardless of the context (i.e. prescribed, dispensed, administered or reviewed). There may be separate data instances for each of these contexts.
Scope Source	Australian Digital Health Agency

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.

	MEDICATION ACTION				
		Therapeutic Good Identification			1..1
		Additional Therapeutic Good Detail			0..*
		Medication Action Instructions			0..*
		Formula			0..1
		Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)			0..*
			ACTIVE INGREDIENT		0..1
				Name (Active Ingredient Name)	1..1
				Compound (Active Ingredient Compound)	0..1

				Strength (Active Ingredient Strength)	0..1
				Role (Active Ingredient Role)	0..1
			Form		0..1
			INACTIVE INGREDIENT		0..*
				Name (Inactive Ingredient Name)	1..1
				Compound (Inactive Ingredient Compound)	0..1
				Strength (Inactive Ingredient Strength)	0..1
				Role (Inactive Ingredient Role)	0..*
		Reason for Action			0..*
		Quantity of Medication (AMOUNT OF MEDICATION)			0..1
			Quantity		0..1
			Dose Unit		0..1
			Quantity Description		0..1
		Medication Action Comment			0..1
		Sequence Number			0..1
		Administration (MEDICATION ADMINISTRATION)			0..*
			Route		0..1
			Anatomical Site		0..1
			Medication Delivery Method		0..1
			Dose Duration		0..1
			Intravenous Administration Details		0..*
		Brand Substitution Occurred			0..1
		Batch Identifier			0..1
		Expiry Date			0..1

		DISPENSED TO	0..1
		Number of this Dispense	0..1
		Maximum Number of Repeats	0..1
		Claim Category	0..1
		Administrative Item Code	0..1
		Administrative Manufacturer Code	0..1
		Administrative System Identifier	0..*
		INFORMATION PROVIDER	0..1
		SUBJECT	0..1
		Medication Action DateTime	1..1
		Medication Action Instance Identifier	0..1
		RELATED INFORMATION	0..*
		Link Nature	1..1
		Link Role	0..1
		Target	1..1
		Detailed Clinical Model Identifier	1..1

3.6 Therapeutic Good Identification

Identification

Label	Therapeutic Good Identification
Metadata Type	Data Element
Identifier	DE-10194
OID	1.2.36.1.2001.1001.101.103.10194

Definition

Definition	The medicine, vaccine or other therapeutic good being ordered for, administered to or used by the subject.
Definition Source	Australian Digital Health Agency
Synonymous Names	Item Name
Context	This includes medications and medical devices. It includes drugs, appliances, dressings, and reagents.
Context Source	Australian Digital Health Agency
Notes	Identifies a therapeutic good, which is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the *Therapeutic Goods Act 1989*). Therapeutic use means use in or in connection with: • preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or • influencing, inhibiting or modifying a physiological process; or • testing the susceptibility of persons to a disease or ailment; or • influencing, controlling or preventing conception; or • testing for pregnancy; or • replacement or modification of parts of the anatomy. From the *Therapeutic Goods Act 1989* [TGA1989a]. The formal definition of a therapeutic good is given in Section 3 of the *Therapeutic Goods Act 1989*.
Data Type	CodeableText
Value Domain	Medicines Terminology

Usage

Conditions of Use	Where the therapeutic good can be identified by an Australian Medicines Terminology (AMT) concept, the value of this data element **SHALL** be the AMT ConceptID and Preferred Term. For details see Medicines Terminology. For items without an AMT code (including some extemporaneous preparations), a text description is suitable. For a medication, this **SHALL** include the name of the medication

	(brand name or generic name equivalent), the strength and, where appropriate, the dose form.
Conditions of Use Source	Australian Digital Health Agency
Examples	Some examples of AMT ConceptIDs and their AMT Preferred Terms are: 1) 23641011000036102 |*paracetamol 500 mg + codeine phosphate 30 mg tablet*| 2) 28329011000036108 |*paracetamol 500 mg + codeine phosphate 30 mg tablet, 20*| 3) 13362011000036106 |*Panadeine Forte tablet: uncoated, 20*| 4) 6647011000036101 |*Panadeine Forte tablet: uncoated*| 5) 20138011000036107 |*Panadeine Forte tablet: uncoated, 20, blister pack*| 6) 51295011000036108 |*bandage compression 10 cm x 3.5 m bandage: high stretch*| 7) 48667011000036100 |*Eloflex (2480) 10 cm x 3.5 m bandage: high stretch*| 8) 926706011000036104 |*Engerix-B Paediatric 10 microgram/0.5 mL injection: suspension, 0.5 mL syringe*|
Misuse	Detailing the formula of a compounded (extemporaneous) medication.
Exceptional Values	Absent values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ACTION	1..1

3.7 Medicines Terminology

Identification

Label	Medicines Terminology
Metadata Type	Value Domain
Identifier	VD-16115
OID	1.2.36.1.2001.1001.101.104.16115

Definition

Definition	A set of values used to refer to medicines and other therapeutic goods.
Definition Source	Australian Digital Health Agency
Notes	An explanation of AMT concepts can be found in *Australian Medicines Terminology v3 Model - Editorial Rules v2.0 [NEHT2014ag]*.

Value Domain

Source	Australian Medicines Terminology
Permissible Values	The permissible values are the members of the following seven AMT reference sets: • 929360061000036106 |*Medicinal product reference set*| • 929360081000036101 |*Medicinal product pack reference set*| • 929360071000036103 |*Medicinal product unit of use reference set*| • 929360021000036102 |*Trade product reference set*| • 929360041000036105 |*Trade product pack reference set*| • 929360031000036100 |*Trade product unit of use reference set*| • 929360051000036108 |*Containered trade product pack reference set*|

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Therapeutic Good Identification	1..1

3.8 Additional Therapeutic Good Detail

Identification

Label	Additional Therapeutic Good Detail
Metadata Type	Data Element
Identifier	DE-16769
OID	1.2.36.1.2001.1001.101.103.16769

Definition

Definition	An item of information about a therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Any

Usage

Conditions of Use	This **SHALL NOT** contradict the value of the *Therapeutic Good Identification* `data element`.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Any.

Relationships

Parents

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

3.9 Medication Action Instructions

Identification

Label	Medication Action Instructions
Metadata Type	Data Element
Identifier	DE-16109
OID	1.2.36.1.2001.1001.101.103.16109

Definition

Definition	Any instructions given to the subject or carer at the time of the action.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION ACTION	0..*

3.10 Formula

Identification

Label	Formula
Metadata Type	Data Element
Identifier	DE-16272
OID	1.2.36.1.2001.1001.101.103.16272

Definition

Definition	The recipe for compounding a medicine.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Salicylic Acid 2% in White Soft Paraffin to 100g: • Salicylic Acid 2g • White Soft Paraffin to 100g
Misuse	Describing off-the-shelf medications.

Relationships

Parents

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

3.11 CHEMICAL DESCRIPTION OF MEDICATION

Identification

Label	Ingredients and Form
Metadata Type	Data Group
Identifier	DG-16408
OID	1.2.36.1.2001.1001.101.102.16408

Definition

Definition	Detailed information about the ingredient(s) including form and strength.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	ACTIVE INGREDIENT	0..1
	Form	0..1
	INACTIVE INGREDIENT	0..*

3.12 ACTIVE INGREDIENT

Identification

Label	ACTIVE INGREDIENT
Metadata Type	Data Group
Identifier	DG-10132
OID	1.2.36.1.2001.1001.101.102.10132

Definition

Definition	Information about an ingredient that is active.
Definition Source	Australian Digital Health Agency
Synonymous Names	Active Pharmaceutical Ingredient Active Pharmaceutical Constituent
Notes	The substance in the medication formulation that is pharmaceutically active and is responsible for the medication's therapeutic effect defined by its identifying name and the strength per dose unit.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..1

Children

Data Type	Name	Occurrences
	Name (Active Ingredient Name)	1..1
	Compound (Active Ingredient Compound)	0..1
	Strength (Active Ingredient Strength)	0..1
	Role (Active Ingredient Role)	0..1

3.13 Active Ingredient Name

Identification

Label	Name
Metadata Type	Data Element
Identifier	DE-10195
OID	1.2.36.1.2001.1001.101.103.10195

Definition

Definition	The name of the chemical or medication.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The identifying name of the active ingredient in the formulated medication.
Data Type	CodedText
Value Domain	*Not specified.* 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[1] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ACTIVE INGREDIENT	1..1

[1] http://www.hl7.org/oid/index.cfm

3.14 Active Ingredient Compound

Identification

Label	Compound
Metadata Type	Data Element
Identifier	DE-16409
OID	1.2.36.1.2001.1001.101.103.16409

Definition

Definition	The detailed chemical name of the compound that is an active ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	ACTIVE INGREDIENT	0..1

3.15 Active Ingredient Strength

Identification

Label	Strength
Metadata Type	Data Element
Identifier	DE-16410
OID	1.2.36.1.2001.1001.101.103.16410

Definition

Definition	The amount or concentration of this ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

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

Relationships

Parents

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

3.16 Active Ingredient Role

Identification

Label	Role
Metadata Type	Data Element
Identifier	DE-16412
OID	1.2.36.1.2001.1001.101.103.16412

Definition

Definition	The role of the ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[2] 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.

Usage

Examples	1) Therapeutic: The chemical has a known and desired effect that is positive. 2) Toxic: This chemical is toxic and has no therapeutic effect. 3) Adjuvant: The chemical is active but aids the therapeutic effect of another ingredient. 4) Other: The chemical has another active role.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

[2] http://www.hl7.org/oid/index.cfm

3.17 Form

Identification

Label	Form
Metadata Type	Data Element
Identifier	DE-10186
OID	1.2.36.1.2001.1001.101.103.10186

Definition

Definition	The formulation or presentation of the overall substance.
Definition Source	Australian Digital Health Agency
Synonymous Names	Manufactured Form Dose Form
Notes	*Form* is used to specify a characteristic of a product as it is manufactured or formulated for dispensing. The form the medication takes when actually administered may vary somewhat from the manufactured form. Tablets may be soluble. Such tablets may or may not be actually dissolved into a solution prior to administration. Similarly with powders and liquids. If it is critical for the care of the patient to differentiate the manufactured form from the administered form, then this should be done via correct labelling and patient instructions. See *Subject of Care Instructions* and *Cautionary Advice*.
Data Type	CodeableText
Value Domain	Medication Form Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Oral drops 4) Effervescent powder

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..1

3.18 Medication Form Reference Set

Identification

Label	Medication Form Reference Set
Metadata Type	Value Domain
Identifier	VD-16618
OID	1.2.36.1.2001.1001.101.104.16618
External Identifier	SNOMED CT-AU Concept Id: 32570621000036105

Definition

Definition	The set of values for the medication form.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Form	1..1

3.19 INACTIVE INGREDIENT

Identification

Label	INACTIVE INGREDIENT
Metadata Type	Data Group
Identifier	DG-16413
OID	1.2.36.1.2001.1001.101.102.16413

Definition

Definition	Ingredients in the substance that are not active.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)	0..*

Children

Data Type	Name	Occurrences
	Name (Inactive Ingredient Name)	1..1
	Compound (Inactive Ingredient Compound)	0..1
	Strength (Inactive Ingredient Strength)	0..1
	Role (Inactive Ingredient Role)	0..*

3.20 Inactive Ingredient Name

Identification

Label	Name
Metadata Type	Data Element
Identifier	DE-16415
OID	1.2.36.1.2001.1001.101.103.16415

Definition

Definition	The name of the inactive substance.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[3] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	INACTIVE INGREDIENT	1..1

[3] http://www.hl7.org/oid/index.cfm

3.21 Inactive Ingredient Compound

Identification

Label	Compound
Metadata Type	Data Element
Identifier	DE-16416
OID	1.2.36.1.2001.1001.101.103.16416

Definition

Definition	The detailed chemical name of the compound that is an inactive ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	INACTIVE INGREDIENT	0..1

3.22 Inactive Ingredient Strength

Identification

Label	Strength
Metadata Type	Data Element
Identifier	DE-16417
OID	1.2.36.1.2001.1001.101.103.16417

Definition

Definition	The amount or concentration of this ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

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

Relationships

Parents

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

3.23 Inactive Ingredient Role

Identification

Label	Role
Metadata Type	Data Element
Identifier	DE-16419
OID	1.2.36.1.2001.1001.101.103.16419

Definition

Definition	The role of the ingredient.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* 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[4] 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.

Usage

Examples	1) Additive: Inert additive. 2) Diluent: Inert diluent. 3) Propellant: Inert propellant. 4) Preservative: The ingredient is present to prolong the life of the substance. 5) Colouring: The ingredient is used to colour the substance.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

[4] http://www.hl7.org/oid/index.cfm

Relationships

Parents

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

3.24 Reason for Action

Identification

Label	Reason for Action
Metadata Type	Data Element
Identifier	DE-16492
OID	1.2.36.1.2001.1001.101.103.16492

Definition

Definition	The reason(s) the specific action or step was carried out.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is not the reason for the medication instruction, rather it is the specific reason for the action, such as for administration of the medication or for ceasing the medication.
Data Type	CodeableText
Value Domain	*Not specified.* 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[5] 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.

Usage

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

Relationships

Parents

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

[5] http://www.hl7.org/oid/index.cfm

3.25 AMOUNT OF MEDICATION

Identification

Label	Quantity of Medication
Metadata Type	Data Group
Identifier	DG-16423
OID	1.2.36.1.2001.1001.101.102.16423

Definition

Definition	The quantity of medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Quantity	0..1
	Dose Unit	0..1
	Quantity Description	0..1

3.26 Quantity

Identification

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

Definition

Definition	The quantity, number or proportion.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The number of doses or physical amount of the therapeutic good.
Data Type	Real Quantity

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Quantity of Medication (AMOUNT OF MEDICATION)	0..1

3.27 Dose Unit

Identification

Label	Dose Unit
Metadata Type	Data Element
Identifier	DE-16524
OID	1.2.36.1.2001.1001.101.103.16524

Definition

Definition	The dose unit of this amount.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Sachet 4) mg 5) mL
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Quantity of Medication (AMOUNT OF MEDICATION)	0..1

3.28 Dose Unit Reference Set

Identification

Label	Dose Unit Reference Set
Metadata Type	Value Domain
Identifier	VD-16523
OID	1.2.36.1.2001.1001.101.104.16523
External Identifier	SNOMED CT-AU Concept Id: 32570641000036102

Definition

Definition	The set of values for dose unit.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Dose Unit	1..1

3.29 Quantity Description

Identification

Label	Quantity Description
Metadata Type	Data Element
Identifier	DE-16525
OID	1.2.36.1.2001.1001.101.103.16525

Definition

Definition	Free text description of the amount which may consist of the quantity and dose unit.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	Quantity of Medication (AMOUNT OF MEDICATION)	0..1

3.30 Medication Action Comment

Identification

Label	Medication Action Comment
Metadata Type	Data Element
Identifier	DE-16044
OID	1.2.36.1.2001.1001.101.103.16044

Definition

Definition	A comment on the action taken.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION ACTION	0..1

3.31 Sequence Number

Identification

Label	Sequence Number
Metadata Type	Data Element
Identifier	DE-16424
OID	1.2.36.1.2001.1001.101.103.16424

Definition

Definition	The sequence number specific to the action being recorded.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Used to specify the sequence number of the dispensing (in a prescription with repeats) or medication administration action.
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)
	MEDICATION ACTION	0..1

3.32 MEDICATION ADMINISTRATION

Identification

Label	Administration
Metadata Type	Data Group
Identifier	DG-10108
OID	1.2.36.1.2001.1001.101.102.10108

Definition

Definition	Details about the administration of the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Usage

Conditions of Use	This data group is repeated for every instance of medication administration being recorded.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Route	0..1
	Anatomical Site	0..1
	Medication Delivery Method	0..1
	Dose Duration	0..1
	Intravenous Administration Details	0..*

3.33 Route

Identification

Label	Route
Metadata Type	Data Element
Identifier	DE-10147
OID	1.2.36.1.2001.1001.101.103.10147

Definition

Definition	The route by which the medication is administered.
Definition Source	Australian Digital Health Agency
Synonymous Names	Route of Administration
Notes	It is used to describe the path or channel by which the substance or agent is introduced or gains access into a patient's body. This includes the route by which medication is administered. Use “Unknown” only for retrospective data collection.
Data Type	CodeableText
Value Domain	Route of Administration Reference Set

Usage

Examples	1) Oral route 2) Subcutaneous route 3) Epidural route 4) Rectal route 5) Otic route

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration (MEDICATION ADMINISTRATION)	0..1

3.34 Route of Administration Reference Set

Identification

Label	Route of Administration Reference Set
Metadata Type	Value Domain
Identifier	VD-10147
OID	1.2.36.1.2001.1001.101.104.10147
External Identifier	SNOMED CT-AU Concept Id: 32570601000036100

Definition

Definition	A list of all possible routes of administration of medication.
Definition Source	Australian Digital Health Agency
Notes	Set of allowable values to describe the way through which a medication is administered.

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Route	1..1

3.35 Anatomical Site

Identification

Label	Anatomical Site
Metadata Type	Data Element
Identifier	DE-10156
OID	1.2.36.1.2001.1001.101.103.10156

Definition

Definition	Description of the site of administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Location on or in the body where the substance or agent entered, or the therapeutic good was administered.
Data Type	CodeableText
Value Domain	Anatomical Location Name Values

Usage

Examples	1) Entire left thigh 2) Upper arm part 3) Entire left renal artery

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration (MEDICATION ADMINISTRATION)	0..1

3.36 Anatomical Location Name Values

Identification

Label	Anatomical Location Name Values
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105 |*Body structure foundation reference set*|

Definition

Definition	The set of values for named anatomical locations.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Anatomical Site	1..1

3.37 Medication Delivery Method

Identification

Label	Medication Delivery Method
Metadata Type	Data Element
Identifier	DE-16470
OID	1.2.36.1.2001.1001.101.103.16470

Definition

Definition	Method by which medication is delivered to the subject.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) Delivery via nebuliser or spacer. 2) Delivery via syringe pump.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration (MEDICATION ADMINISTRATION)	0..1

3.38 Dose Duration

Identification

Label	Dose Duration
Metadata Type	Data Element
Identifier	DE-16471
OID	1.2.36.1.2001.1001.101.103.16471

Definition

Definition	The length of time over which to administer each dose.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Duration

Usage

Examples	1) An intravenous injection may be administered over a period of 5 minutes.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administration (MEDICATION ADMINISTRATION)	0..1

3.39 Intravenous Administration Details

Identification

Label	Intravenous Administration Details
Metadata Type	Data Element
Identifier	DE-16634
OID	1.2.36.1.2001.1001.101.105.16634

Definition

Definition	Details of intravenous administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, *Known Issues* for further information.
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)
	Administration (MEDICATION ADMINISTRATION)	0..*

3.40 Brand Substitution Occurred

Identification

Label	Brand Substitution Occurred
Metadata Type	Data Element
Identifier	DE-16064
OID	1.2.36.1.2001.1001.101.103.16064

Definition

Definition	A different brand of the same medicine, vaccine or other therapeutic good was substituted for the one nominated in the order.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Boolean

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Boolean.
Misuse	Using this data element for therapeutic substitution. Using this data element for medical appliances.

Relationships

Parents

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

3.41 Batch Identifier

Identification

Label	Batch Identifier
Metadata Type	Data Element
Identifier	DE-16273
OID	1.2.36.1.2001.1001.101.103.16273

Definition

Definition	A code assigned by the manufacturer to identify the manufactured batch of an item.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	MEDICATION ACTION	0..1

3.42 Expiry Date

Identification

Label	Expiry Date
Metadata Type	Data Element
Identifier	DE-16425
OID	1.2.36.1.2001.1001.101.103.16425

Definition

Definition	The expiry date as documented by the manufacturer.
Definition Source	Australian Digital Health Agency
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)
	MEDICATION ACTION	0..1

3.43 DISPENSED TO

Identification

Label	DISPENSED TO
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The name of the person to whom this was dispensed, if not the subject.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *Subject of Care* of the enclosing Structured Document. 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*. • Participation Type **SHALL** have an implementation-specific value equivalent to "Dispensed To". • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

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

3.44 Number of this Dispense

Identification

Label	Number of this Dispense
Metadata Type	Data Element
Identifier	DE-16106
OID	1.2.36.1.2001.1001.101.103.16106

Definition

Definition	A numeric value that represents the dispense number or sequence number that has been reached for a therapeutic good prescribed with repeats. This count includes the first dispense. It has the value 1 when there are no repeats.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Each prescribed item logically possesses a pre-determined number of times it may be dispensed; the number is 1 (for the original prescription) + the maximum number of repeats. This data element (Number of this Dispense) indicates which dispensing of the item is being attempted by the dispense act that this dispense record documents. Its value is one more than the number of times the prescribed item has successfully been dispensed prior to this dispensing. Its value increments by one each time a dispense act is successfully completed. The value of this term is one more than the commonly used term “number this repeat”.
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)
	MEDICATION ACTION	0..1

3.45 Maximum Number of Repeats

Identification

Label	Maximum 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 times the supply of the prescribed item may be repeated under the terms of the prescription.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Note that the initial supply under the prescription is not counted as a repeat. PBS and RPBS items specify a maximum number of permitted repeats within the Schedules. This number is not to be exceeded on a prescription without the appropriate authorisation. When a prescription for a PBS medicine asks for repeat supplies, the pharmacist prepares a Repeat Authorisation Form to be attached to the “Pharmacist/Subject of Care” copy. An exception to this is when the prescription is marked “Regulation 24”, where all repeats are supplied at once with the original prescription. A similar exception is permitted for RPBS prescriptions endorsed with “hardship conditions apply”.
Data Type	Integer

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Integer.
Default Value	0

Relationships

Parents

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

3.46 Claim Category

Identification

Label	Claim Category
Metadata Type	Data Element
Identifier	DE-16060
OID	1.2.36.1.2001.1001.101.103.16060

Definition

Definition	The category of reimbursement or subsidy sought for the item.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The primary purpose of this data element is to enable the determination of the source of any applicable financial subsidy for the item. Not to be confused with Concession Benefit.
Data Type	CodeableText
Value Domain	Therapeutic Good Claim Category Reference Set

Usage

Conditions of Use	This data element only relates to Dispense Records of successful dispense events.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) General PBS benefit 2) Safety Net Concession benefit 3) Safety Net Entitlement Card benefit

Relationships

Parents

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

3.47 Therapeutic Good Claim Category Reference Set

Identification

Label	Therapeutic Good Claim Category Reference Set
Metadata Type	Value Domain
Identifier	VD-16060
OID	1.2.36.1.2001.1001.101.104.16060
External Identifier	SNOMED CT-AU Concept Id: 32570711000036105

Definition

Definition	The set of values of *Claim Category*.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Claim Category	1..1

3.48 Administrative Item Code

Identification

Label	Administrative Item Code
Metadata Type	Data Element
Identifier	DE-16646
OID	1.2.36.1.2001.1001.101.103.16646

Definition

Definition	Administrative code of the pharmaceutical item supplied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This element is to be used to assist with claims processing.
Data Type	CodeableText
Value Domain	Administrative Item Code Values

Usage

Conditions of Use	This would typically be used for the PBS Scheduled Item Code, a Department of Health allocated detailed code that specifies the use, and funding about the use, of a particular medication.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

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

3.49 Administrative Item Code Values

Identification

Label	Administrative 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 values of *Administrative Item Code*.
Definition Source	Australian Digital Health Agency
Notes	This will have a set of values appropriate to its use. If *Administrative Item Code* is used to hold a PBS Item Code, the set of values will be the set of PBS Item Code values.

Value Domain

Source	Department of Health, PBS Schedule item code.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Administrative Item Code	1..1

3.50 Administrative Manufacturer Code

Identification

Label	Administrative Manufacturer Code
Metadata Type	Data Element
Identifier	DE-16648
OID	1.2.36.1.2001.1001.101.103.16648

Definition

Definition	Administrative code of the manufacturer of the therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This element can assist with claims processing. This element is typically used for the PBS Manufacturer's Code, a Department of Health allocated detailed code that specifies the sponsor of the pharmaceutical item supplied.
Data Type	CodeableText
Value Domain	Administrative Manufacturer Code Values

Usage

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

Relationships

Parents

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

3.51 Administrative Manufacturer Code Values

Identification

Label	Administrative 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 of *Administrative Manufacturer Code*.
Definition Source	Australian Digital Health Agency
Notes	The set of values will be appropriate to the type of Administrative Manufacturer Code chosen. If the data element is instantiated as the PBS Manufacturer Code, then the value set Australian PBS Manufacturer Code (OID 1.2.36.1.2001.1005.23) should be used.

Value Domain

Source	Department of Health, PBS manufacturer code.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Administrative Manufacturer Code	1..1

3.52 Administrative System Identifier

Identification

Label	Administrative System Identifier
Metadata Type	Data Element
Identifier	DE-16786
OID	1.2.36.1.2001.1001.101.103.16786

Definition

Definition	A system identifier of additional administrative information relevant to this medication action.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text UniqueIdentifier Link

Usage

Conditions of Use	The value **SHOULD** be unique. The value **MAY** be not unique.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) Australian Pharmacy Approval Number 2) Australian Unique Pharmacy Prescription Number

Relationships

Parents

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

3.53 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or 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)
	MEDICATION ACTION	0..1

3.54 SUBJECT

Identification

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

Definition

Definition	The individual about whom the medication action information is being recorded.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • 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)
	MEDICATION ACTION	0..1

3.55 Medication Action DateTime

Identification

Label	Medication Action DateTime
Metadata Type	Data Element
Identifier	DE-16591
OID	1.2.36.1.2001.1001.101.103.16591

Definition

Definition	Time period over which the medication action is carried out, or the date, and optionally time, that the medication action is completed.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime TimeInterval

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)
	MEDICATION ACTION	1..1

3.56 Medication Action Instance Identifier

Identification

Label	Medication Action Instance Identifier
Metadata Type	Data Element
Identifier	DE-16637
OID	1.2.36.1.2001.1001.101.103.16637

Definition

Definition	A globally unique identifier for each instance of *Medication Action* action.
Definition Source	Australian Digital Health Agency
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.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

3.57 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Medication Action*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Link Nature	1..1

Data Type	Name	Occurrences
	Link Role	0..1
	Target	1..1

3.58 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1) is related to 2) is confirmed by or authorised by 3) is related to the same problem or health issue
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

3.59 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698
External Identifier	LINK_NATURE

Definition

Definition	Set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*. The values are listed here with brief descriptions.

LINK-A0, is related to	The most general category of Link.
LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or supplementary explanatory information.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Nature	1..1

3.60 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1) unspecified link 2) suggests 3) endorses 4) evidence for 5) outcome 6) is documented by 7) excerpts

Relationships

Parents

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

3.61 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699
External Identifier	LINK_ROLE

Definition

Definition	Set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*, together with brief descriptions, are:

LINK-A1, unspecified link	This can be used to say explicitly “there is no semantic information available for this Link”.
LINK-B1, endorses	The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target.
LINK-C3, evidence for	The source describes evidence for the situation (or interpretation) described in the target.
LINK-D1, outcome	The source describes an outcome of the situation (or interpretation) that the target describes.
LINK-E1, documented by	The source is a less formal description of the situation (or interpretation) documented by the target.
LINK-E4, excerpts	The source is an extract (copy) of part or all of the information contained within the target.
LINK-E5, derived from	The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used for *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Role	1..1

3.62 Target

Identification

Label	Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

3.63 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	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16210
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ACTION	1..1

4 Exclusion Statement – Medications Detailed Clinical Model

This chapter describes version 1.4 of the *Exclusion Statement - Medications* Detailed Clinical Model.

4.1 Purpose

To positively record the absence or exclusion of any medication use within the health record.

4.2 Use

Use to record the positive exclusion or absence of medication use within the health record. This detailed clinical model (DCM) avoids the need to use terminology to express negation about any item within the health record.

This DCM is only to be used to record 'point in time' or event-based information. It is not to be used for a persistent storage of information as the patient should always be questioned about current or past medication use prior to initiation of any treatment or management plan.

4.3 UML Class Diagrams

The following figure represents the data hierarchy using a UML 2.0 class diagram. The diagram displays data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes; data groups 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.

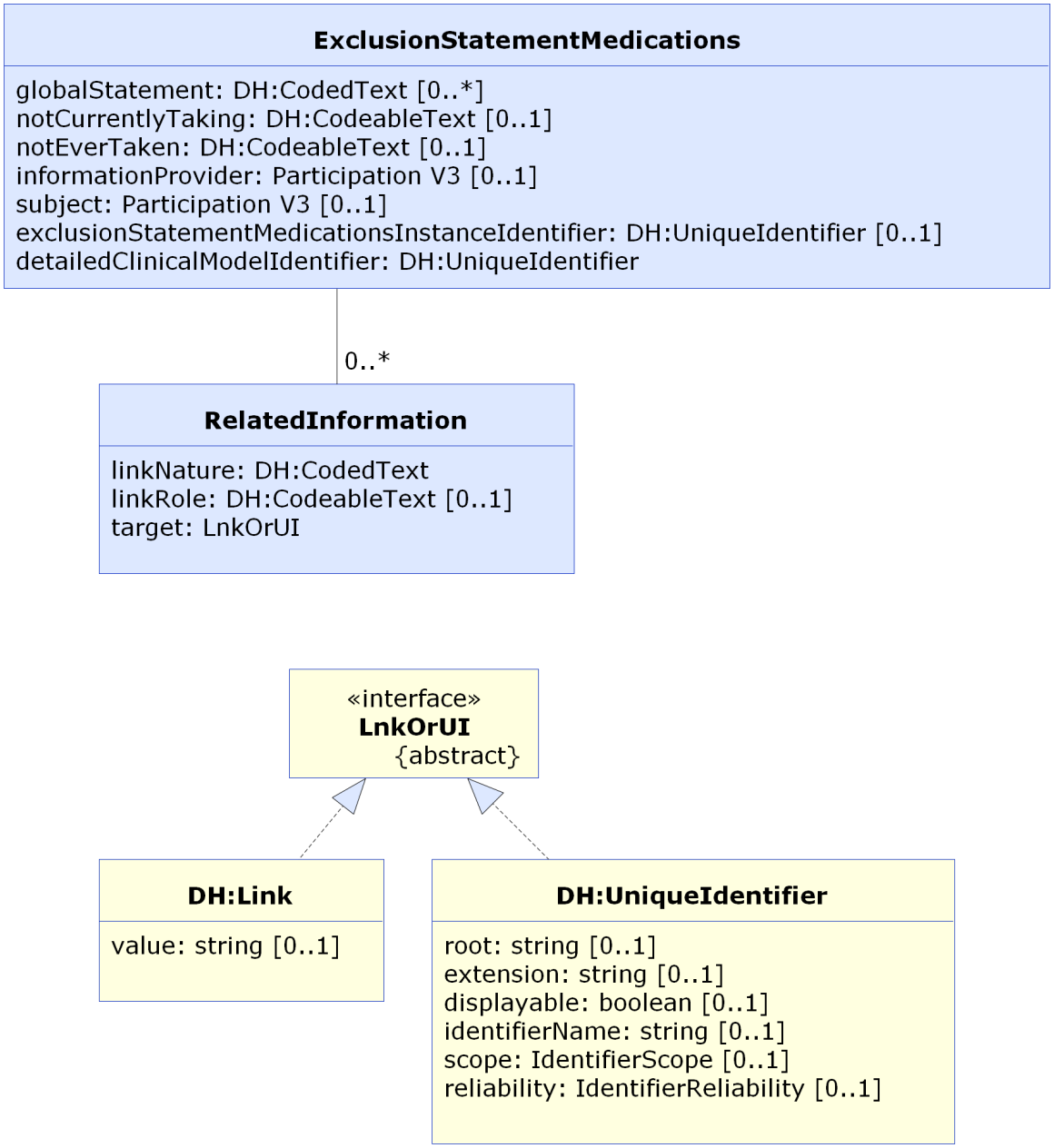

Figure 4.1. Exclusion Statement - Medications

4.4 EXCLUSION STATEMENT - MEDICATIONS

Identification

Label	EXCLUSION STATEMENT - MEDICATIONS
Metadata Type	Data Group
Identifier	DG-16136
OID	1.2.36.1.2001.1001.101.102.16136

Definition

Definition	Statement to positively assert that the patient has not been prescribed or is not taking certain medication.
Definition Source	openEHR Foundation
Scope	To positively record the absence or exclusion of any medication use within the health record.
Scope Source	openEHR Foundation

Usage

Conditions of Use	Use to record the positive exclusion or absence of medication use within the health record. This Detailed Clinical Model (DCM) avoids the need to use terminology to express negation about any item within the health record. It is important to note that exclusion statement information is time-specific. Its validity may not extend beyond the point in time that information is recorded. The patient should always be asked to verify previous statements on any exclusion statement about medications.
Conditions of Use Source	Australian Digital Health Agency

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.

	EXCLUSION STATEMENT - MEDICATIONS		
	001011001	Global Statement	0..*
	001011001	Not Currently Taking	0..1
	001011001	Not Ever Taken	0..1

		INFORMATION PROVIDER		0..1
		SUBJECT		0..1
		Exclusion Statement - Medications Instance Identifier		0..1
		RELATED INFORMATION		0..*
			Link Nature	1..1
			Link Role	0..1
			Target	1..1
		Detailed Clinical Model Identifier		1..1

4.5 Global Statement

Identification

Label	Global Statement
Metadata Type	Data Element
Identifier	DE-16302
OID	1.2.36.1.2001.1001.101.103.16302

Definition

Definition	The statement about the absence or exclusion of certain medication.
Definition Source	openEHR Foundation
Synonymous Names	
Context	This can be used to capture any information that is needed to be explicitly recorded within the record as being absent or excluded.
Context Source	openEHR Foundation
Data Type	CodedText
Value Domain	Global Statement Values

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - MEDICATIONS	0..*

4.6 Global Statement Values

Identification

Label	Global Statement Values
Metadata Type	Value Domain
Identifier	VD-16299
OID	1.2.36.1.2001.1001.101.104.16299

Definition

Definition	The set of values for the statement about the absence or exclusion.
Definition Source	openEHR Foundation

Value Domain

Source	Australian Digital Health Agency	
Permissible Values	01, None known	No information about taking any medication is known.
	02, Not asked	No information about taking any medication is available because the patient was not asked or not able to be asked.
	03, None supplied	No information about taking any medication is supplied.
	Please see Appendix A, *Known Issues*.	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Global Statement	1..1

4.7 Not Currently Taking

Identification

Label	Not Currently Taking
Metadata Type	Data Element
Identifier	DE-16310
OID	1.2.36.1.2001.1001.101.103.16310

Definition

Definition	Positive statement about medications that are explicitly not being taken or used at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* 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[1] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - MEDICATIONS	0..1

[1] http://www.hl7.org/oid/index.cfm

4.8 Not Ever Taken

Identification

Label	Not Ever Taken
Metadata Type	Data Element
Identifier	DE-16311
OID	1.2.36.1.2001.1001.101.103.16311

Definition

Definition	Positive statement about medications that are explicitly known not to have ever been taken or used at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* 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[2] 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.

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - MEDICATIONS	0..1

[2] http://www.hl7.org/oid/index.cfm

4.9 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or 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)
	EXCLUSION STATEMENT - MEDICATIONS	0..1

4.10 SUBJECT

Identification

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

Definition

Definition	The individual about whom the medication information is being recorded.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • 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)
	EXCLUSION STATEMENT - MEDICATIONS	0..1

4.11 Exclusion Statement - Medications Instance Identifier

Identification

Label	Exclusion Statement - Medications Instance Identifier
Metadata Type	Data Element
Identifier	DE-16709
OID	1.2.36.1.2001.1001.101.103.16709

Definition

Definition	A globally unique object identifier for each instance of an *Exclusion Statement - Medications* evaluation.
Definition Source	Australian Digital Health Agency
Synonymous Names	
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)
	EXCLUSION STATEMENT - MEDICATIONS	0..1

4.12 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Exclusion Statement - Medications*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - MEDICATIONS	0..*

Children

Data Type	Name	Occurrences
	Link Nature	1..1

Data Type	Name	Occurrences
	Link Role	0..1
	Target	1..1

4.13 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1) is related to 2) is confirmed by or authorised by 3) is related to the same problem or health issue
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

4.14 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698
External Identifier	LINK_NATURE

Definition

Definition	Set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009	
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*. The values are listed here with brief descriptions.	
	LINK-A0, is related to	The most general category of Link.
	LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
	LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
	LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
	LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or supplementary explanatory information.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Nature	1..1

4.15 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1) unspecified link 2) suggests 3) endorses 4) evidence for 5) outcome 6) is documented by 7) excerpts

Relationships

Parents

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

4.16 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699
External Identifier	LINK_ROLE

Definition

Definition	Set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*, together with brief descriptions, are:

LINK-A1, unspecified link	This can be used to say explicitly “there is no semantic information available for this Link”.
LINK-B1, endorses	The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target.
LINK-C3, evidence for	The source describes evidence for the situation (or interpretation) described in the target.
LINK-D1, outcome	The source describes an outcome of the situation (or interpretation) that the target describes.
LINK-E1, documented by	The source is a less formal description of the situation (or interpretation) documented by the target.
LINK-E4, excerpts	The source is an extract (copy) of part or all of the information contained within the target.
LINK-E5, derived from	The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used for *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Role	1..1

4.17 Target

Identification

Label	Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

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

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

4.18 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	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16136
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - MEDICATIONS	1..1

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.
Data Hierarchies	Only the parts of these detailed clinical models (DCMs) required for current structured content specifications have been mapped to HL7 CDA. Mapping the remaining parts to CDA may reveal inconsistencies in the data hierarchies, requiring normative change.
Undefined Value Domains	The following data elements lack a defined value domain: *Active Ingredient Name*, *Active Ingredient Role*, *Inactive Ingredient Name*, *Inactive Ingredient Role*, *Reason for Action*, *Intervention Day of Week*, *Not Currently Taking*, and *Not Ever Taken*. We are in the process of developing national code sets for these items. In the meantime, you are free to use your own code sets, providing any code set used **SHALL** be registered, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. Note that when national standard code sets do become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.
Undefined Data Structures	The following data components lack a defined data structure: *Intravenous Administration Details*. A free text data element is currently used as an interim solution.
Information Provider	We are considering making *Information Provider* one of a pair of data components: *Information Provider* for the source of the information, typically the subject of care of the enclosing structured document and *Reporter* for the author of the information, typically the author of the enclosing structured document. *Reporter* has not been added to this DCM. More investigation is needed to make a decision.
Chemical Description of Medication Data Group	This data group is immature and may need revision. The data groups *ACTIVE INGREDIENT* and *INACTIVE INGREDIENT* may require different structures. The chosen example values for *Active Ingredient Role* and *Inactive Ingredient Role* are likely to be revised. There is no distinct data element for an unstructured description of extemporaneous medications.
Timing (MEDICATION TIMING)	Definitions of the data elements within this data group need to be improved.
Clinical Indication	The data element is a candidate for terminology. In the future its data type is to be changed to *Codeable Text*.
Medication Delivery Method	The data element is a candidate for terminology. In the future its data type is to be changed to *Codeable Text*.
Quantity	The correctness of the solution presented in this specification is uncertain; this data element needs to be able to cater for quantities of non-medications.
Intravenous Administration Details	This data group has not yet been designed.
Indication for Authorised Use	This data element is intended to record values such as PBS/RPBS Authority Approval Numbers, PBS/RPBS Streamline Authority Approval Numbers, State Authority Numbers and PBS Item Codes. The current design allows multiple values to be recorded, but does not allow the type of value to be recorded (e.g. State Authority Number or PBS/RPBS Authority Approval Number). This will be corrected in a future revision.

Reference	Description
Early supply of medication	There is no distinct data element in *Medication Action* to indicate early supply with pharmaceutical benefit.
Medication Timing Start Date Stop Date	These two data elements should be merged into a single time interval data element.
Change Description	The data element is a candidate for terminology. In the future its data type is to be changed to *Codeable Text*.
Medication Action DateTime	There is no guidance on the usage of *Medication Action DateTime* for either the action occurring on a single day or the action being completed at a point in time.
Global Statement Values Value Domain	The list of permissible values is a sample set to initiate discussion and collaboration to develop the correct set of values.
Exclusion Statement	The exclusion statement DCMs are the subject of ongoing development and review and may well change in the future.

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 that 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 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.

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.

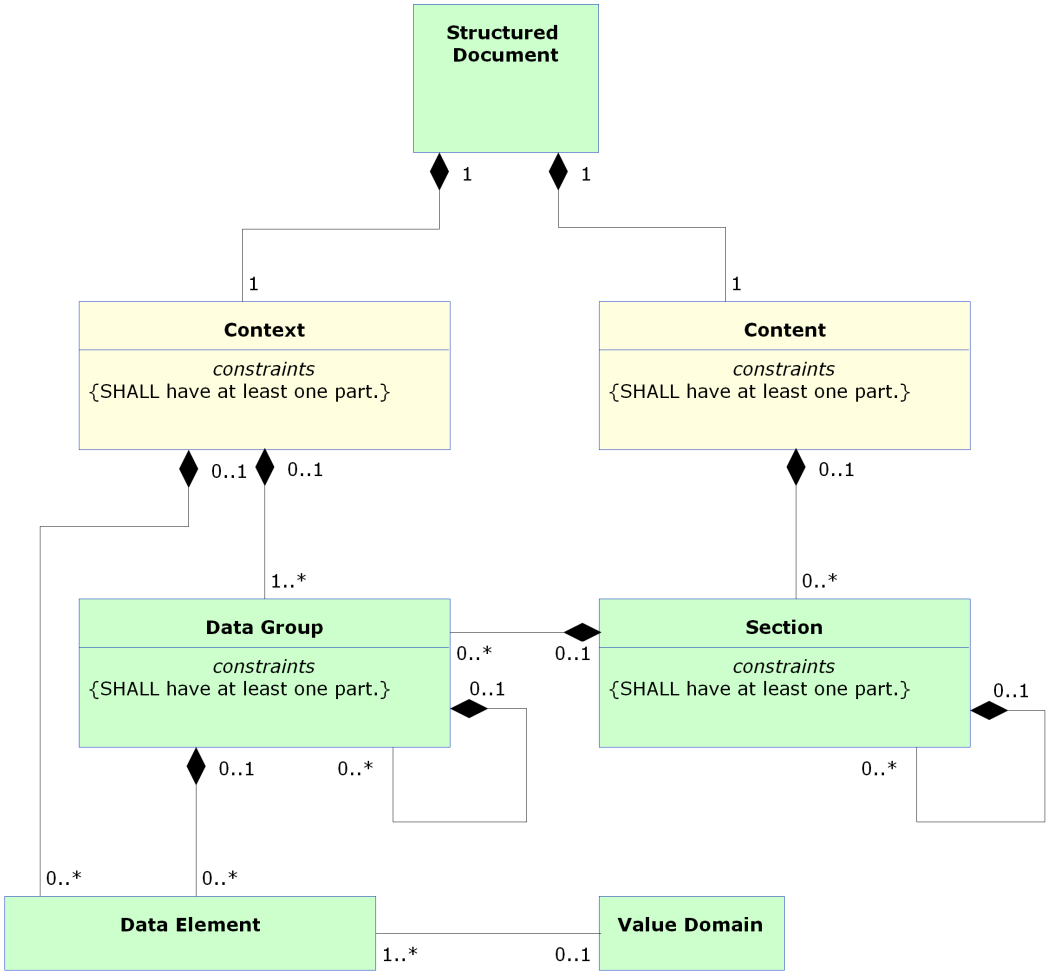

Figure 1: SCS Metamodel

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. Examples 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.

Our *Participation Data Specification [NEHT2011v]* defines the full Participation specification.

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. 4) The *extension* attribute **SHALL** be used. **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	

Level	Code	Term	Abnormal	Absent
3	TRC	Trace	Abnormal	
2	MSK	Masked		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 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.

In some documents the right-hand side of the data hierarchy contains 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 data components **SHALL** be implemented.

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.

	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.

Appendix C. Change History

A summary of changes from one document version to the next. Changes to the change history are excluded.

C.1 Changes Since Version 2.3 - 18 December 2015

Generic changes

Various changes to rebrand the document from the National E-Health Transition Authority (NEHTA) to the Australian Digital Health Agency (the Agency):

- Definition Source, Scope Source, Context Source, Condition of Use Source and Value Domain Source updated from “NEHTA” to “Australian Digital Health Agency”;
- references to “National E-Health Transition Authority” and “NEHTA” have been replaced with references to the “Australian Digital Health Agency” and “the Agency” respectively; and
- all NEHTA URLs have been updated to redirect to the Agency website.

The generic text in examples that references the appendix specification guide for use has had editorial changes.

Preliminary Pages

Document Information section has been changed to include the latest release details.

Chapter 1 Introduction

Various editorial changes to presentation and wording, including replacing the expression “PCEHR” with “My Health Record”.

Chapter 2 Medication Instruction Detailed Clinical Model

The version of the DCM used has changed from 3.3 to 3.4.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *MEDICATION INSTRUCTION* > *Therapeutic Good Identification*;
- *MEDICATION INSTRUCTION* > *CHEMICAL DESCRIPTION OF MEDICATION* > *ACTIVE INGREDIENT* > *Active Ingredient Name*;
- *MEDICATION INSTRUCTION* > *CHEMICAL DESCRIPTION OF MEDICATION* > *ACTIVE INGREDIENT* > *Active Ingredient Role*;
- *MEDICATION INSTRUCTION* > *CHEMICAL DESCRIPTION OF MEDICATION* > *INACTIVE INGREDIENT* > *Inactive Ingredient Name*;
- *MEDICATION INSTRUCTION* > *CHEMICAL DESCRIPTION OF MEDICATION* > *INACTIVE INGREDIENT* > *Inactive Ingredient Role*;

- *MEDICATION INSTRUCTION > AMOUNT OF MEDICATION > Dose Unit*;
- *MEDICATION INSTRUCTION > MEDICATION TIMING > TIMING > Intervention Day of Week*;
- *MEDICATION INSTRUCTION > DISPENSING > AMOUNT OF MEDICATION > Dose Unit*;
- *MEDICATION INSTRUCTION > DISPENSING > Grounds for Concurrent Supply*;
- *MEDICATION INSTRUCTION > Change Type*;
- *MEDICATION INSTRUCTION > Change Status*;
- *MEDICATION INSTRUCTION > Medication Instruction Instance Identifier*;
- *MEDICATION INSTRUCTION > RELATED INFORMATION > Link Nature*; and
- *MEDICATION INSTRUCTION > Detailed Clinical Model Identifier*.

In section 2.2 Use, there were various editorial changes.

In section 2.5 MEDICATION INSTRUCTION, the data hierarchy was updated to reflect modified names of six data elements.

In 2.6 Therapeutic Good Identification, there was an editorial change to the definition.

In 2.8 Additional Therapeutic Good Detail, a constraint and its source has been added as a condition of use, regarding not to contradict the value in the *Therapeutic Good Identification* .

In 2.32 TIMING, six data element names have been updated in the children table.

In 2.33 Intervention Frequency Range, the label has been renamed from the original “Frequency Range”. There were also editorial changes to the definition.

In 2.34 Intervention Interval Range, the label has been renamed from the original “Interval Range”. There were also editorial changes to the definition and notes.

In 2.35 Intervention Time of Day, the label has been renamed from the original “Time”. There were also editorial changes to the definition.

In 2.36 Intervention Day of Week, the label has been renamed from the original “Day of Week”. There were also editorial changes to the definition.

In 2.37 Intervention Day of Month, the label has been renamed from the original “Day of Month”. There were also editorial changes to the definition.

In 2.38 Intervention Date, the label has been renamed from the original “Date”. There was an editorial change to the definition. A constraint has been added as a condition of use, regarding not to include a time component.

In 2.39 PRN, there was an editorial change to the definition.

In 2.41 Medication Timing Start Date, there was an editorial change to the definition.

In 2.43 Stop Date, there was an editorial change to the definition.

In 2.48 Clinical Indication, there was an editorial change to the notes.

In 2.61 Dose Unit, there were editorial changes to the examples.

In 2.65 Minimum Interval Between Repeats, there was an editorial change to the notes.

In 2.67 Grounds for Concurrent Supply, there was an editorial change to the notes.

In 2.70 Change Type, the examples were updated.

In 2.72 Change Status, a list of examples was added.

In 2.74 Change Description, there was an editorial change to the definition.

In 2.80 DateTime Medication Instruction Written, there was an editorial change to the definition.

In 2.83 INFORMATION PROVIDER, this follows current design for specifying *Information Provider*.

In 2.84 SUBJECT, there were editorial changes to the scope and conditions of use.

In 2.86 DateTime Medication Instruction Expires, there was an editorial change to the definition.

In 2.90 Link Nature Values, there were editorial changes to the permissible values.

In 2.91 Link Role, there was an editorial change to the definition and notes.

In 2.92 Link Role Values, the permissible values have been updated and editorial changes have been made in the condition of use.

In 2.94 Detailed Clinical Model Identifier, there was an editorial change to the definition.

Chapter 3 Medication Action Detailed Clinical Model

The version of the DCM used has changed from 4.1 to 4.2.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *MEDICATION ACTION > Therapeutic Good Identification*;
- *MEDICATION ACTION > CHEMICAL DESCRIPTION OF MEDICATION > ACTIVE INGREDIENT > Active Ingredient Name*;
- *MEDICATION ACTION > CHEMICAL DESCRIPTION OF MEDICATION > ACTIVE INGREDIENT > Active Ingredient Role*;
- *MEDICATION ACTION > CHEMICAL DESCRIPTION OF MEDICATION > INACTIVE INGREDIENT > Inactive Ingredient Name*;
- *MEDICATION ACTION > CHEMICAL DESCRIPTION OF MEDICATION > INACTIVE INGREDIENT > Inactive Ingredient Role*;
- *MEDICATION ACTION > AMOUNT OF MEDICATION > Dose Unit*;
- *MEDICATION ACTION > Medication Action Instance Identifier*;
- *MEDICATION ACTION > RELATED INFORMATION > Link Nature*; and
- *MEDICATION ACTION > Detailed Clinical Model Identifier*.

In section 3.2 Use, there were various editorial changes.

In 3.5 MEDICATION ACTION, there were editorial changes to the scope.

In 3.5 MEDICATION ACTION, the data hierarchy was updated to reflect modified names of six data elements.

In 3.6 Therapeutic Good Identification, there was an editorial change to the definition.

In 3.8 Additional Therapeutic Good Detail, a constraint has been added as a condition of use, along with its source.

In 3.9 Medication Action Instructions, there was an editorial change to the definition.

In 3.27 Dose Unit, there were editorial changes to the examples.

In 3.32 MEDICATION ADMINISTRATION, three data element names have been updated in the children table.

In 3.33 Route, the condition of use was moved into a note. There were also editorial changes to the notes and examples.

In 3.34 Route of Administration Reference Set, there was an editorial changes to the notes.

In 3.35 Anatomical Site, the label has been renamed from the original “Site”. The value domain has changed to “Anatomical Location Name Values”. There were also editorial changes to the definition, notes and examples.

In 3.36 Anatomical Location Name Values, the name has been changed from the original “Body Structure Foundation Reference Set”. The external identifier has been updated accordingly. The parents relationship table was updated with the new name of *Anatomical Site*.

In 3.37 Medication Delivery Method, the label has been renamed from the original “Delivery Method”. There were also editorial changes to the definition.

In 3.39 Intravenous Administration Details, the label has been renamed from the original “Intravenous Details”.

In 3.43 DISPENSED TO, there was an editorial change to the definition.

In 3.53 INFORMATION PROVIDER, this follows current design for specifying *Information Provider*.

In 3.54 SUBJECT, there were editorial changes to the scope and conditions of use.

In 3.55 Medication Action DateTime, the datatype of “TimeInterval” has been added and the definition has been updated to reflect the change.

In 3.59 Link Nature Values, there were editorial changes to the permissible values.

In 3.60 Link Role, there was an editorial change to the notes.

In 3.61 Link Role Values, the permissible values have been updated and editorial changes have been made in the condition of use.

Chapter 4 Exclusion Statement – Medications Detailed Clinical Model

The version of the DCM used has changed from 1.3 to 1.4.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *EXCLUSION STATEMENT - MEDICATIONS* > *Global Statement*;
- *EXCLUSION STATEMENT - MEDICATIONS* > *Exclusion Statement - Medications Instance Identifier*;
- *EXCLUSION STATEMENT - MEDICATIONS* > *RELATED INFORMATION* > *Link Nature*; and
- *EXCLUSION STATEMENT - MEDICATIONS* > *Detailed Clinical Model Identifier*.

In 4.5 Global Statement, the condition of use constraint to not use “Not asked” has been removed.

In 4.9 INFORMATION PROVIDER, this follows current design for specifying *Information Provider*.

In 4.10 SUBJECT, there was an editorial change to the scope and conditions of use.

In 4.14 Link Nature Values, there were editorial changes to the permissible values.

In 4.15 Link Role, there was an editorial change to the notes.

In 4.16 Link Role Values, the permissible values have been updated and editorial changes have been made in the conditions of use.

In 4.18 Detailed Clinical Model Identifier, there was an editorial change to the definition.

Appendix A. Known Issues

A known issue regarding *Information Provider* was added.

A known issue regarding *Timing (MEDICATION TIMING)* was added.

A known issue regarding *Medication Timing Start Date* and *Stop Date* was added.

Appendix B. Specification Guide for Use

Various editorial changes.

Renamed the section B.4 “Abnormal and Absent Values” to “Exceptional Values” and updated explanatory text throughout accordingly.

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