Kingdom of Saudi Arabia

Ministry of Health

National eHealth Strategy and Change Management Office

(SCMO)

Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Clinical Documents Constrains Interoperability Specifications

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Confidentiality statement:

Document Revision History

Version	Date	Type of update	Prepared/Revised by
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PREFACE

DOCUMENT PURPOSE

The purpose of this document is to support several Core Interoperability Specifications and their associate use case, in a specific area of interoperability. This area is centered on the common clinical content found in Saudi eHealth Interoperability Specifications that are based upon the HL7 Clinical Document Architecture Release 2.0 (CDA) standard. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Supporting Interoperability Specification is applicable to existing and new information systems that will connect to exchange Health Information. In particular this Interoperability Specification applies to the deployment of eHealth Information Exchange Platforms such as the Saudi Health Exchange (SeHE).

HOW TO READ THIS DOCUMENT

This document contains eight sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and scope, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications in the SeHE System.

Section 2: This section establishes the Content and Conformance Requirements for the Interoperability Specification.

Section 3: This section describes the attributes of various CDA data types that are constrained by this specification, and provides an explanation of these constraints.

Section 4: This section describes the attributes found in the CDA Header that are constrained by this specification, and provides an explanation of these constraints.

Section 5: This section is an introduction to the organization of the Saudi eHealth HL7 CDA R2 documents including the necessary data elements identified by the stakeholder

Section 0: This section describes the attributes of sections found in a CDA document and explains the constraints on those sections.

Section 7: This section describes the attributes of entries found in a CDA document and explains the constraints on those sections.

Section 8: This section lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: Provides examples that conform to the requirements of this specification.

This document fits into an overall specification framework described in Figure i1 References to the Saudi eHealth Clinical Documents Constrains Interoperability Specifications below. Further descriptions and references for the documents identified in that figure are provided in Section 8.

REFERENCES

This document is a Supporting Interoperability Specification that may be referenced by a number of Core Interoperability Specifications, as shown by example in Figure i1 References to the Saudi eHealth Clinical Documents Constrains Interoperability Specifications Interoperability Specification.

A Saudi eHealth Supporting Interoperability Specification (IS) may be referenced by multiple Core Interoperability Specifications and may also be referenced by other Supporting Interoperability Specifications. An example is shown in Figure i1 References to the Saudi eHealth Clinical Documents Constrains Interoperability Specifications. It is a specification targeted to be testable unit of the Core Interoperability Specification for the technology developers, the compliance assessment testing and certification, and the purchaser of IT systems in terms of technical requirements that will ensure interoperability.

Further descriptions and references for the documents identified below are provided in Section 8.

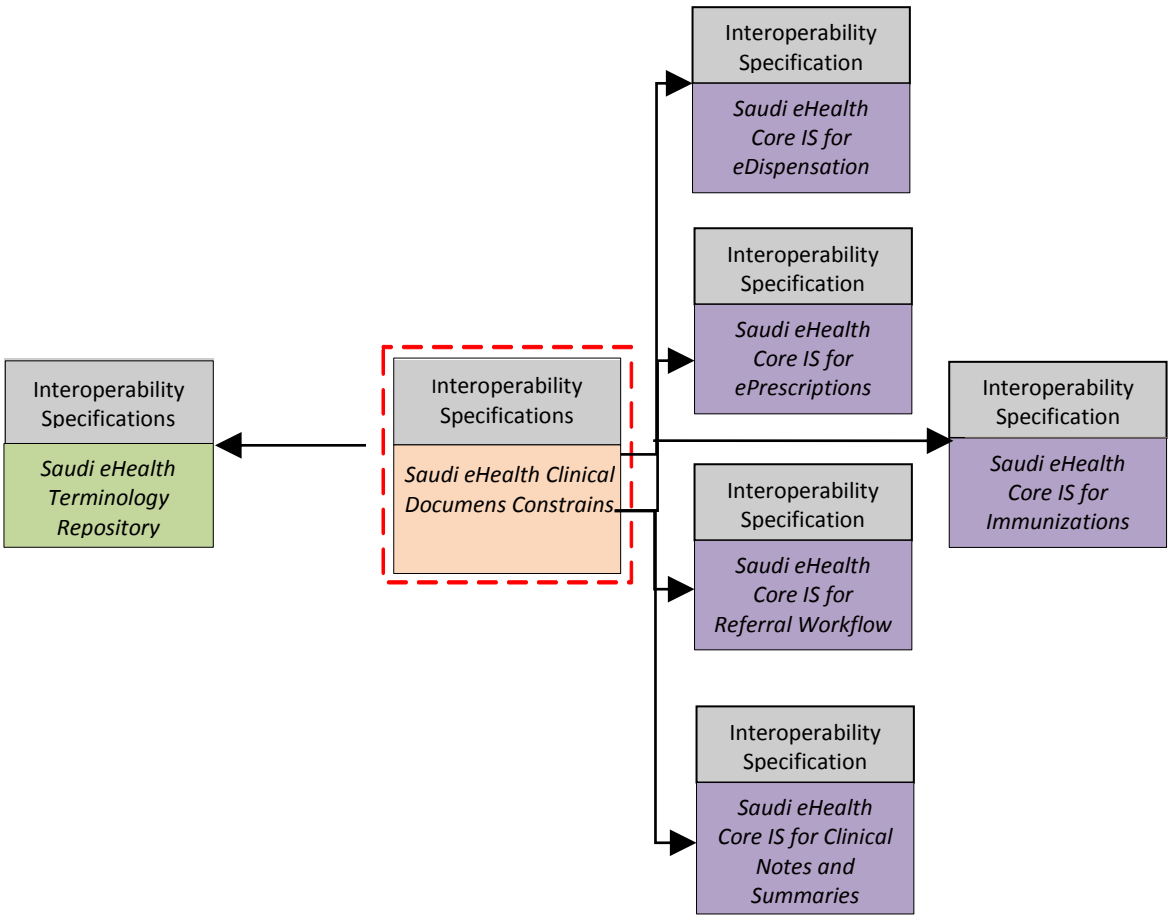

FIGURE I1 REFERENCES TO THE SAUDI EHEALTH CLINICAL DOCUMENTS CONSTRAINS INTEROPERABILITY SPECIFICATIONS

DESCRIPTION

This Supporting Interoperability Specification describes how elements for date, time, personal names, and common metadata about persons and organizations are to be provided in documents using the HL7 Clinical Document Architecture R2 (CDA) Standard.

DOCUMENT CONVENTIONS

How to Read the Tables

There are is one kind of table regularly used in this document and it looks like the one below.

TABLE 3.3-1 IDENTIFIER ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
id	The identifier.	i d	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4
Assigning Authority	A value that identifies the assigner of the identifier.	. / @ r o o t	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4
Identifier	The identifier value.	. / @ e x t e n s i o n	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4

Attribute: This column provides a descriptive name for the attribute that will be used in any constraints following the table.

Attribute Definition: This column describes the purpose and definition of the attribute.

CDA Location: This column provides an XPath expression[1] that is used to describe the location of the data element in the CDA document.

Cross Ref.: This column provides a reference to additional sections or tables which further constrain the data element in more detail.

[1] See XML Path Language (XPath) Version 1.0 http://www.w3.org/TR/xpath/

Following that table is a list of constraints formatted as shown in the example below:

[CDAH-0046] The **Name SHALL** have at most one [0..1] **Name Prefix**.

Constraint Identifier: The first item is the constraint identifier uniquely identifies the constraint within this document.

Constraint Definition: It is followed by a constraint definition provides a text definition of the constraint using the name of the attribute being constrained. These constraints use the terms **SHALL, SHOULD** and **MAY** as described below under Document Conventions.

Requirements Numbering Conventions:

All Saudi eHealth Interoperability Specifications contain numbered requirements that follow this format:

- [ABCD-####], where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and #### is the unique number for that requirement within the Interoperability Specification.
- Where a specific value set or code is required to be used, it can be found in the "IS0200 Saudi eHealth Terminology Repository". The location and process to access the terminology repository will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can claim conformance to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system **SHALL** be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

Please note that all Saudi eHealth numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

Constraint Language

Throughout this document the following conventions[2] are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification.

SHALL NOT: the definition is an absolute prohibition of the specification.

SHOULD: there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

SHOULD NOT: there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

[2] Definitions based upon RFC 2119

MAY or **OPTIONAL**: means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

Use of XPath in Tables

The XPath1 expressions found in this document work very much like directory paths on a file system. Each string in the expression represents the name of an XML Element in the document. Child elements are separated from their parents by a slash (/). Greyed boxes in the table set a context from which the following expressions that begin with a dot (.) will start from. So, `/ClinicalDocument/id` is talking about the `<id>` element that is a child of the `<ClinicalDocument>` element.

Occasionally you will see subscripts in the middle of the XPath expression, for example: `[@moodCode='RQO']`. These expressions are filters on the elements that they follow based upon attribute or child element values. The expression `./observation[@moodCode='RQO']` means select the first `<observation>` child element in the current context where the `moodCode` attribute has the value `RQO`. In the example below, only the second `<observation>` element matches the filter when the outer `<entry>` matches the context.

```
<entry>
   <observation moodCode='EVN'>
      …
   </observation>
</entry>
<entry>
   <observation moodCode='RQO'>
      …
   </observation>
</entry>
```

FIGURE I1 EXAMPLE FOR XPATH

Occasionally filters are also used to select elements by order. When the filter only contains a number N (e.g., `./given[2]`), it indicates that the N^{th} occurrence of the element should be selected.

METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during the development of the Saudi eHealth Core Interoperability Specifications for Sharing Images and Imaging Reports, Sharing Coded Laboratory Results, and Sharing Coded Laboratory Orders. This input was gathered over several months through workshops and teleconferences. Stakeholders included leaders at several hospitals, the Riyadh Regional Laboratory, and National Guard, as well as clinicians in facilities.

Many of the constraints in the document were developed based upon existing national policies with respect to vocabularies already used in the Kingdom of Saudi Arabia, or data that must be gathered to document clinical care.

1. USE CASE OVERVIEW

This section provides an overview of the Saudi eHealth Clinical Documents Constrains. This document provides content and additional specifications for Interoperability Specifications including:

- IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*
- IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*
- IS0007 *Saudi eHealth Core Interoperability Specifications for Clinical Notes and Summaries*
- IS0008 *Saudi eHealth Core Interoperability Specifications for ePrescriptions*
- IS0009 *Saudi eHealth Core Interoperability Specifications for eDispensation*
- IS0010 *Saudi eHealth Core Interoperability Specifications for Immunization*
- IS0103 *Saudi eHealth Radiology Reports Interoperability*

1.1 SCOPE

In Scope:

The scope of this document is the specification of the header, sections, entries and data types that appear within CDA documents exchanged via the Health Information Exchange (HIE) platform in support of several Use Cases, including the Clinical Notes and Summaries Use Case, the Medication Use Case, the Immunization Use Case, the eReferral and Transfer Use Case, the Laboratory Sharing Use Case, and the Sharing Imaging and Imaging Reports Use Case.

The following topics are in scope for this Interoperability Specification:

- Constraints on data types used within CDA documents.
- Constraints on the cardinality of common data elements appearing within CDA documents.
- Constraints on sections and entries which are used in one or more Interoperability Specifications and which are common in all cases.

Out of Scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- Constraints applicable to a single Interoperability Specification.
- Constraints that vary according to usage across Interoperability Specifications.
- Constraints that apply to the sections that must be contained within a CDA document.

1.2 DESIGN CONSTRAINTS AND ASSUMPTIONS

It is expected that all services initiated or provided by these Actors operate in accordance to the Saudi eHealth Information Exchange Polices.

2. CONFORMANCE REQUIREMENTS

The CDA standard has been identified as the preferred standard for use in HIE Systems used in Saudi. This interoperability specification establishes the conformance requirements for documents using the HL7 Clinical Document Architecture R2 (CDA) standard in HIE Systems used in Saudi.

[CDAH-0103] Requirements of the HL7 Clinical Document Architecture Release 2 (CDA R2) **SHALL** apply to all Saudi eHealth clinical documents.

Systems **SHOULD NOT** claim conformance to this Interoperability Specification, but **SHOULD** claim conformance to the requirements defined in Core Interoperability Specifications that reference this document. However, this specification has been designed to provide a general set of constraints that apply to all CDA documents being exchanged via the HIE Platform.

Conformance to this specification is required of all Content Creator actors creating documents using the CDA standard. CDA documents created by systems conforming to this specification must assert conformance by including the appropriate identifier in a `<realmCode>` element inside the `<ClinicalDocument>` element. An example of this is shown in the figure below.

```
<ClinicalDocument>
   <realmCode code='SA'>
      …
</ClinicalDocument>
```

FIGURE 1.2-1 REALMCODE EXAMPLE

[CDAH-0050] The **Clinical Document SHALL** contain at least one [1..1] **realmCode** where @code='SA'

Content creator actors creating CDA documents must comply with this specification when creating data types, header elements, sections or entries. When creating a data element, header element, section or entry in a CDA Document for which this specification has requirements, those requirements shall be applied.

[CDAH-0100] The HL7 CDA R2 constraints for data types, CDA structures found in Section 3 CDA Data Type Attributes and Constraints **SHALL** apply to all Saudi eHealth Clinical Documents.

[CDAH-0101] A Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Clinical Document **SHALL** support the Saudi eHealth CDA Header attributes and constraints (i.e., name format, date format, etc.) defined in the Section 4 CDA Header Attributes and Constraints.

[CDAH-0102] A Content Creator creating the HL7 CDA Release 2 document body for a Saudi eHealth Clinical Document **SHALL** support the additional attributes and constraints specific to the Clinical Document defined in Sections0 This Section provides Saudi eHealth constraints to be implemented for Immunization Summary documents as defined in this Supporting Interoperability Specification.

[CDAH-0450] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Summary documents.

2.1.1 HL7 CDA Header Attributes Being Constrained for Immunization Summaries

[CDAH-0451] An Immunization Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.9.1-1 Additional constrained HL7 CDA Header Attributes for Immunization Summaries.

TABLE 5.9.1-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR IMMUNIZATION SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below
Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication./languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0452] The **Clinical Document/code SHALL** contain 11369-6 History of Immunizations.

[CDAH-0453] **The Clinical Document/languageCommunication SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the “Language” value set.

[CDAH-0454] The **Clinical Document/participant/associatedEntity/scopingOrganization MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0455] The **Clinical Document//patient/guardian SHALL** contain one [0..1] **guardian** if one exists.

2.1.2 Additional Content Modules and Constraints for Immunization Summary Documents

This section describes the additional specific constraints for Immunization Summary documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0456] An Immunization Summary Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module

attributes and constraints in Table 5.9-2 Content Modules for Immunization Summary Documents.

TABLE 5.9-2 CONTENT MODULES FOR IMMUNIZATION SUMMARY DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']	6.10
Active Problems	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']	See Below
History of Past Illness	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.8']	See Below
Allergies and Other Adverse Reactions	The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']	See Below
Medications	The current medications and pertinent medication history at the end of the encounter. (Note 1)	//section[templateId/@root=' 1.3.6.1.4.1.19376.1.5.3.1.3.19']/	See Below
Pregnancy History	The pregnancy history section contains coded entries describing a current pregnancy of the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']	See Below
Coded Results	Coded results may include laboratory results showing the presence or absence of immunity for specific conditions.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below
Immunization Recommendations	The schedule of vaccinations that are intended or proposed for the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1']	See Below
List of Surgeries and Coded List of Surgeries Sections	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	List of Surgeries //section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Coded Social History	Includes social factors such as home life, community life, work life, hobbies, and behavioral risk factors that may indicate or contraindicate vaccinations.	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	See Below

Note 1 The Immunization Summary Information Requirements are constrained to those problems, medications, and allergies that are needed to review to inform the immunization decision. General problem lists are available through Clinical Notes and Summary documents (e.g. iEHR).

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0457] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0458] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Active Problems Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, conforming to the requirements found in Section 6.1, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related problems exist.,.

[CDAH-0459] An **Immunization Summary Document MAY** contain at most one [0..1] **History of Past Illness Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related problems exist. Specifications.

[CDAH-0460] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Allergies and Other Adverse Reactions Section,** to identify allergies relative to immunization from the "KSA Vaccine Risk Factors – Allergies" value set, and **SHALL** include documentation of adverse events associated with vaccination events, conforming to the requirements found in Section 6.2, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related allergies exist.

[CDAH-0461] An **Immunization Summary Document MAY** contain at most one [0..1] **Pregnancy History Section** to indicate pregnancy status as an immunization risk factor.

[CDAH-0462] An **Immunization Summary Document MAY** contain at most one [0..1] **Coded Results Section** to identify serology relative to immunization from the "KSA Serology Results" value set, conforming to the requirements found in Section 6.12.

[CDAH-0463] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunization Recommendations Section** which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood..

[CDAH-1120] **Immunization Recommendation** entries in the **Immunization Recommendations Section SHALL** set the `moodCode` attribute to 'PRP'.

[CDAH-0464] An Immunization Summary document **SHALL** contain exactly one [1..1] Medications Section to identify medications relative to immunization from the "KSA Vaccine Risk Factors – Medications" value set with the additional constraints specified in Section 6.3 **IF KNOWN** and **SHALL** use appropriate null flavors to indicate rationale if no immunization related medications exist.

[CDAH-0465] An Immunization Summary document **SHALL** contain exactly one [1..1] List of Surgeries Section to identify surgeries relative to immunization from the "KSA Vaccine Risk Factors – Procedures" value set **IF KNOWN**.

[CDAH-0466] An Immunization Summary document **SHALL** reflect gestational age at birth for individuals that were born prematurely, using the Simple Observation entry in the Active Problems up to age 3 years, and in the History of Past Illness up to the age of 18 years, using SNOMED CT 268477000 (fetal gestation) to identify the observation.

[CDAH-0467] An Immunization Summary document **MAY** contain exactly one [0..1] Comments Section.

[CDAH-0468] An Immunization Summary document **SHOULD** contain exactly one [0..1] Coded Social History Section to indicate vaccination indications, including employment, travel, and other social risk factors that are vaccine indications.

2.2 IMMUNIZATION CARD DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Immunization Card documents as defined in this Supporting Interoperability Specification.

[CDAH-0500] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Card documents.

2.2.1 HL7 CDA Header Attributes Being Constrained for Immunization Card Documents

[CDAH-0501] An Immunization Card Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Card document SHALL also support the additional Clinical CDA Header attributes and constraints in * MERGEFORMAT Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

.Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below
Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication/languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0502] The `Clinical Document//code` **SHALL** contain 11369-6 History of Immunizations.

[CDAH-0503] The `Clinical Document//languageCommunication` **SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the "Language" value set.

[CDAH-0504] The `Clinical Document//participant/associatedEntity/scopingOrganization` **MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0505] The `Clinical Document//patient/guardian` **SHALL** contain one [0..1] guardian if one exists.

2.2.2 Additional Content Modules and Constraints for Immunization Card Documents

This section describes the additional specific constraints for Immunization Card documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0506] An Immunization Card Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.10-2 Content Modules for Immunization Card Documents.

TABLE 5.10-2 CONTENT MODULES FOR IMMUNIZATION CARD DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.23']	6.10
Immunization Recommendations	The Immunization Recommendations Section documents the schedule of vaccinations that are intended or proposed for the patient.	1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0507] An **Immunization Card Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0508] An **Immunizations Section SHALL** provide human readable narrative both in Arabic and English for patient consumption.

[CDAH-0509] An Immunization Summary document **SHALL** exactly one [1..1] Immunization Recommendations Section, which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate

the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood.

[CDAH-0510] An Immunization Card document **MAY** contain exactly one [0..1] Comments Section.HL7 CDA Constraints for clinical scanned documents

2.3 HL7 CDA CONSTRAINTS FOR CLINICAL SCANNED DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for clinical scanned documents (PDF or plaintext documents) as defined in this Supporting Interoperability Specification.

[CDAH-0550] Constraints in the IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option **SHALL** apply to all clinical scanned clinical documents.

2.3.1 HL7 CDA header attributes being constrained for Clinical Scanned Documents

No additional HL7 CDA header constraints are defined beyond those specified in IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document (XDS-SD) Profile and Section 4 of this specification.

2.3.2 Additional Content Modules and Constraints For Clinical Scanned Documents

This section describes the additional specific constraints for scanned clinical documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

[CDAH-0551] A Content Creator Actor creating the document body of a scanned clinical document **SHALL** support the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

2.4 HL7 CDA CONSTRAINTS FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral Request documents and Transfer Request documents as defined in this Supporting Interoperability Specification. The Referral Request document is used to request a referral. The Transfer Request document is used to request a Transfer. Within this section, constraints specific to the Referral Request or Transfer Request will specify the type of Request Document that the constraint applies to. Constraints that apply to both types of document will just refer to them as Request documents.

[CDAH-0960] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to Request documents.

2.4.1 HL7 CDA Header Attributes Being Constrained for Request Documents

[CDAH-0961] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Request document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.12-1 Additional constrained HL7 CDA Header Attributes for Referral Request and Transfer Request document.

TABLE 5.12-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		/ClinicalDocument/	
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	./patient/participant[@typeCode='IND']/associatedEntity [@classCode='NOK']	See Below
Requesting Healthcare Provider	The healthcare provider requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity	See Below
Requesting Healthcare Organization	The healthcare organization requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1101] The **Title** for the Referral Request Document **SHALL** be set to “Referral Request”.

[CDAH-1102] The **Title** for the Transfer Request Document **SHALL** be set to “Transfer Request”

[CDAH-0962] The **Code** for the Referral Request Document **SHALL** be set to '57133-1' Referral Note from LOINC.

[CDAH-0963] The **Code** for the Transfer Request Document **SHALL** be set to '18761-7' Transfer Summary Note from LOINC.

[CDAH-0964] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-0965] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-0966] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-0967] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-0968] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-0969] The **Next of Kin** should specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-0970] The **Next of Kin Relationship SHALL** come from the "***KSA Personal Relationship Role"*** Value Set.

[CDAH-0971] If the referral or transfer is for a new born baby there **SHALL** be a Next of Kin using code/@code='MTH' from the "***HL7 Personal Relationship Role Type"*** Value Set (2.16.840.1.113883.1.11.19563) to describe the mother if she is alive and known.

[CDAH-0972] The **Next of Kin** for the mother as described above **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID

[CDAH-0973] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Provider.**

[CDAH-0974] The **Requesting Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-0975] The **Requesting Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-0976] The **Requesting Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-0977] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Organization.**

[CDAH-0978] The **Requesting Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

2.4.2 Additional Content Modules and Constraints for Request Documents

This section describes the additional specific constraints for Request documents. The IHE constraints on the content modules found below are specified in IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0979] A Clinical Summary Content Creator Actor creating a Saudi eHealth Request document **SHALL** also support the additional content module attributes and constraints in Table 5.12-2 Additional Content Modules for Referral Request and Transfer Request document.

TABLE 5.12-2 ADDITIONAL CONTENT MODULES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENT

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Coded Reason for Referral	Contains a narrative and coded description of the reason that the patient is being referred or transferred.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.2']	See Below

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Care Plan Section	Contains information about the requested services.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Request document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0980] The **Request document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-0981] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-0982] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set.

[CDAH-0983] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-0984] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-0985] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-0986] The **Request document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and **SHALL NOT** be empty.

[CDAH-0987] The **Request document SHALL** contain exactly one [1..1] **KSA Care Plan Section IF KNOWN**.

[CDAH-0988] The **Care Plan Section SHALL** contain [0..*] zero or more **Plan of Care Activity** entries conforming to the **HL7 Plan of Care Activity** template (2.16.840.1.113883.10.20.1.25) representing the desired services being requested in order by importance.

[CDAH-0990] The code/@code attribute of a **Plan of Care Activity** entry **SHALL** be present to indicate the service requested.

[CDAH-0991] The code/@code attribute of a **Plan of Care Activity** entry may be populated from the "***KSA Radiology Procedure"*** value set.

[CDAH-0992] The priorityCode/@code attribute of the **Plan of Care Activity SHALL** be populated from the "***KSA Referral and Transfer Priority"*** value set.

[CDAH-0993] The specialty of the performer of the requested service may be specified in performer/assignedEntity/code/@code attribute of the **Plan of Care Activity** entry.

[CDAH-0994] The specialty of the performer **SHALL** contain a value from the "***KSA Individual Provider Specialty"*** value set.

[CDAH-0995] The Receiving Organization **MAY** be specified in performer/assignedEntity/representedOrganization.

[CDAH-0996] The **Request document SHALL** contain exactly one [1..1] **Transport Section** IF KNOWN.

[CDAH-0997] The required **Transport Entry** in the **Transport Section SHALL** specify the **Intended Mode of Transport** in the Act/code/@code attribute.

[CDAH-0998] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-0999] The **effectiveTime MAY** be set to null flavor "UNK".

2.5 HL7 CDA CONSTRAINTS FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral/Transfer Response documents as defined in this Supporting Interoperability Specification.

[CDAH-1000] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to all clinical Referral/Transfer Response documents.

2.5.1 HL7 CDA Header Attributes Being Constrained for Response Documents

[CDAH-1001] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.13-1 Additional constrained HL7 CDA Header Attributes for Referral Response and Transfer Response document.

TABLE 5.13-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	`./patient/participant[@typeCode='IND']/associatedEntity[@classCode='NOK'`	See Below

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Receiving Healthcare Provider	The healthcare provider receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity`	See Below
Receiving Healthcare Organization	The healthcare organization receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1103] The **Title** for the Response Document **SHALL** be set to "Referral/Transfer Response Document"

[CDAH-1104] The **Code** for the Response Document **SHALL** be set to 'ReferralTransferResponseDocument' from the "KSA Referral and Transfer Document Type" Value Set.

[CDAH-1002] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-1003] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-1004] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-1005] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-1006] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-1007] The **Next of Kin SHOULD** specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-1008] The **Next of Kin Relationship SHALL** come from the "***KSA Personal RelationshipRole"*** Value Set.

[CDAH-1009] If the referral or transfer is for a new born baby, there **SHALL** be a **Next of Kin** using code/@code='MTH' from the "***KSA Personal Relationship Role"*** Value Set to describe the mother, if she is alive and known.

[CDAH-0x59] The **Next of Kin** for the mother **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID.

[CDAH-1010] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Provider.**

[CDAH-1011] The **Receiving Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-1012] The **Receiving Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1013] The **Receiving Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1014] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Organization.**

[CDAH-1015] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1016] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

2.5.2 Additional Content Modules and Constraints for Response Documents

This section describes the additional specific constraints for Referral/Transfer Response documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-1017] A Clinical Summary Content Creator Actor creating a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional content module attributes and constraints in Table 5.13-2 Additional Content Modules for Referral Response and Transfer Response document.

TABLE 5.13-2 ADDITIONAL CONTENT MODULES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Care Plan Section	Contains information about the requested services or the reason for aborting the transfer or referral.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Response document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1018] The **Response Document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-1019] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-1020] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set .

[CDAH-1021] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-1022] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-1023] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-1024] The **Response document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and SHALL NOT be empty.

[CDAH-1025] The **Response document SHALL** contain exactly one [1..1] **KSA Care Plan Section**.

[CDAH-1026] The **Response document SHALL** contain exactly one [1..1] **Transport Section IF KNOWN.**

[CDAH-1027] The **Transport SHALL** specify the **Intended Mode of Transport** in the code/@code attribute.

[CDAH-1028] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-1029] The **effectiveTime MAY** be set to null flavor "UNK".

CDA Section Attributes and Constraints, and Section 7 CDA Entry Attributes and Constraints.

3. CDA DATA TYPE ATTRIBUTES AND CONSTRAINTS

This section describes the attributes of various CDA data types that are constrained by this specification, and provides an explanation of these constraints.

3.1 DATE AND TIME ATTRIBUTES AND CONSTRAINTS

CDA uses the Time Stamp (TS) and Interval of Time (IVL_TS) data types to record dates and times. For all documents using the CDA standard, time stamps and time intervals **SHALL** be recorded using the Gregorian calendar. The dates and times value is implemented using the ISO 8601 standard which requires numbers **without** dashes (-) between date components, nor time separator character (T), nor colon (:) between time components. The syntax is CCYYMMDDhhmmss.SSS[+|-ZZzz] where:

TABLE 3.1-1 TIME COMPONENTS

Symbol	Description
CC	Is the century.
YY	Is the year.
MM	Is the month.
DD	Is the date.
hh	Is the hour.
Mm	Is the month.
ss	Is the seconds.
SSS	Is fractional seconds.
+|-	Is the direction of time offset from UTC.
ZZ	Is the offset from UTC in hours.
zz	Is the offset from UTC in minutes.

Dates and Date/Time stamps should be recorded in the greatest precision available. When information is supplied by the patient (e.g., Date of Birth), but precision is not available, it is acceptable to provide a time stamp that is precise to the year, to the month, or to the day.

A time stamp represents an activity occurring at a single point in time, such as the creation of a document, the date of a visit, the signing of a document, or the performance of an imaging study or laboratory test.

A time interval represents an activity that occurs over a period of time, usually days, such as a hospital stay or the time over which a diagnosis is active.

The table below shows where the components of a Time Stamp or Time Interval appear.

TABLE 3.1-2 DATE AND TIME ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Time Stamp Attribute	The attribute of a time stamp	`effectiveTime | time`	N/A

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Time Stamp Value	The value of the timestamp	`./@value`	N/A
Time Interval	The attribute for a time interval	`effectiveTime`	N/A
Start Date	The starting value of the time interval	`low/@value`	N/A
End Date	The ending value of the time interval	`high/@value`	N/A

The list below provides the constraints for date and time values recorded in a CDA document.

[CDAH-0056] A **Time Stamp Value**, **Start Date** or **End Date SHALL** contain the Century and Year.

[CDAH-0057] A **Time Stamp Value**, **Start Date** or **End Date SHALL** contain the Month **IF KNOWN**.

[CDAH-0058] A **Time Stamp Value**, **Start Date** or **End Date SHALL** contain the Date **IF KNOWN**.

[CDAH-0059] A **Time Stamp Value**, **Start Date** or **End Date MAY** contain time information (Hours, Minutes, Seconds, and Fractional Seconds).

[CDAH-0060] A **Time Stamp Value**, **Start Date** or **End Date SHALL** contain the Time Zone if Hours are included.

3.2 NAME ATTRIBUTES AND CONSTRAINTS

Within a CDA document, names are captured in the `<name>` element, which allows for a number of components to be provided. It is common in many situations for a person to have one or more first names, middle names and last names. However, many information systems only support first, middle and last name. To support maximum interoperability, the first name is treated as the first `<given>` element, and a two part first name is recorded using spaces to separate the name parts. The middle name is similarly treated, and is stored in the second `<given>` element. The family name is also treated in this fashion, save that it is stored in the family name element.

Suffixes are used on names of Western origin to distinguish between members of the same family with the same name (e.g., Jr., Sr., III). A suffix may also be used on some names to denote degrees or honors earned. Degrees or honors earned should only be used with the names of physicians or other healthcare providers to enable others to distinguish their experience. Only one `<prefix>` or `<suffix>` element is allowed.

The CDA standard accounts for the fact that many different cultures order names differently. Information systems processing names should retain the order of the `<given>` and `<family>` elements but are not required to do so.

People can be known by multiple names, due to a name change, or to reflect variant spellings of the name.

Information systems processing names must be able to capture names written in Arabic or Western scripts and should support all scripts.

TABLE 3.2-1 NAME ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Name	The name of a person.	`name`	N/A
Name Type	The type of name.	`./@use`	3.2.1
Name Prefix	A prefix or honorific associated with the name (e.g., Dr.).	`./prefix`	See Below
Given Name	The first given name.	`./given[1]`	See Below
Middle Name	The second given name.	`./given[2]`	See Below
Family Name	The family name.	`./family`	See Below
Name Suffix	A suffix or degree associated with the name (e.g., Jr.).	`./suffix`	See Below

The list below enumerates the constraints on the name. Note that more than one name may be present, and that these constraints apply only within the name.

[CDAH-0061] The **Name SHOULD** have at least one and no more than two values [1..2] for **Name Type**.

[CDAH-0062] The **Name SHALL** have at most one [0..1] **Name Prefix**.

[CDAH-0063] The **Name SHALL** have exactly one [1..1] **Family Name IF KNOWN**.

[CDAH-0064] The **Name SHALL** have no more than 2 [0..2] <given> elements**.**

[CDAH-0065] The **Name SHALL** have exactly one [1..1] **First Name** stored in the <given[1]> element **IF KNOWN**.

[CDAH-0066] The **Name SHALL** have exactly one [1..1] **Middle Name** stored in the <given[2]> element **IF KNOWN**.

[CDAH-0067] The **Name MAY** have a no more than one [0..1] suffix elements.

3.2.1 Name Type

The name of the person **MAY** be represented in Arabic, Western scripts, or other scripts. They **MAY** also be identified as being the legal name, or have other purposes.

[CDAH-0068] The **Name Type** for the **Name SHALL** contain the value ‘L’ when the name specified is the legal name. This value may be combined with other name type values described below.

[CDAH-0045] Only one **Name SHALL** have a **Name Type** that represents the legal name of a person.

[CDAH-0044] When the **Name** is represented in Arabic or other syllabic script (e.g., Hiragana or Katakana), the **Name Type SHALL** have the value ‘SYL’.

[CDAH-0041] When the **Name** is represented in Western script, the **Name Type SHALL** have the value ‘ABC’.

[CDAH-0042] When the **Name** is represented in Kanji or other Ideographic script (e.g., Kanji), the **Name Type SHALL** have the value ‘IDE’.

3.3 IDENTIFIER ATTRIBUTES AND CONSTRAINTS

Identifiers in the HIE are all globally unique. Most identifiers have two parts: a component that uniquely identifies the assigning authority and another component that provides what is the identifier assigned by that authority. The two components together provide a universally unique identifier.

TABLE 3.3-1 IDENTIFIER ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
id	The identifier.	`id`	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4
Assigning Authority	A value that identifies the assigner of the identifier.	`./@root`	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4
Identifier	The identifier value.	`./@extension`	See 3.3.1, 3.3.2, 3.3.3 and 3.3.4

3.3.1 Patient Identifier Constraints

Patients are identified in the HIE using an MOH Assigned Health Identifier for each patient. This identifier may be obtained using services describe in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

[CDAH-0039] The **Assigning Authority** for the patient identifier **SHALL** be valued with '2.16.840.1.113883.3.3731.1.1.100.1'.

[CDAH-0038] The **Identifier SHALL** be valued with the MOH assigned Health ID.

3.3.2 Physician and Healthcare Professional Identifier Constraints

Physicians and other Healthcare Professionals are identified in the HIE using their MOH assigned identifier. This identifier may be obtained using the services described in IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*.

[CDAH-0037] The **Assigning Authority** for a physician or healthcare professional identifier **SHALL** be valued with '2.16.840.1.113883.3.3731.1.2.1'.

3.3.3 Organization Identifier Constraints

Healthcare organizations are identified in The HIE using their MOH assigned identifier. This identifier may be obtained using the services described in IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*.

[CDAH-0036] The **Assigning Authority** for an organization identifier **SHALL** be valued with '2.16.840.1.113883.3.3731.1.2.2'.

3.3.4 Document Identifiers

Document identifiers must be unique every time a new version of the document is published. Each system assigning clinical document identifiers must have a unique assigning authority.

[CDAH-0070] The **Assigning Authority** for a document identifier **SHALL** be the value assigned to the Content Creator actor that generated the document.

3.4 ADDRESS ATTRIBUTES AND CONSTRAINTS

Physical postal address information.

TABLE 0-1 ADDRESS ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Postal Address	Physical postal	addr	N/A
Street Address	The street address. May be repeated.	./streetAddress	See Below
City	The city	./city	See Below
Postal Code + Wasel Code	The postal code, and if available, the Wasel Code	./postalCode	See Below
Country	Country	./country	See Below

The list below enumerates the constraints on the postal address. Note that more than one address may be present, and that these constraints apply only within a single address.

[CDAH-1030] The **Postal Address SHALL** have one or more [1..*] **Street Address**.

[CDAH-1031] The **Postal Address SHALL** have exactly one [1..1] **City**.

[CDAH-1032] The **City SHALL** contain a value from the "***KSA City"*** value set.

[CDAH-1033] The **Postal Address SHALL** have exactly one [1..1] **Postal Code**.

[CDAH-1034] The **Postal Code SHALL** contain a value from the "***KSA Postal Code"*** value set.

[CDAH-1035] The **Postal Address SHALL** have exactly one [1..1] **Wasel Code IF KNOWN**.

[CDAH-1036] The **Country SHALL** have exactly one [1..1] **Country** if the **Postal Address** is outside of Saudi Arabia.

[CDAH-1037] The **Country SHALL** contain a value from the "***Nationality"*** value set.

4. CDA HEADER ATTRIBUTES AND CONSTRAINTS

This section describes the attributes found in the CDA Header that are constrained by this specification, and provides an explanation of these constraints.

The tables below describe the content of the CDA header of the clinical document and the constraints placed upon them by this interoperability specification. These constraints shall apply to all healthcare documents based upon the HL7 CDA Release 2 standard that are exchanged via the HIE platform. Only those HL7 CDA header attributes listed have been constrained, attributes not listed shall follow the requirements of the HL7 CDA Release 2 standard.

Specific Interoperability Specifications may create additional HL7 CDA Header attribute constraints or override these requirements. If so, they only apply to that specific Interoperability Specification.

The columns of the table are described below:

Attribute: This column provides a descriptive name for the attribute that will be used in any constraints following the table.

Attribute Definition: This column describes the purpose and definition of the attribute.

CDA Location: This column provides an XPath expression that is used to describe the location of the data element in the CDA document.

Cross Ref.: This column provides a reference to additional sections or tables which further constrain the data element in more detail.

Please see the sections referenced in the last column of the first table for more detailed constraints on the data elements listed in the first column.

TABLE 0-1 CONSTRAINED HL7 CDA HEADER ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Clinical Document	Represents the Clinical Document.	`/ClinicalDocument/`	See Below
Document Identifier	Represents the unique instance identifier of a clinical document.	`./id`	3.3.4
Code	The code specifying the particular kind of document.	`./code`	See Below
Title	Represents the title of the document.	`./title`	See Below
Effective Time	Signifies the document creation date and time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, this is the time the original document is created.	`./effectiveTime`	3.1
Confidentiality Code	Confidentiality is a required contextual component of CDA, where the value expressed in the header holds true for the entire document, unless overridden by a nested value.	`./confidentialityCode`	See Below

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Patient Information	Contains information about the patient about whom this document is written.	`./recordTarget`	4.1
Author	Contains information about the authors who wrote this document.	`./author`	4.2
Custodian	Contains information about the organization who maintains this document.	`./custodian`	4.3
Legal Authenticator	Contains information about the person who signed this document and takes final responsibility for its content.	`./legalAuthenticator`	4.4
Authenticator	Contains information about the person who reviewed this document but does not take final responsibility for its content.	`./authenticator`	4.5
Performers	Contains information about people performing the tasks associated with the document.	`./documentationOf/serviceEvent/performer`	4.6
Previous Version	Identifies the previous document this document updates (if any).	`/ClinicalDocument/relatedDocument [@typeCode="RPLC"]/parentDocument`	0

The following list enumerates the constraints on the above attributes. This list is described below:

Constraint Identifier: The first item is the constraint identifier uniquely identifies the constraint within this document.

Constraint Definition: It is followed by a constraint definition provides a text definition of the constraint using the name of the attribute being constrained. These constraints use the terms **SHALL, SHOULD** and **MAY** as described below under Document Conventions.

[CDAH-0001] The **Clinical Document SHALL** contain exactly one [1..1] **Document Identifier** that **SHALL NOT** be null flavor.

[CDAH-0002] The **Clinical Document SHALL** contain exactly one [1..1] **Code** that **SHALL NOT** be null flavor. The **Code** is specialized by each specific type of document.

[CDAH-0003] The **Clinical Document SHALL** contain exactly one [1..1] **Title** that **SHALL NOT** be null flavor.

[CDAH-0004] The **Clinical Document SHALL** contain exactly one [1..1] **Effective Time** that **SHALL NOT** be null flavor.

[CDAH-0005] The **Clinical Document SHALL** contain exactly one [1..1] **Confidentiality Code** and **SHALL NOT** be null flavor.

[CDAH-0034] The **Clinical Document Confidentiality Code SHALL** be set to values defined by the Saudi eHealth Security and Privacy Interoperability Specification.

[CDAH-0022] The **Clinical Document SHALL** contain exactly one [1..1] **Legal Authenticator** if the document is signed.

4.1 PATIENT INFORMATION ATTRIBUTES AND CONSTRAINTS

Patient information attributes include the patient identifier, name, gender, birth time, religion and nationality. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

TABLE 4.1-1 PATIENT INFORMATION ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Patient Information	Represents the Patient Information.	/ClinicalDocument/ recordTarget/patient Role/ patient/	See Below
Patient Identifier	This identifier is used to link the document to the correct patient.	./id	3.3.1
Patient Name	Specifies the given name of the person identified in this document.	./name	3.2
Patient Address	Specifies the physical address contact information for the person identified in this document.	./addr	See Below
Patient Telecom	Specifies the physical telecom contact information for the person identified in this document.	./telecom	See Below
Patient Gender	The administrative sex of the patient.	./administrativeGend erCode	See Below
Patient Birth Time	The date and time of the birth of the patient.	./birthTime	3.1
Patient Religion	The religious preference of the patient.	./religiousAffiliati onCode	See Below
Patient Marital Status	The marital status of the patient.	./maritalStatusCode	See Below
Patient Language	The primary language used by the patient.	./languageCommunicat ion/ languageCode	See Below
Patient Nationality	The nationality of the patient.	ClinicalDocument/ participant[@typeCode='SBJ']/ associatedEntity[@classCode='CIT']/co de	See Below

Note: patientRole/patient/id is used rather than patientRole/id. The use of patientRole/patient/id is discouraged in CDA R2 specification (section 4.2.2.11 of the normative description of CDA) because many nations do not have a singular ID for patients. This is not the case in KSA. Since patientRole/id is required by the CDA Schema it SHALL be present and nullFlavor.

The list below provides constraints on the patient information attributes. See the Preface Section How to Read the Tables for more information.

[CDAH-0007] The **Clinical Document SHALL** contain exactly one [1..1] **Patient Information** that **SHALL NOT** be null flavor.

[CDAH-0048] The **Patient Information MAY** contain at most one [0..1] Patient Religion which **SHALL** contain a religiousAffiliationCode/@code from the "**KSA Religion"** value set.

[CDAH-0071] The **Patient Information MAY** contain at most one [0..1] Patient Marital Status which **SHALL** contain a maritalStatusCode/@code from the "**KSA Marital Status"** value set.

[CDAH-0051] The **Patient Information SHALL** contain exactly one [1..1] Patient Nationality which **SHALL** contain code/@code from the "**Nationality"** value set.

[CDAH-0008] The **Patient Information SHALL** contain exactly one [1..1] **Patient Identifier** that **SHALL NOT** be null flavor.

[CDAH-0009] The **Patient Information SHALL** contain one or more [1..*] **Name** that **SHALL NOT** be null flavor.

[CDAH-0011] The **Patient Information SHALL** contain exactly one [1..1] **Gender** that **SHALL NOT** be null flavor.

[CDAH-0032] The **Gender SHALL** contain exactly one code/@code from the "***KSA Gender"*** value set.

[CDAH-0012] The **Patient Information SHALL** contain exactly one [1..1] **Birth Time** that **SHALL NOT** be null flavor.

[CDAH-0072] The **Patient Information SHALL** contain one or more [1..*] **Address IF KNOWN**.

[CDAH-0074] The **Patient Information SHALL** contain one or more [1..*] **Telecom IF KNOWN**.

[CDAH-0075] The **Patient Information SHALL** contain exactly one [1..1] **Language IF KNOWN**.

4.2 AUTHOR ATTRIBUTES AND CONSTRAINTS

The author attributes describe the person writing the document, including their unique identifier, name, and organization. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

TABLE 4.2-1 AUTHOR ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Author Information	Represents the Author of the Document.	`/ClinicalDocument/author/`	See Below
Authoring Time	The start date/time of the author creating the content of the document.	`./time`	3.1
Author Functional Role	Specifies the functional role of the author of this document (e.g., Medical practitioner, Director of Nursing).	`./functionCode`	See below
Author Identifier	An ID to identify the author of this document.	`./assignedAuthor/id`	3.3.2
Author Specialty	Specifies the specialty of the author of this document (e.g., Endocrinology, Internal Medicine).	`./assignedAuthor/code`	See below
Author Address	Specifies the physical address contact information for the author of this document.	`./assignedAuthor/addr`	See below

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Author Telecom	Specifies the physical telecom contact information for the author of this document.	`./assignedAuthor/telecom`	See below
Author Device	Specifies the Author of the document if it is a Device.	`./assignedAuthoringDevice`	See below
Author Name	The given name of the author of this document.	`./assignedAuthor/assignedPerson/name`	3.2
Organization Identifier	Identifies the organization that the author of this document belongs to.	`./assignedAuthor/representedOrganization/id`	3.3.3
Organization Name	The name of the organization that the author of this document belongs to.	`./assignedAuthor/representedOrganization/name`	See Below

The list below provides constraints on the author attributes. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0076] The **Author SHALL** contain exactly one [1..1] **Author Information** that **SHALL NOT** be null flavor.

[CDAH-0013] The **Author SHALL** contain exactly one [1..1] **Time** and **SHALL NOT** be null flavor.

[CDAH-0077] There **SHALL** be one **assignedAuthor** or **assigned AuthoringDevice**.

[CDAH-0014] The **Author SHALL** contain exactly one [1..1] **Author Identifier IF KNOWN**.

[CDAH-0015] [RETIRED].

[CDAH-0016] The **Author SHALL** contain at least one [1..1] **Author Name** and **SHALL NOT** be null flavor.

[CDAH-0018] The **Author SHALL** contain exactly one [1..1] **Organization Identifier IF KNOWN.**

[CDAH-0019] The **Author SHALL** contain exactly one [1..1] **Organization Name** and **SHALL NOT** be null flavor.

[CDAH-0078] The **Author Specialty SHALL** contain exactly one code/@code from the "***KSA Individual Provider Specialty"*** value set.

[CDAH-0079] The **Author Functional Role SHALL** contain exactly one code/@code from the "***KSA Individual Provider Type"*** value set.

[CDAH-0080] The **Author Information SHALL** contain one or more [1..*] **Address IF KNOWN**.

[CDAH-0081] The **Author Information SHALL** contain one or more [1..*] **Telecom IF KNOWN**.

Where the document is created by a device (.i.e. automatically generated by a machine rather a person):

[CDAH-0082] If the **Clinical Document/Author** is a device, the **Author Information SHALL** contain exactly one [1..1] **Author Device**.

4.3 CUSTODIAN ATTRIBUTES AND CONSTRAINTS

The custodian attributes describe the organization that maintains a true and accurate copy of the original document shared within The HIE. These attributes are defined in the table below. See

TABLE 4.3-1 CUSTODIAN ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Custodian Information	Represents the organization in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document.	`/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization`	N/A
Custodian Identifier	The identifier of the organization.	`./id`	3.3.3
Custodian Name	The name of the organization.	`./name`	N/A

[CDAH-0083] The **Custodian SHALL** contain exactly one [1..1] **Custodian Information** that **SHALL NOT** be null flavor.

4.4 LEGAL AUTHENTICATOR ATTRIBUTES AND CONSTRAINTS

The legal authenticator attributes describe the person who legally signed the document taking final responsibility for its content. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

TABLE 4.4-1 LEGAL AUTHENTICATOR ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Legal Authenticator Information	Identified the legal authenticator of the document. The legal authenticator is a person accepting responsibility for the document.	`/ClinicalDocument/legalAuthenticator/assignedEntity/`	See Below
Legal Authenticator Identifier	The identifier of the legal authenticator.	`./id`	3.3.2
Legal Authenticator Name (Note 1)	The name of the legal authenticator.	`./assignedPerson/name`	See Below

Note 1: The Legal Authenticator of the document for Clinical Notes and Summaries is typically the Most Responsible Physician or Surgeon.

The list below provides constraints on the legal authenticator attributes. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0084] The **Legal Authenticator SHALL** contain exactly one [1..1] **Legal Authenticator Information** that **SHALL NOT** be null flavor.

[CDAH-0023] The **Legal Authenticator SHALL** contain exactly one [1..1] **Legal Authenticator Identifier** if known.

[CDAH-0024] The **Legal Authenticator SHALL** contain at least one [1..*] **Name** and **SHALL NOT** be null flavor.

[CDAH-0052] Exactly one **Name** in the **Legal Authenticator SHALL** be marked as the legal name of the **Legal Authenticator**. See [CDAH-0068] in section 3.2.1.

4.5 AUTHENTICATOR ATTRIBUTES AND CONSTRAINTS

The authenticator attributes describe the person who reviewed the document without taking final responsibility for its content. These attributes are defined in the table below. In radiology reporting environments, the authenticator would typically be a resident who dictated the initial report and reviewed and approved the transcribed version, but the report would still need to be legally authenticated by an attending radiologist. See the Preface section How to Read the Tables for more information on interpreting this table.

TABLE 4.5-1 AUTHENTICATOR ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Authenticator Information	Represents the person authenticating the content of the document.	`/ClinicalDocument/authenticator/assignedEntity/`	See Below
Authenticator Identifier	Identifies the participant's ID who attested to the accuracy of the information in the document.	`./id`	3.3.2
Authenticator Name	Identifies the participant's given name who attested to the accuracy of the information in the document.	`./assignedPerson/name`	3.2

The list below provides constraints on the authenticator attributes. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0085] The **Authenticator MAY** contain zero to many [0..*] **Authenticator Information** that **SHALL NOT** be null flavor.

[CDAH-0027] The **Authenticator SHALL** contain exactly one [1..1] **Author Identifier** if known.

[CDAH-0029] The **Authenticator SHALL** contain at least one [1..*] **Name** that **SHALL NOT** be null flavor.

[CDAH-0053] Exactly one **Name** in the **Authenticator SHALL** be marked as the legal name of the Authenticator. See [CDAH-0068] in section 3.2.1.

4.6 PERFORMER ATTRIBUTES AND CONSTRAINTS

The performer attributes describe the person(s) providing the care (e.g. Healthcare Provider, Surgeon, Pharmacist), including their unique identifier, name, and organization. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

TABLE 4.6-1 PERFORMER ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Performer Information	Represents the person(s) providing the care.	documentationOf/serviceEvent/performer	See Below
Performing Time	The start date/time the care was given.	./time	3.1
Performer Address	Specifies the physical address contact information for the performer(s) identified in this document.	./assignedEntity/addr	N/A
Performer Telecom	Specifies the physical telecom contact information for the performer(s) identified in this document.	./assignedEntity/telecom	N/A
Performer Identifier	An ID to identify the performer(s) of this document.	./assignedEntity/assignedPerson/id	3.3.2
Performer Name	The given name of the performer associated with this document.	./assignedEntity/assignedPerson/name	3.2
Performer Specialty	This is the Specialty field of the Healthcare Provider.	./assignedEntity/assignedPerson/code	See Below
Performer Organization Identifier	Identifies the organization that the performer belongs to.	./assignedEntity/representedOrganization/id	3.3.3
Performer Organization Name	The name of the organization that the performer belongs to.	./assignedEntity/representedOrganization/name	See Below
Performer Organization Phone Number	The phone number of the organization that the performer belongs to.	./assignedEntity/representedOrganization/telecom	See Below
Performer Organization Address	The address of the organization that the performer belongs to.	./assignedEntity/representedOrganization/addr	See Below
Performer Organization Sector	The classification of the organization with respect to sector (e.g., MOH, Medical City, National Guard, Private Sector, etc.)	./assignedEntity/representedOrganization/standardIndustryClassCode	See Below

The list below provides constraints on the author attributes. These attributes are defined in the table below. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0086] The **Performer SHALL** contain zero or more [0..*] **Performer Information** and **SHALL NOT** be null flavor.

[CDAH-0087] The **Performer SHALL** contain exactly one [1..1] **Performer Time** and **SHALL NOT** be null flavor.

[CDAH-0088] The **Performer SHALL** contain exactly one [1..1] **Performer Identifier IF KNOWN**.

[CDAH-0089] The **Performer SHALL** contain exactly one [1..1] **Performer Name** and **SHALL NOT** be null flavor.

[CDAH-0090] The **Performer SHALL** contain exactly one [1..1] **Performer Identifier IF KNOWN**.

[CDAH-0091] The **Performer SHALL** contain exactly one [1..1] **Performer Specialty If KNOWN**.

[CDAH-0092] The **Performer Specialty SHALL** contain exactly one code/@code from the "***KSA Individual Provider Specialty" value set*** .

[CDAH-0093] The **Performer SHALL** contain exactly one [1..1] **Performer Organization Identifier IF KNOWN.**

[CDAH-0094] The **Performer SHALL** contain exactly one [1..1] **Performer Organization Name** and **SHALL NOT** be null flavor.

[CDAH-0xx8] The **Performer MAY** contain zero or more [0..*] **Performer Organization Address.**

[CDAH-0xx9] The **Performer MAY** contain zero or more [0..*] **Performer Organization Phone Number.**

[CDAH-0x10] The **Performer MAY** contain exactly one [1..1] **Performer Organization Sector.**

[CDAH-0x11] The **Performer Organization Sector SHALL** contain exactly one code/@code from the "***KSA Organization Sector"*** value set.

4.7 PREVIOUS VERSION ATTRIBUTES AND CONSTRAINTS

The previous version attributes identity the prior version of this document if any. These attributes are defined in the table below.

TABLE 4.7-1 PREVIOUS VERSION ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF.
Previous Version	Contains information about the prior version of the document.	`/ClinicalDocument/ relatedDocument [@typeCode="RPLC"]/ parentDocument`	0
Document Identifier	Identifies the previous document that was replaced.	`./id`	3.3.4

[CDAH-0021] The **Previous Version SHALL** contain exactly one [1..1] **Document Identifier** and **SHALL NOT** be null flavor.

There are no further constraints on the Previous Version beyond those identified in the table above (and in the CDA standard).

5. SAUDI EHEALTH HL7 CDA R2 DOCUMENT CONTENT

This section is an introduction to the organization of the Saudi eHealth HL7 CDA R2 documents including the necessary data elements identified by the stakeholders.

All Saudi eHealth clinical documents are to be expressed as Clinical Documents using the HL7 Clinical Document Architecture (CDA) Release 2 (R2).

An HL7 CDA R2 document consists of two parts: the header and the body. The header identifies and classifies the document and provides information on the authentication, the encounter, the patient, and the involved providers. The body contains the clinical note or summary information, organized into sections whose narrative content can be encoded using standard vocabularies. An HL7 CDA R2 document consists of a single header and a body containing sections and content modules.

By defining the requirements for a specific HL7 CDA R2 document type, one has the ability to enable interoperability between systems. This is accomplished by providing a set of HL7 CDA R2 templates which constrain the CDA specification within a particular implementation and provide validating rule sets that check conformance to these constraints.

A number of the requirements that have been encountered in the development of the Saudi eHealth clinical document specification are common across all Saudi eHealth specifications. This includes the specification of such data types as person names, date/time and identifiers for Organizations and Professional Practitioners. These data type requirements are specified in the Section 3 CDA Data Type Attributes and Constraints.

5.1 DESIGN CONSTRAINTS AND ASSUMPTIONS

The Saudi eHealth Standards-Based Interoperability Project is built upon the foundation of a number of existing HL7 Standards and IHE Technical Frameworks which already constrain the content in the area of clinical documents. Additional general design constraints have been created as a result of requirements set forth by the Project, and apply to all of the Saudi eHealth Content Interoperability Specifications. These design constraints are specified in Sections, 4 CDA Header Attributes and Constraints, 0 This Section provides Saudi eHealth constraints to be implemented for Immunization Summary documents as defined in this Supporting Interoperability Specification.

[CDAH-0450] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Summary documents.

5.1.1 HL7 CDA Header Attributes Being Constrained for Immunization Summaries

[CDAH-0451] An Immunization Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.9.1-1 Additional constrained HL7 CDA Header Attributes for Immunization Summaries.

TABLE 5.9.1-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR IMMUNIZATION SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below
Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication./languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0452] The **Clinical Document/code SHALL** contain 11369-6 History of Immunizations.

[CDAH-0453] **The Clinical Document/languageCommunication SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the "Language" value set.

[CDAH-0454] The **Clinical Document/participant/associatedEntity/scopingOrganization MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0455] The **Clinical Document//patient/guardian SHALL** contain one [0..1] **guardian** if one exists.

5.1.2 Additional Content Modules and Constraints for Immunization Summary Documents

This section describes the additional specific constraints for Immunization Summary documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0456] An Immunization Summary Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.9-2 Content Modules for Immunization Summary Documents.

TABLE 5.9-2 CONTENT MODULES FOR IMMUNIZATION SUMMARY DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']	6.10
Active Problems	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']	See Below
History of Past Illness	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.8']	See Below
Allergies and Other Adverse Reactions	The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']	See Below
Medications	The current medications and pertinent medication history at the end of the encounter. (Note 1)	//section[templateId/@root=' 1.3.6.1.4.1.19376.1.5.3.1.3.19']/	See Below
Pregnancy History	The pregnancy history section contains coded entries describing a current pregnancy of the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']	See Below
Coded Results	Coded results may include laboratory results showing the presence or absence of immunity for specific conditions.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below
Immunization Recommendations	The schedule of vaccinations that are intended or proposed for the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1']	See Below
List of Surgeries and Coded List of Surgeries Sections	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	List of Surgeries //section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Coded Social History	Includes social factors such as home life, community life, work life, hobbies, and behavioral risk factors that may indicate or contraindicate vaccinations.	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	See Below

Note 1 The Immunization Summary Information Requirements are constrained to those problems, medications, and allergies that are needed to review to inform the immunization decision. General problem lists are available through Clinical Notes and Summary documents (e.g. iEHR).

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0457] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0458] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Active Problems Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, conforming to the requirements found in Section 6.1, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related problems exist.,.

[CDAH-0459] An **Immunization Summary Document MAY** contain at most one [0..1] **History of Past Illness Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related problems exist. Specifications.

[CDAH-0460] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Allergies and Other Adverse Reactions Section,** to identify allergies relative to immunization from the "KSA Vaccine Risk Factors – Allergies" value set, and **SHALL** include documentation of adverse events associated with vaccination events, conforming to the requirements found in Section 6.2, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related allergies exist.

[CDAH-0461] An **Immunization Summary Document MAY** contain at most one [0..1] **Pregnancy History Section** to indicate pregnancy status as an immunization risk factor.

[CDAH-0462] An **Immunization Summary Document MAY** contain at most one [0..1] **Coded Results Section** to identify serology relative to immunization from the "KSA Serology Results" value set, conforming to the requirements found in Section 6.12.

[CDAH-0463] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunization Recommendations Section** which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood..

[CDAH-1120] **Immunization Recommendation** entries in the **Immunization Recommendations Section SHALL** set the `moodCode` attribute to 'PRP'.

[CDAH-0464] An Immunization Summary document **SHALL** contain exactly one [1..1] Medications Section to identify medications relative to immunization from the "KSA Vaccine Risk Factors – Medications" value set with the additional constraints specified in Section 6.3 **IF KNOWN** and **SHALL** use appropriate null flavors to indicate rationale if no immunization related medications exist.

[CDAH-0465] An Immunization Summary document **SHALL** contain exactly one [1..1] List of Surgeries Section to identify surgeries relative to immunization from the "KSA Vaccine Risk Factors – Procedures" value set **IF KNOWN**.

[CDAH-0466] An Immunization Summary document **SHALL** reflect gestational age at birth for individuals that were born prematurely, using the Simple Observation entry in the

Active Problems up to age 3 years, and in the History of Past Illness up to the age of 18 years, using SNOMED CT 268477000 (fetal gestation) to identify the observation.

[CDAH-0467] An Immunization Summary document **MAY** contain exactly one [0..1] Comments Section.

[CDAH-0468] An Immunization Summary document **SHOULD** contain exactly one [0..1] Coded Social History Section to indicate vaccination indications, including employment, travel, and other social risk factors that are vaccine indications.

5.2 IMMUNIZATION CARD DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Immunization Card documents as defined in this Supporting Interoperability Specification.

[CDAH-0500] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Card documents.

5.2.1 HL7 CDA Header Attributes Being Constrained for Immunization Card Documents

[CDAH-0501] An Immunization Card Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Card document SHALL also support the additional Clinical CDA Header attributes and constraints in * MERGEFORMAT Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

.Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below
Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication/languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0502] The `Clinical Document//code` **SHALL** contain 11369-6 History of Immunizations.

[CDAH-0503] The `Clinical Document//languageCommunication` **SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the “Language” value set.

[CDAH-0504] The `Clinical Document//participant/associatedEntity/scopingOrganization` **MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0505] The `Clinical Document//patient/guardian` **SHALL** contain one [0..1] guardian if one exists.

5.2.2 Additional Content Modules and Constraints for Immunization Card Documents

This section describes the additional specific constraints for Immunization Card documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0506] An Immunization Card Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.10-2 Content Modules for Immunization Card Documents.

TABLE 5.10-2 CONTENT MODULES FOR IMMUNIZATION CARD DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.23']	6.10
Immunization Recommendations	The Immunization Recommendations Section documents the schedule of vaccinations that are intended or proposed for the patient.	1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0507] An **Immunization Card Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0508] An **Immunizations Section SHALL** provide human readable narrative both in Arabic and English for patient consumption.

[CDAH-0509] An Immunization Summary document **SHALL** exactly one [1..1] Immunization Recommendations Section, which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood.

[CDAH-0510] An Immunization Card document **MAY** contain exactly one [0..1] Comments Section.HL7 CDA Constraints for clinical scanned documents

5.3 HL7 CDA CONSTRAINTS FOR CLINICAL SCANNED DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for clinical scanned documents (PDF or plaintext documents) as defined in this Supporting Interoperability Specification.

[CDAH-0550] Constraints in the IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option **SHALL** apply to all clinical scanned clinical documents.

5.3.1 HL7 CDA header attributes being constrained for Clinical Scanned Documents

No additional HL7 CDA header constraints are defined beyond those specified in IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document (XDS-SD) Profile and Section 4 of this specification.

5.3.2 Additional Content Modules and Constraints For Clinical Scanned Documents

This section describes the additional specific constraints for scanned clinical documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

[CDAH-0551] A Content Creator Actor creating the document body of a scanned clinical document **SHALL** support the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

5.4 HL7 CDA CONSTRAINTS FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral Request documents and Transfer Request documents as defined in this Supporting Interoperability Specification. The Referral Request document is used to request a referral. The Transfer Request document is used to request a Transfer. Within this section, constraints specific to the Referral Request or Transfer Request will specify the type of Request Document that the constraint applies to. Constraints that apply to both types of document will just refer to them as Request documents.

[CDAH-0960] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to Request documents.

5.4.1 HL7 CDA Header Attributes Being Constrained for Request Documents

[CDAH-0961] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Request document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.12-1 Additional

constrained HL7 CDA Header Attributes for Referral Request and Transfer Request document.

TABLE 5.12-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		/ClinicalDocument/	
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	./patient/participant[@typeCode='IND']/associatedEntity [@classCode='NOK']	See Below
Requesting Healthcare Provider	The healthcare provider requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity	See Below
Requesting Healthcare Organization	The healthcare organization requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1101] The **Title** for the Referral Request Document **SHALL** be set to "Referral Request".

[CDAH-1102] The **Title** for the Transfer Request Document **SHALL** be set to "Transfer Request"

[CDAH-0962] The **Code** for the Referral Request Document **SHALL** be set to '57133-1' Referral Note from LOINC.

[CDAH-0963] The **Code** for the Transfer Request Document **SHALL** be set to '18761-7' Transfer Summary Note from LOINC.

[CDAH-0964] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-0965] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-0966] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-0967] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-0968] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-0969] The **Next of Kin** should specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-0970] The **Next of Kin Relationship SHALL** come from the "***KSA Personal Relationship Role"*** Value Set.

[CDAH-0971] If the referral or transfer is for a new born baby there **SHALL** be a Next of Kin using code/@code='MTH' from the "***HL7 Personal Relationship Role Type"*** Value Set (2.16.840.1.113883.1.11.19563) to describe the mother if she is alive and known.

[CDAH-0972] The **Next of Kin** for the mother as described above **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID

[CDAH-0973] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Provider.**

[CDAH-0974] The **Requesting Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-0975] The **Requesting Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-0976] The **Requesting Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-0977] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Organization.**

[CDAH-0978] The **Requesting Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

5.4.2 Additional Content Modules and Constraints for Request Documents

This section describes the additional specific constraints for Request documents. The IHE constraints on the content modules found below are specified in IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0979] A Clinical Summary Content Creator Actor creating a Saudi eHealth Request document **SHALL** also support the additional content module attributes and constraints in Table 5.12-2 Additional Content Modules for Referral Request and Transfer Request document.

TABLE 5.12-2 ADDITIONAL CONTENT MODULES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENT

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Coded Reason for Referral	Contains a narrative and coded description of the reason that the patient is being referred or transferred.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.2']	See Below
Care Plan Section	Contains information about the requested services.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Request document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0980] The **Request document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-0981] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-0982] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set.

[CDAH-0983] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-0984] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-0985] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-0986] The **Request document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and **SHALL NOT** be empty.

[CDAH-0987] The **Request document SHALL** contain exactly one [1..1] **KSA Care Plan Section IF KNOWN**.

[CDAH-0988] The **Care Plan Section SHALL** contain [0..*] zero or more **Plan of Care Activity** entries conforming to the **HL7 Plan of Care Activity** template (2.16.840.1.113883.10.20.1.25) representing the desired services being requested in order by importance.

[CDAH-0990] The code/@code attribute of a **Plan of Care Activity** entry **SHALL** be present to indicate the service requested.

[CDAH-0991] The code/@code attribute of a **Plan of Care Activity** entry may be populated from the "***KSA Radiology Procedure"*** value set.

[CDAH-0992] The priorityCode/@code attribute of the **Plan of Care Activity SHALL** be populated from the "***KSA Referral and Transfer Priority"*** value set.

[CDAH-0993] The specialty of the performer of the requested service may be specified in performer/assignedEntity/code/@code attribute of the **Plan of Care Activity** entry.

[CDAH-0994] The specialty of the performer **SHALL** contain a value from the "***KSA Individual Provider Specialty"*** value set.

[CDAH-0995] The Receiving Organization **MAY** be specified in performer/assignedEntity/representedOrganization.

[CDAH-0996] The **Request document SHALL** contain exactly one [1..1] **Transport Section** IF KNOWN.

[CDAH-0997] The required **Transport Entry** in the **Transport Section SHALL** specify the **Intended Mode of Transport** in the Act/code/@code attribute.

[CDAH-0998] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-0999] The **effectiveTime MAY** be set to null flavor "UNK".

5.5 HL7 CDA CONSTRAINTS FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral/Transfer Response documents as defined in this Supporting Interoperability Specification.

[CDAH-1000] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to all clinical Referral/Transfer Response documents.

5.5.1 HL7 CDA Header Attributes Being Constrained for Response Documents

[CDAH-1001] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.13-1 Additional constrained HL7 CDA Header Attributes for Referral Response and Transfer Response document.

TABLE 5.13-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	`./patient/participant[@typeCode='IND']/associatedEntity[@classCode='NOK'`	See Below
Receiving Healthcare Provider	The healthcare provider receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity`	See Below
Receiving Healthcare Organization	The healthcare organization receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1103] The **Title** for the Response Document **SHALL** be set to "Referral/Transfer Response Document"

[CDAH-1104] The **Code** for the Response Document **SHALL** be set to 'ReferralTransferResponseDocument' from the "KSA Referral and Transfer Document Type" Value Set.

[CDAH-1002] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-1003] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-1004] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-1005] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-1006] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-1007] The **Next of Kin SHOULD** specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-1008] The **Next of Kin Relationship SHALL** come from the "***KSA Personal RelationshipRole"*** Value Set.

[CDAH-1009] If the referral or transfer is for a new born baby, there **SHALL** be a **Next of Kin** using code/@code='MTH' from the "***KSA Personal Relationship Role"*** Value Set to describe the mother, if she is alive and known.

[CDAH-0x59] The **Next of Kin** for the mother **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID.

[CDAH-1010] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Provider.**

[CDAH-1011] The **Receiving Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-1012] The **Receiving Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1013] The **Receiving Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1014] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Organization.**

[CDAH-1015] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1016] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

5.5.2 Additional Content Modules and Constraints for Response Documents

This section describes the additional specific constraints for Referral/Transfer Response documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-1017] A Clinical Summary Content Creator Actor creating a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional content module attributes and constraints in Table 5.13-2 Additional Content Modules for Referral Response and Transfer Response document.

TABLE 5.13-2 ADDITIONAL CONTENT MODULES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Care Plan Section	Contains information about the requested services or the reason for aborting the transfer or referral.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Response document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1018] The **Response Document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-1019] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-1020] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set .

[CDAH-1021] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-1022] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-1023] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-1024] The **Response document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and SHALL NOT be empty.

[CDAH-1025] The **Response document SHALL** contain exactly one [1..1] **KSA Care Plan Section**.

[CDAH-1026] The **Response document SHALL** contain exactly one [1..1] **Transport Section IF KNOWN.**

[CDAH-1027] The **Transport SHALL** specify the **Intended Mode of Transport** in the code/@code attribute.

[CDAH-1028] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-1029] The **effectiveTime MAY** be set to null flavor "UNK".

CDA Section Attributes and Constraints, and 7 CDA Entry Attributes and Constraints and apply to all Saudi eHealth clinical documents. It is assumed that the implementer of products that create Saudi eHealth clinical documents will take into account all of the constraints in this specification and the other referenced specifications.

The HL7 CDA R2 Document specifications provided in this Specification are not Implementation Guides, but rather document constraint specifications for the Saudi eHealth Standards-Based Interoperability Project.

5.6 HL7 CDA CONSTRAINTS FOR OUTPATIENT ENCOUNTER SUMMARY DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for clinical Outpatient Encounter Summary documents as defined in this Supporting Interoperability Specification.

[CDAH-0110] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.2 (XDS-MS) **SHALL** apply to all clinical Outpatient Encounter Summary documents.

5.6.1 HL7 CDA Header Attributes Being Constrained for Clinical Outpatient Encounter Summaries

[CDAH-0111] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth clinical Outpatient Encounter Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.6-1 Additional constrained HL7 CDA Header Attributes for Clinical Outpatient Encounter Summaries.

TABLE 5.6-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR CLINICAL OUTPATIENT ENCOUNTER SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Encounter Start Date	The start date/time of the patient encounter.	`encompassingEncounter/effectiveTime/low`	See Below
Encounter End Date	The end date/time of the patient encounter.	`encompassingEncounter/effectiveTime/high`	See Below
Patient Administrative Identifiers	Patient Demographic Information.	`patientRole/id`	
Performers	Represents the person(s) providing the care.	`documentOf/Service/performer`	

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0112] A **Clinical Document SHALL** contain one [1..1] **Encounter Start Date**.

[CDAH-0113] A **Clinical Document SHALL** contain one [1..1] **Encounter End Date**.

[CDAH-0114] A **Clinical Document SHALL** contain one [1..1] **Patient Administrative Identifiers**.

[CDAH-0115] The **Clinical Document SHALL** contain zero or one [0..1] **Performers**.

5.6.2 Additional Content Modules and Constraints for Outpatient Encounter Summary Documents

This section describes the additional specific constraints for Outpatient Encounter Summary documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0096] A Clinical Summary Content Creator Actor creating a Saudi eHealth Outpatient Encounter Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.6-2 Additional Content Modules for Outpatient Encounter Summary Documents

TABLE 5.6-2 ADDITIONAL CONTENT MODULES FOR OUTPATIENT ENCOUNTER SUMMARY DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Chief Complaint Section (Chief Complaint)	The Chief Complaint is free text subjective statement made by a patient describing the most significant or serious symptoms or signs of illness or dysfunction that caused him or her to seek healthcare.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1']/`	See Below

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Active Problems Section (Problem List)	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems. (Note 1)	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.6']/	6.1
Medications Section (Medications)	The current medications and pertinent medication history at the end of the encounter.	//section[templateId/@root= , 1.3.6.1.4.1.19376.1.5.3.1.3.19']/	6.3
History of Present Illness Section (History of Present Illness)	The History of Present Illness describes the history related to the reason for the encounter. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.4']/	See Below
List of Surgeries and Coded List of Surgeries Sections (History of Procedures)	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	List of Surgeries //section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Allergies and Adverse Reactions Section (Allergies)	Allergies list and describe any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of healthcare delivery. Allergies to drugs are to be coded.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.13']/	6.2
Physical Examination Section (Physical Examination)	The Physical Exam includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.24']/	See Below
Immunizations Section (Immunizations)	The Immunization contains a list of the vaccinations administered to the patient during the encounter.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.23']/	6.10
Coded Vital Signs Sections (Vital Signs)	The Vital Signs include a group of data elements containing relevant vital signs such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pain assessment and pulse oximetry.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']/	6.9
Visible Implanted Medical Devices Section (Devices)	Devices include a description of the medical devices apparent on physical exam that have been inserted into the patient, whether internal or partially external.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.9.48']/	See Below

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Surgical Drains Section (Drains)	The Drains describe any drains implanted during a procedure.	//section[templateId/@root= '2.16.840.1.113883.10.20.7.13']/	6.11
Care Plan Section (Recommendation /Plan of Care)	The Plan of Care data elements define any pending orders, interventions, encounters, services and procedures for the patient after the completion of the Outpatient encounter. The Plan of Care may also include other information such as patient education, nutritional diet, follow-up orders, etc.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31 ']/	See Below
Coded Results Section (Blood Group) Blood Type Section	The results section shall contain the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules. Note 2	Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28	6.12
Reason for Referral Section. (Diagnosis)	The Diagnosis contains information on the primary reason for the encounter.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.1']/	6.8
Assessment and Plan Section (Outpatient Course)	The assessment and plan is a description of the assessment of the patient condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5']/	See Below

Note 1: The Clinical Notes and Summaries Information Requirements specified that the Problem List includes both active and recently resolved problems. The IHE definition of the Problem List contains only the Active Problems. Recently resolved problems are found in the History of Present Illnesses.

Note 2: A patient's blood group is determined through laboratory testing. The reporting of the blood group is part of a Laboratory Results Report.

The list below provides the Saudi eHealth specific constraints on the content modules associated with an Outpatient Encounter Summary document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0116] An **Outpatient Summary document SHALL** contain exactly one [1..1] **Chief Complaint Section** and **SHALL NOT** be empty.

[CDAH-0117] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Active Problems Section** with the additional constraints specified in Section 7.3 **IF KNOWN**.

[CDAH-0118] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Medications Section** with the additional constraints specified in Section 6.3 **IF KNOWN**.

[CDAH-0119] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **History of Present Illness Section IF KNOWN.**

[CDAH-0120] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **List of Surgeries Section IF KNOWN**.

[CDAH-0121] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Allergies and Adverse Reactions Section** with the additional constraints specified in Section 6.2**.**

[CDAH-0122] An **Outpatient Encounter Summary document SHALL** contain a **Physical Examination Section IF KNOWN.**

[CDAH-0123] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Immunization Section** with the additional constraints specified in Section 6.10 **IF KNOWN**.

[CDAH-0124] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Coded Vital Signs Section** with the additional constraints specified in Section 6.9 **IF KNOWN**.

[CDAH-0125] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Visible Implanted Medical Devices Section IF KNOWN**.

[CDAH-0126] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Surgical Drains Section** with the additional constraints specified in Section 6.11 **IF KNOWN**.

[CDAH-0127] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Care Plan Section.**

[CDAH-0128] An **Outpatient Encounter Summary document MAY** contain zero or one [0..1] **Coded Results Section** with the additional constraints specified in Section 6.12.

[CDAH-0129] An **Outpatient Encounter Summary document SHALL** contain exactly one [1..1] **Reason for Referral Section** with the additional constraints specified in Sections 6.8.

[CDAH-0130] An **Outpatient Encounter Summary document MAY** contain an **Assessment and Plan Section**.

5.7 HL7 CDA CONSTRAINTS FOR DISCHARGE SUMMARY DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for clinical Discharge Summary documents as defined in this Supporting Interoperability Specification.

[CDAH-0150] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.4 (XDS-MS) with the Discharge Option **SHALL** apply to all clinical Discharge Summary documents.

[CDAH-0267] Constraints in the IHE Patient Care Coordination (PCC) CDA Content Modules Supplement **SHALL** apply to Maternal and Newborn Discharge Summaries.

5.7.1 HL7 CDA Header Attributes Being Constrained for Clinical Discharge Summaries

[CDAH-0151] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth clinical Discharge Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.7-1 Additional constrained HL7 CDA Header Attributes for Clinical Discharge Summaries.

TABLE 5.7-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR CLINICAL DISCHARGE SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Admission Date	The start date/time the patient was admitted to the Hospital.	`encompassingEncounter/effectiveTime/low`	See Below
Discharge Date	The end date/time the patient was discharged from the Hospital or the Outpatient encounter.	`encompassingEncounter/effectiveTime/high`	See Below
Performers	Represents the person(s) providing the care.	`documentOf/Service/Performers`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0152] A **Clinical Document SHALL** contain one [1..1] **Admission Date**.

[CDAH-0153] A **Clinical Document SHALL** contain one [1..1] **Discharge Date**.

If medical assistance is provided prior to entering the Emergency Department (e.g. Ambulance Delivery, Home Delivery, Roadside delivery) the people assisting the patient should be document.

[CDAH-0154]If assistance if provided prior to reaching the Emergency Department, the **Clinical Document SHALL** contain one or more [1..*] **Performer Information (**See Section 4.6).

5.7.2 Content Modules and Constraints for all clinical Discharge Summary Documents

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared clinical Discharge Summary documents including, Discharge Summary, Maternal Discharge Summary and Newborn Discharge Summary documents. These constraints are in addition to the Discharge Summary document specified by IHE-PCC TF-2 Section 6.3.1.4 Discharge Summary Specification.

[CDAH-0155] A Clinical Summary Content Creator Actor creating a Saudi eHealth Clinical Discharge Summary document SHALL also support the additional content module attributes and constraints in Table 5.7-2 Content Modules for All Clinical Discharge Summary Documents

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TABLE 5.7-2 CONTENT MODULES FOR ALL CLINICAL DISCHARGE SUMMARY DOCUMENTS

CONTENT MODULES (Use Case Concept)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Chief Complaint Section (Chief Complaint)	The Chief Complaint is free text subjective statement made by a patient describing the most significant or serious symptoms or signs of illness or dysfunction that caused him or her to seek healthcare.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1']/	See Below
Active Problems Section (Problem List)	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems. (Note 1)	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']/	6.1
Admission History Medications Section (Pre-Admission Medications)	The admission medication history section contains the relevant medications administered to a patient prior to admission to a facility.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.20']/	6.4
History of Present Illness Section (History of Present Illness)	The History of Present Illness describes the history related to the reason for the encounter. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/	N/A
List of Surgeries and Coded List of Surgeries Sections (History of Procedures)	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Allergies and Adverse Reactions Section (Allergies)	Allergies list and describe any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of healthcare delivery.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']/	6.2
Hospital Admission Diagnosis Section (Pre-Admission Diagnosis)	The Admitting Diagnosis contains a narrative description of the primary reason for the encounter.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.3 ']/	6.8

CONTENT MODULES (Use Case Concept)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Physical Examination Section (Physical Examination)	The Physical Exam includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.24']/	N/A
Immunizations Section (Immunizations)	The Immunization contains a list of the vaccinations administered to the patient during the encounter.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.23']/	6.10
Coded Vital Signs Sections (Vital Signs)	The Vital Signs include a group of data elements containing relevant vital signs such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pain assessment and pulse oximetry	Coded Vital Signs //section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']/	6.9
Visible Implanted Medical Devices Section (Devices)	Devices include a description of the medical devices apparent on physical exam that have been inserted into the patient, whether internal or partially external.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.9.48']/	See Below
Surgical Drains Section (Drains)	The Drains describe any drains implanted during a procedure.	//section[templateId/@root= '2.16.840.1.113883.10.20.7.13']/	6.11
Medications Administered Section (In-Hospital Medications)	The In-Hospital Medications contain the relevant medications administered to the patient during the hospital stay.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.21'']/	6.5
Hospital Discharge Medications Section (Discharge Medications)	The Discharge Medications contain the patient's current medications and pertinent medication history at the end of the hospital stay.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.22']/	6.6
Care Plan Section (Recommendation /Plan of Care)	The Plan of Care data elements define any pending orders, interventions, encounters, services and procedures for the patient after the completion of the Outpatient encounter. The Plan of Care may also include other information such as patient education, nutritional diet, follow-up orders, etc.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31 ']/	N/A

CONTENT MODULES (Use Case Concept)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Coded Results Section (Blood Group)	The results section shall contain the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules. (Note 2)	`Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28`	6.12
Discharge Diagnosis Section (Discharge Condition)	The Diagnosis contains information on the primary reason for the encounter.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.7']/`	6.8
Hospital Course Section (Hospital Course)	The Hospital Course describes the sequence of events during the course of the hospital stay.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.5']/`	N/A
Discharge Disposition Section (Discharge Destination)	The Discharge Disposition contains the place the patient is going or being sent upon discharge from the hospital.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.32']/`	6.17

Note 1: The Clinical Notes and Summaries Information Requirements specified that the Problem List includes both active and recently resolved problems. The IHE definition of the Problem List contains only the Active Problems. Recently resolved problems are found in the History of Preset Illnesses.

Note 2: A patient's blood group is determined through laboratory testing. The reporting of the blood group is part of a Laboratory Results Report.

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0156] A **Discharge Summary document SHALL** contain exactly one [1..1] **Chief Complaint Section** and **SHALL NOT** be empty.

[CDAH-0157] A **Discharge Summary document Active Problems Sections SHALL** conform to the additional constraints specified in Section 6.1.

[CDAH-0158] A **Discharge Summary document Admission History Medication Sections SHALL** conform to the additional constraints specified in Section 6.3.

[CDAH-0159] A **Discharge Summary document SHALL** contain exactly one [1..1] **List of Surgeries Section IF KNOWN**.

[CDAH-0160] A **Discharge Summary document Allergies and Adverse Reaction Sections SHALL** conform to the additional constraints specified in Section 6.2.

[CDAH-0265] A **Discharge Summary document SHALL** contain a **Physical Examination Section IF KNOWN.**

[CDAH-0161] A **Discharge Summary document Hospital Admission Diagnosis Sections SHALL** conform to the additional constraints specified in Section 6.8.

[CDAH-0162] A **Discharge Summary document MAY** contain exactly one [1..1] **Visible Implanted Medical Devices Section IF KNOWN**.

[CDAH-0163] A **Discharge Summary document SHALL** contain exactly one [1..1] **Immunization Section** with the additional constraints specified in Section 6.10 **IF KNOWN**.

[CDAH-0164] A **Discharge Summary document Coded Vital Signs Sections SHALL** conform to the additional constraints specified in Section 6.9.

[CDAH-0165] A **Discharge Summary document SHALL** contain exactly one [1..1] **Surgical Drains Section** with the additional constraints specified in Section 6.11 **IF KNOWN**.

[CDAH-0166] A **Discharge Summary document Medication Administered Sections SHALL** conform to the additional constraints specified in Section 6.3.

[CDAH-0167] A **Discharge Summary document Hospital Discharge Medication Sections SHALL** conform to the additional constraints specified in Section 6.3.

[CDAH-0168] A **Discharge Summary document SHALL** contain exactly one [1..1] **Coded Results Section** with the additional constraints specified in Section 6.12 **IF KNOWN**.

[CDAH-0266] A **Discharge Summary document SHALL** contain exactly one [1..1] **Care Plan Section.**

[CDAH-0169] A **Discharge Summary document Discharge Diagnosis Sections SHALL** conform to the additional constraints specified in Section 6.8.

[CDAH-0170] A **Discharge Summary document SHALL** contain exactly one [1..1] **Discharge Disposition Section** with the additional constraints specified in Section 6.17.

5.7.2.1 Additional Content Modules and Constraints for the Maternal Discharge Summary Documents

The Maternal Discharge Summary is a specialized version of the Discharge Summary and contains all of the Discharge content modules plus the list of content modules in

[CDAH-0171] Constraints in IHE Patient Care Coordination (PCC) Technical Framework Supplement Maternal Discharge Summary Content Profile (MDS) **SHALL** apply to all Maternal Discharge Summary documents.

[CDAH-0172] A Clinical Summary Content Creator Actor creating a Saudi eHealth Maternal Discharge Summary document SHALL also support the additional content module attributes and constraints in Table 5.7-2 Content Modules for All Clinical Discharge Summary Documents

and **Error! Reference source not found.**Table 5.7-3 Additional Content Modules for Maternal Discharge summaries

CONTENT MODULE	CONTENT MODULE DEFINITION	CDA LOCATION	SECTION REF.
Pregnancy History Section (Maternal History)	The Pregnancy History contains information gathered about a woman's prior pregnancies, how the baby was born and any problems related to the pregnancy.	`//section[templateId/@root=` `'1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4']/`	N/A

CONTENT MODULE	CONTENT MODULE DEFINITION	CDA LOCATION	SECTION REF.
Labor and Delivery Events: Procedures and Interventions Section (Mode of Delivery and , Delivery Outcomes)	Labor and Delivery Events shall include information about the delivery type (e.g. vaginal, vaginal birth after cesarean section), whether an episiotomy was done, and if a treatment for RH Factor was needed. In the case of non-hospital delivery outcome information on how the cord was handled and if the environment was sterile.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']/	6.13
Delivery Event Outcome Section (Delivery Outcome)	The Delivery Outcome Event describes the end result of the delivery. Delivery Outcome must include the birth status, post-partum complications.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.21.2.9']/	6.14
Newborn Status at Maternal Discharge Section (Baby's Discharge Condition)	Observations of problems or other clinical statements captured about the baby at the completion of the encounter which represent the ongoing process tracked over time.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.21.2.8']/	**Error! Reference source not found.**

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0173] A **Maternal Discharge Summary Labor and Delivery Events – Procedures and Intervention Section SHALL** conform to the additional constraints specified in Sections 6.13.

[CDAH-0174] A **Maternal Discharge Summary Delivery Outcome Section SHALL** conform to the additional constraints specified in Sections 6.14.

CDAH-175] A **Maternal Discharge Summary Newborn Status Maternal Discharge Section SHALL** conform to the additional constraints specified in Section **Error! Reference source not found.**.

5.7.2.2 Additional Content Modules and Constraints for the Newborn Discharge Summary Documents

The Newborn Discharge Summary is a specialized version of the Discharge Summary and contains all of the Discharge content modules plus the list of content modules in

[CDAH-0176] Constraints in IHE Patient Care Coordination (PCC) Technical Framework Supplement Newborn Discharge Summary Content Profile (NDS) **SHALL** apply to all Newborn Discharge Summary documents.

[CDAH-0177] A Clinical Summary Content Creator Actor creating a Saudi eHealth Maternal Discharge Summary document SHALL also support the additional content module attributes and constraints in Table 5.7-2 Content Modules for All Clinical Discharge Summary Documents

and Table 5.7-3 Additional Content Modules for Maternal Discharge summaries

TABLE 5.7-4 ADDITIONAL CONTENT MODULES FOR NEWBORN DISCHARGE SUMMARIES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Pregnancy History Section (Maternal History)	The Pregnancy History contains information gathered about a woman's prior pregnancies, how the baby was born and any problems related to the pregnancy.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4']/	N/A
Coded Results Section (Newborn Screening)	The Newborn Screening contains the status of the performed on newborns to screen for serious treatable diseases most of which are genetic.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']/	6.12
Labor and Delivery Events: Procedures and Interventions Section (Mode of Delivery and , Delivery Outcomes)	Labor and Delivery Events shall include information about the delivery type (e.g., vaginal, vaginal birth after cesarean section), whether an episiotomy was done, and if a treatment for RH Factor was needed. In the case of non-hospital delivery outcome information on how the cord was handled and if the environment was sterile.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']/	6.13
Delivery Event Outcome (Delivery Outcome)	The Delivery Outcome Event describes the end result of the delivery. Delivery Outcome must include the birth status, post-partum complications.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.21.2.9']/	6.14
Newborn Delivery Information Section (Newborn data: Apgar, Gestational Age)	This section should contain information about: gestational age, size, birth order, Apgar scores, height, weight and cephalic circumference, and resuscitation measures.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.21.2.4']/	6.15

[CDAH-0178] A **Newborn Discharge Summary Coded Results Section SHALL** conform to the additional constraints specified in Section 6.12.

[CDAH-0179] A **Newborn Discharge Summary Labor and Delivery Events – Procedures and Intervention Section SHALL** conform to the additional constraints specified in Sections 6.13.

[CDAH-0180] A **Newborn Discharge Summary Delivery Outcome Section SHALL** conform to the additional constraints specified in Section 6.14.

[CDAH-0181] A **Newborn Discharge Summary Newborn Delivery Information Section SHALL** conform to the additional constraints specified in Section 6.15.

5.8 HL7 CDA CONSTRAINTS FOR CLINICAL NOTE DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for a Clinical Note document as defined in this Supporting Interoperability Specification.

The HL7 CDA R2 Operative Note Draft Standard for Trial Use (DSTU) describes sections that may be used in a clinical note, and these are used to augment this specification. That DSTU describes a clinical document conforming to US realm specifications, rather than Saudi realm

requirements with respect to vocabulary. Therefore, the Clinical Note document uses that DSTU as guidance, but cannot conform to it for a Clinical Note as used in Saudi.

[CDAH-0200] Where sections in Clinical Note documents have the same purpose, they **SHALL** comply with constraints in the HL7 CDA R2 IHE Health Story Consolidation Operative Note DSTU.

5.8.1 HL7 CDA Header Attributes Being Constrained for Clinical Note documents

[CDAH-0201] A Clinical Note Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth clinical Note document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.8-1 Additional constrained HL7 CDA Header Attributes for Clinical Note documents.

TABLE 5.8-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR CLINICAL NOTE DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Operative Time In	The Operative time in is the time the patient is brought into the Operating Room.	`encompassingEncounter/effectiveTime/low`	See Below
Operative Time Out	The Operative time out .is the time the patient is taken to recovery.	`encompassingEncounter/effectiveTime/high`	See Below
Performer (Operative Personnel)	The Operative Personnel contains the names of the personnel performing the procedures or treatments.	`./documentationOf/serviceEvent/performer`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0202] A **Clinical Document SHALL** contain one [1..1] **Operative Time In**.

[CDAH-0203] A **Clinical Document SHALL** contain one [1..1] **Operative Time Out**.

[CDAH-0204] The **Performer SHALL** contain one or more [1..*] **Performer Information** and **SHALL NOT** be null flavor.

5.8.2 Content Modules and Constraints for Clinical Notes documents

[CDAH-0205] A Clinical Note Content Creator Actor creating a Saudi eHealth Clinical Note document SHALL also support the additional content module attributes and constraints in Table 5.8-2 Content Modules for All Clinical Note documents

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TABLE 5.8-2 CONTENT MODULES FOR ALL CLINICAL NOTE DOCUMENTS

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Active Problems Section (Problem List)	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems. (Note 1)	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']/	6.1
Preoperative Diagnosis Section (Pre-Operative Condition)	The Preoperative Diagnosis section records the surgical diagnosis or diagnoses assigned to the patient before a surgical procedure and is the reason for the surgery. The preoperative diagnosis is, in the opinion of the surgeon, the diagnosis that will be confirmed during surgery.	//section[templateId/@root='2.16.840.1.113883.10.20.22.2.34 ']/	6.8
Postprocedure Diagnosis Section (Post-Operative Diagnosis)	The Post-Operative Diagnosis records the diagnosis or diagnoses confirmed during the procedure.	//section[templateId/@root='2.16.840.1.113883.10.20.22.2.36 ']/	6.4
Visible Implanted Medical Devices Section (Devices)	Devices include a description of the medical devices apparent on physical exam that have been inserted into the patient, whether internal or partially external.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.48']/	6.18
Surgical Drains Section (Drains)	The Drains describe any drains implanted during a procedure.	//section[templateId/@root='2.16.840.1.113883.10.20.7.13']/	6.11
Plan of Care Section (Post-Operative Instructions, Post-Operative Orders)	The Plan of Care section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders.	//section[templateId/@root='2.16.840.1.113883.10.20.22.2.10 ']/	See Below
Postoperative Diagnosis Section (Post-Operative Condition)	Observations of problems or other clinical statements captured at the completion of the procedure or treatment, which represent the ongoing process tracked over time. Often it is the same as the preoperative diagnosis.	//section[templateId/@root='2.16.840.1.113883.10.20.22.2.35']/	6.8
Acuity Assessment Section (Acuity)	The Acuity Assessment contains a description of the acuity (keenness of vision, thought, etc.) of the patient upon presentation to the encounter.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.2']/	6.16

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Planned Procedure Section (Planned Procedure)	The Planned Procedures for this encounter include interventional, surgical, diagnostic, or therapeutic procedures or treatments.	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.30']/`	6.20
Planned Procedure Section (Type of Procedure)	Indicator on the priority of the Procedure. (i.e., Emergency (immediate), Urgent (short term) or Elective (scheduled based on availability)).	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.30']/priorityCode`	6.20
Operative Note Surgical Procedure Section (Procedures Performed)	The Procedures performed for this encounter include interventional, surgical, diagnostic, or therapeutic procedures or treatments.	`//section[templateId/@root='2.16.840.1.113883.10.20.7.14']/`	See Below
Anesthesia Section (Anesthesia Type)	The Anesthesia Type records the type of anesthesia used (e.g., Local or general).	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.25']/`	N/A
Complications Section (Complications)	The Complications record information on any issues that arose during the procedure.	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.37']/`	N/A
Procedure Specimens Taken Section (Specimens)	Specimens describe any samples or pathology obtained for Laboratory testing during the surgery.	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.31']/`	N/A
(Estimated Blood Loss)	The Estimated Blood Loss describes the amount of blood loss during the procedure.	`//section[templateId/@root='2.16.840.1.113883.10.20.18.2.9']/`	N/A
Operative Note Fluids Section (Fluids)	The Fluids records information about the in-take or out-take of fluids during the procedure.	`//section[templateId/@root='2.16.840.1.113883.10.20.7.12']/`	See Below
Procedure Findings Section (Findings)	The Findings is a narrative description of ay observation made during the time of the procedure or treatment	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.28']/`	N/A
Procedure Description Section (Preparation) (Operative Course)	The Procedure Description section records the particulars of the procedure and may include procedure site preparation, surgical site preparation and other pertinent details. Local practices often identify the level and type of detail required based on the procedure or specialty.	`//section[templateId/@root='2.16.840.1.113883.10.20.22.2.27']/`	6.21

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Procedure Disposition Section (Post-Operative Condition)	The Procedure Disposition section records the status and condition of the patient at the completion of the procedure or surgery. It often also states where the patent was transferred to for the next level of care.	`//section[templateId/@root='2.16.840.1.113883.10.20.18.2.12']/`	N/A
History of Blood Transfusion Section (Transfusions)	The History of Blood Transfusion section shall contain a narrative description of the blood products the patient has received in the past, including any reactions to blood.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.12']/`	6.19

Note 1: The Clinical Notes and Summaries Information Requirements specified that the Problem List includes both active and recently resolved problems. The IHE definition of the Problem List contains only the Active Problems. Recently resolved problems are found in the History of Preset Illnesses.

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0206] A **Clinical Note document SHALL** contain exactly one [1..1] **Active Problems Sections** with the additional constraints specified in Sections 6.1.

[CDAH-0207] A **Clinical Note document Preoperative Diagnosis Section SHALL** conform to the additional constraints specified in Section 6.8 and 7.3.

[CDAH-0208] A **Clinical Note document MAY** contain zero or one [0..1] **Visible Implanted Medical Devices Section** with the additional constraints specified in Section 6.18.

[CDAH-0209] A **Clinical Note document SHALL** contain exactly one [1..1] **Surgical Drains Section IF KNOWN**.

[CDAH-0210] A **Clinical Note document SHALL** contain exactly one [1..1] **Plan of Care Section IF KNOWN**.

[CDAH-0211] A **Clinical Note document Postoperative Diagnosis Section SHALL** conform to the additional constraints specified in Sections 6.8.

[CDAH-0212] A **Clinical Note document SHALL** contain exactly one [1..1] **Acuity Assessment Section** with the constraints specified in Section 6.16

[CDAH-0213] A **Clinical Note document SHALL** contain exactly one [1..1] **Planned Procedure Section** with the constraints specified in Section 6.20.

[CDAH-0214] A **Clinical Note document SHALL** contain exactly one [1..1] **Operative Note Surgical Procedure Section**.

[CDAH-0215] A **Clinical Note document SHALL** contain exactly one [1..1] **Operative Note Fluids Section IF KNOWN**.

[CDAH-0216] A **Clinical Note document Procedure Description Section SHALL** conform to the additional constraints specified in Section.6.21.

[CDAH-0217] A **Clinical Note document SHALL** contain exactly one [1..1] **History of Transfusions Section IF KNOWN**.

5.9 HL7 CDA CONSTRAINTS FOR iEHR ON-DEMAND SUMMARY DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for iEHR On-Demand Summary Documents as defined in this Supporting Interoperability Specification.

[CDAH-0250] Constraints in IHE Patient Care Coordination (PCC) Volume 1 (PCCTF-1) Section 4 (XPHR) **SHALL** apply to all iEHR On-Demand summary documents.

5.9.1 HL7 CDA Header Attributes Being Constrained for iEHR On-Demand Summary documents

[CDAH-0251] An iEHR On-Demand Document Source Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth clinical iEHR On-Demand Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.9-1 Additional constrained HL7 CDA Header Attributes for iEHR On-Demand Summaries.

TABLE 5.9-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR iEHR ON-DEMAND SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Author Device	Specifies the Author of the document if it is a Device.	`./author/assignedAuthoringDevice`	See below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0252] The **Clinical Document Author Information SHALL** contain exactly one [1..1] **Author Device**.

5.9.2 Content Modules and Constraints for iEHR On-Demand Summary Documents

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared iEHR On-Demand Summary documents.

[CDAH-0253] An iEHR On-Demand Document Source Actor creating a Saudi eHealth Clinical Discharge iEHR On-Demand Summary document SHALL support the content module attributes and constraints in Table 5.9-2 Content Modules for iEHR On-Demand Document

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TABLE 5.9-2 CONTENT MODULES FOR IEHR ON-DEMAND DOCUMENT

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Active Problems Section (Problem List)	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems. (Note 1)	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']/	6.1
Medications List Section (Medications)	The current list of medications containing out-patient medication information (Dispensations, Prescriptions) as well as in-patient medication information (Administered Medication during a hospital stay).	//section[templateId/@root='1.3.6.1.4.1.19376.1.9.1.2.5']/	6.7
Immunizations Section (Immunizations)	The Immunization contains a list of the vaccinations administered to the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']/	6.10
List of Surgeries and Coded List of Surgeries Sections (History of Procedures)	The History of Procedures defines all the historically pertinent interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient.	List of Surgeries//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Allergies and Adverse Reactions Section (Allergies)	Allergies list and describe any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of healthcare delivery. Allergies to drugs are to be coded.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']/	6.2
Visible Implanted Medical Devices Section (Devices)	Devices include a description of the medical devices apparent on physical exam that have been inserted into the patient, whether internal or partially external.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.48']/	See Below
Coded Vital Signs Sections (Vital Signs)	The Vital Signs include a group of data elements containing relevant vital signs such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pain assessment and pulse oximetry.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']/	6.9
Care Plan Section (Recommendation /Plan of Care)	The Plan of Care data elements define any pending orders, interventions, encounters, services and procedures for the patient after the completion of the Outpatient encounter. The Plan of Care may also include other information such as patient education, nutritional diet, follow-up orders, etc.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.31 ']/	See Below

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Coded Results Section (Blood Group)	The results section shall contain the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules. (Note 2)	`Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28`	6.12
Assessment and Plan Section (Outpatient Course)	The assessment and plan is a description of the assessment of the patient condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5']/`	See Below
Social History Section	The social history is a description of the person's beliefs, home life, community life, work life, hobbies, and risky habits.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.16']/`	See Below
Family Medical History Section	The family history contains a description of the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.14']/`	See Below

Note 1: The Clinical Notes and Summaries Information Requirements specified that the Problem List includes both active and recently resolved problems. The IHE definition of the Problem List contains only the Active Problems. Recently resolved problems are found in the History of Present Illnesses.

Note 2 A patient's blood group is determined through laboratory testing. The reporting of the blood group is part of a Laboratory Results Report.

The list below provides the Saudi eHealth specific constraints on the content modules associated with an iEHR On-Demand Summary document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0254] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Active Problems Section** with the additional constraints specified in Section 6.1 **IF KNOWN**.

[CDAH-0255] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Medications List Section** with the additional constraints specified in Section 6.7 **IF KNOWN**.

[CDAH-0256] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **List of Surgeries Section IF KNOWN**.

[CDAH-0257] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Allergies and Adverse Reactions Section** with the additional constraints specified in Section 6.2.

[CDAH-0258] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Immunization Section** with the additional constraints specified in Section 6.10 **IF KNOWN**.

[CDAH-0259] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Coded Vital Signs Section** with the additional constraints specified in Section 6.9 **IF KNOWN**.

[CDAH-0260] An **iEHR On-Demand Summary document MAY** contain zero or one [0..1] **Visible Implanted Medical Devices Section**.

[CDAH-0261] The **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Assessment and Plan Section IF KNOWN.**

[CDAH-0262] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Coded Results Section** with the additional constraints specified in Section 6.12 **IF KNOWN**.

[CDAH-0263] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Social History Section IF KNOWN**.

[CDAH-0264] An **iEHR On-Demand Summary document SHALL** contain exactly one [1..1] **Family Medical History Section IF KNOWN**.

5.10 HL7 CDA CONSTRAINTS FOR PRESCRIPTION DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Prescription documents as defined in this Supporting Interoperability Specification.

[CDAH-0300] Constraints in IHE Pharmacy Technical Framework Supplement "Pharmacy Prescription" (PHARM-TF Supplement: PRE) Volume 3 Section 6.3.1.1 **SHALL** apply to all Prescription documents.

5.10.1 HL7 CDA Header Constraints

[CDAH-0301] The Patient Information: **Patient Martial Status SHALL NOT** be present.

[CDAH-0302] The Patient Information: **Patient Religion SHALL NOT** be present.

[CDAH-0303] The Author: **Author Functional Role SHALL** be present.

[CDAH-0304] The Author: **Author Specialty SHALL** be present.

[CDAH-0305] The Author: **Author Address SHALL** be present.

[CDAH-0306] The Author: **Author Telecom SHALL** be present.

[CDAH-0320] Exactly one `<documentationOf>` element **SHALL** be present containing exactly one `<serviceEvent>` element containing the following information:

[CDAH-0321] Prescription type: Exactly one <code> element **SHALL** be present and **SHALL** contain a code that comes from the "KSA Medication Prescription Type" value set. It **SHALL NOT** be null flavor.

[CDAH-0322] Validity date of the prescription: Exactly one <effectiveTime> element **SHALL** be present.

[CDAH-0323] The <effectiveTime> element **SHALL** contain a <low> sub-element which **SHALL** be populated with the start date and time of the validity of the prescription and **SHALL NOT** be null flavor.

[CDAH-0324] The <effectiveTime> element **SHALL** contain a <high> sub-element which **SHALL** be populated with the end date and time of the validity of the prescription and **SHALL NOT** be null flavor.

5.10.2 Content Modules and Constraints for Prescription Documents

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared Prescription documents. The Prescription document for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: PRE, Section 6.3.1.1 Pharmacy Prescription Specification.

Table 5.10-1 Content Modules for Prescription Documents contains a list of the content modules with specific Saudi eHealth constraints that pertain to all Prescription documents:

TABLE 5.10-1 CONTENT MODULES FOR PRESCRIPTION DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Authorization	Each <authorization> element in the CDA Header represents an informed consent.	Authorization `ClinicalDocument/authorization`	See Below
Patient Contacts	Persons acting as guardian to a patient as well as other participants related to the patient.	`//patient/guardian` `//participant[typeCode='IND']`	See Below
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7']/`	See Below
Coded Vital Signs	The weight section contains the weight of the patient. It is based on the Coded Vital Signs section.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']/`	6.22
Allergies and Other Adverse Reactions	The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']/`	See Below
Active Problems	The diagnosis section contains diagnosis relevant for the prescription given below. It is based on the Active Problems section.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']/`	See Below
History of Past Illness	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.8']/`	See Below
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']/`	See Below
Pregnancy History	The pregnancy history section contains coded entries describing a current pregnancy of the patient.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/`	See Below
Prescription Section	The Prescription Section contains a description of the medications in a given prescription for the patient. It includes entries for each Prescription Item.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.9.1.2.1']/`	6.23

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0307] The **Authorization Section SHALL NOT** be present.

[CDAH-0308] The **Patient Contacts Section SHALL NOT** be present.

[CDAH-0309] The **Payers Section SHALL NOT** be present.

[CDAH-0310] A **Prescription Document MAY** contain exactly one [1..1] **Coded Vital Signs Section** with the additional constraints specified in Section6.22.

[CDAH-0311] The **Allergies and Other Adverse Reactions Section SHALL NOT** be present.

[CDAH-0312] A **Prescription Document MAY** contain exactly one [1..1] **Active Problems Section** with the additional constraints specified in Section 6.8.

[CDAH-0313] If at least one of the Prescription Items of the prescription contains a **Reason**, the **Prescription Document SHALL** contain exactly one [1..1] **Active Problems Section** with the additional constraints specified in Section 6.8.

[CDAH-0314] The **History of Past Illness Section SHALL NOT** be present.

[CDAH-0315] The **Immunizations Section SHALL NOT** be present.

[CDAH-0316] The **Pregnancy History** Section **SHALL NOT** be present.

[CDAH-0317] A **Prescription Document SHALL** contain exactly one [1..1] **Prescription Section** with the additional constraints specified in Section 6.23.

5.11 HL7 CDA CONSTRAINTS FOR DISPENSATION DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Dispensation documents as defined in this Supporting Interoperability Specification.

[CDAH-0350] Constraints in IHE Pharmacy Technical Framework Supplement "Pharmacy Dispensation" (PHARM-TF Supplement: DIS) Volume 3 Section 6.3.1.3 **SHALL** apply to all Dispensation documents.

5.11.1 HL7 CDA Header Constraints

[CDAH-0351] The Patient Information: **Patient Martial Status SHALL NOT** be present.

[CDAH-0352] The Patient Information: **Patient Religion SHALL NOT** be present.

[CDAH-0353] The Author: **Author Functional Role SHALL** be present.

[CDAH-0354] The Author: **Author Specialty SHALL** be present.

[CDAH-0355] The Author: **Author Address SHALL** be present.

[CDAH-0356] The Author: **Author Telecom SHALL** be present.

5.11.2 Content Modules and Constraints for Dispensation Documents

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared Dispensation documents. The Dispensation document for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: DIS, Section 6.3.1.3 Pharmacy Dispense Specification.

Table 5.11.2-1 Content Modules for Dispensation Documents contains a list of the content modules with specific Saudi eHealth constraints that pertain to all Dispensation documents:

TABLE 5.11.2-1 CONTENT MODULES FOR DISPENSATION DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Authorization	Each `<authorization>` element in the CDA Header represents an informed consent.	`ClinicalDocument/authorization`	See Below
Patient Contacts	Persons acting as guardian to a patient as well as other participants related to the patient.	`//patient/guardian` `//participant[typeCode='IND']`	See Below
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7']/`	See Below
Coded Vital Signs	The weight section contains the weight of the patient. It is based on the Coded Vital Signs section.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']/`	6.22
Allergies and Other Adverse Reactions	The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']/`	See Below
Active Problems	The diagnosis section contains diagnosis relevant for the prescription given below. It is based on the Active Problems section.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']/`	See Below
History of Past Illness	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.8']/`	See Below
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']/`	See Below
Pregnancy History	The pregnancy history section contains coded entries describing a current pregnancy of the patient.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/`	See Below
Dispense Section	The Dispense Section contains a description of a medication dispensed for the patient. It includes exactly one Dispense Item entry.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.9.1.2.3']/`	6.24

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0357] The **Authorization** Section **SHALL NOT** be present.

[CDAH-0358] The **Patient Contacts** Section **SHALL NOT** be present.

[CDAH-0359] The **Payers** Section **SHALL NOT** be present.

[CDAH-0360] The **Coded Vital Signs** Section **SHALL NOT** be present.

[CDAH-0361] The **Allergies and Other Adverse Reactions** Section **SHALL NOT** be present.

[CDAH-0362] The **Active Problems** Section **SHALL NOT** be present.

[CDAH-0363] The **History of Past Illness** Section **SHALL NOT** be present.

[CDAH-0364] The **Immunizations** Section **SHALL NOT** be present.

[CDAH-0365] The **Pregnancy History** Section **SHALL NOT** be present.

[CDAH-0366] A **Dispensation Document SHALL** contain exactly one [1..1] **Dispense Section** with the additional constraints specified in Section 6.24.

5.12 HL7 CDA CONSTRAINTS FOR PHARMACEUTICAL ADVICE DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Pharmaceutical Advice documents as defined in this Supporting Interoperability Specification.

A Pharmaceutical Advice document is used to manage Prescription- or Dispensation Items (e.g., change, cancel, etc.) as well as to document Medication Interaction Checking Issues and their resolutions.

[CDAH-0400] Constraints in IHE Pharmacy Technical Framework Supplement "Pharmacy Pharmaceutical Advice" (PHARM-TF Supplement: PADV) Volume 3 Section 6.3.1.2 **SHALL** apply to all Pharmaceutical Advice documents.

5.12.1 HL7 CDA Header Constraints

[CDAH-0401] The Patient Information: **Patient Martial Status SHALL NOT** be present.

[CDAH-0402] The Patient Information: **Patient Religion SHALL NOT** be present.

[CDAH-0403] The Author: **Author Functional Role SHALL** be present.

[CDAH-0404] The Author: **Author Specialty SHALL** be present.

[CDAH-0405] The Author: **Author Address SHALL** be present.

[CDAH-0406] The Author: **Author Telecom SHALL** be present.

5.12.2 Content Modules and Constraints for Pharmaceutical Advice Documents

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared Pharmaceutical Advice documents. The Pharmaceutical Advice document for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: PADV, Section 6.3.1.2 Pharmacy Pharmaceutical Advice Specification.

Table 5.12.1-1 Content Modules for Pharmaceutical Advice Documents contains a list of the content modules with specific Saudi eHealth constraints that pertain to all Pharmaceutical Advice documents:

TABLE 5.12.1-1 CONTENT MODULES FOR PHARMACEUTICAL ADVICE DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Authorization	Each <authorization> element in the CDA Header represents an informed consent.	`ClinicalDocument/authorization`	See Below
Pharmaceutical Advice Section	The Pharmaceutical Advice section contains a pharmaceutical advice to a medication prescribed or dispensed for the patient. It shall include exactly one Pharmaceutical Advice entry.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.9.1.2.2']/`	6.25

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0407] The Authorization Section **SHALL NOT** be present.

[CDAH-0408] A **Pharmaceutical Advice Document SHALL** contain exactly one [1..1] **Pharmaceutical Advice Section** with the additional constraints specified in Section 6.25.

5.13 IMMUNIZATION SUMMARY DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Immunization Summary documents as defined in this Supporting Interoperability Specification.

[CDAH-0450] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Summary documents.

5.13.1 HL7 CDA Header Attributes Being Constrained for Immunization Summaries

[CDAH-0451] An Immunization Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Summary document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.9.1-1 Additional constrained HL7 CDA Header Attributes for Immunization Summaries.

TABLE 5.9.1-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR IMMUNIZATION SUMMARIES

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below

Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication./languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0452] The **Clinical Document/code SHALL** contain 11369-6 History of Immunizations.

[CDAH-0453] **The Clinical Document/languageCommunication SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the "Language" value set.

[CDAH-0454] The **Clinical Document/participant/associatedEntity/scopingOrganization MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0455] The **Clinical Document//patient/guardian SHALL** contain one [0..1] **guardian** if one exists.

5.13.2 Additional Content Modules and Constraints for Immunization Summary Documents

This section describes the additional specific constraints for Immunization Summary documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0456] An Immunization Summary Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.9-2 Content Modules for Immunization Summary Documents.

TABLE 5.9-2 CONTENT MODULES FOR IMMUNIZATION SUMMARY DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.23']`	6.10
Active Problems	The Problem List contains the problems currently being monitored for the patient, including currently active and recently resolved problems.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.6']`	See Below
History of Past Illness	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past.	`//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.8']`	See Below

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Allergies and Other Adverse Reactions	The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.13']	See Below
Medications	The current medications and pertinent medication history at the end of the encounter. (Note 1)	//section[templateId/@root=, 1.3.6.1.4.1.19376.1.5.3.1.3.19']/	See Below
Pregnancy History	The pregnancy history section contains coded entries describing a current pregnancy of the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']	See Below
Coded Results	Coded results may include laboratory results showing the presence or absence of immunity for specific conditions.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below
Immunization Recommendations	The schedule of vaccinations that are intended or proposed for the patient.	//section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1']	See Below
List of Surgeries and Coded List of Surgeries Sections	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	List of Surgeries //section[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.3.11']/	See Below
Coded Social History	Includes social factors such as home life, community life, work life, hobbies, and behavioral risk factors that may indicate or contraindicate vaccinations.	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	See Below

Note 1 The Immunization Summary Information Requirements are constrained to those problems, medications, and allergies that are needed to review to inform the immunization decision. General problem lists are available through Clinical Notes and Summary documents (e.g. iEHR).

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0457] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0458] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Active Problems Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, conforming to the requirements found in Section 6.1, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related problems exist.,.

[CDAH-0459] An **Immunization Summary Document MAY** contain at most one [0..1] **History of Past Illness Section** to identify history of problems that the patient suffered in the past relative to immunization from the "KSA Vaccine Risk Factors – Problems" value set, and **SHALL**

use appropriate null flavors to indicate rationale if no immunization related problems exist. Specifications.

[CDAH-0460] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Allergies and Other Adverse Reactions Section,** to identify allergies relative to immunization from the "KSA Vaccine Risk Factors – Allergies" value set, and **SHALL** include documentation of adverse events associated with vaccination events, conforming to the requirements found in Section 6.2, and **SHALL** use appropriate null flavors to indicate rationale if no immunization related allergies exist.

[CDAH-0461] An **Immunization Summary Document MAY** contain at most one [0..1] **Pregnancy History Section** to indicate pregnancy status as an immunization risk factor.

[CDAH-0462] An **Immunization Summary Document MAY** contain at most one [0..1] **Coded Results Section** to identify serology relative to immunization from the "KSA Serology Results" value set, conforming to the requirements found in Section 6.12.

[CDAH-0463] An **Immunization Summary Document SHALL** contain exactly one [1..1] **Immunization Recommendations Section** which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood..

[CDAH-1120] **Immunization Recommendation** entries in the **Immunization Recommendations Section SHALL** set the `moodCode` attribute to 'PRP'.

[CDAH-0464] An Immunization Summary document **SHALL** contain exactly one [1..1] Medications Section to identify medications relative to immunization from the "KSA Vaccine Risk Factors – Medications" value set with the additional constraints specified in Section 6.3 **IF KNOWN** and **SHALL** use appropriate null flavors to indicate rationale if no immunization related medications exist.

[CDAH-0465] An Immunization Summary document **SHALL** contain exactly one [1..1] List of Surgeries Section to identify surgeries relative to immunization from the "KSA Vaccine Risk Factors – Procedures" value set **IF KNOWN**.

[CDAH-0466] An Immunization Summary document **SHALL** reflect gestational age at birth for individuals that were born prematurely, using the Simple Observation entry in the Active Problems up to age 3 years, and in the History of Past Illness up to the age of 18 years, using SNOMED CT 268477000 (fetal gestation) to identify the observation.

[CDAH-0467] An Immunization Summary document **MAY** contain exactly one [0..1] Comments Section.

[CDAH-0468] An Immunization Summary document **SHOULD** contain exactly one [0..1] Coded Social History Section to indicate vaccination indications, including employment, travel, and other social risk factors that are vaccine indications.

5.14 IMMUNIZATION CARD DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Immunization Card documents as defined in this Supporting Interoperability Specification.

[CDAH-0500] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.1.10 Immunization Content Specification (IC) **SHALL** apply to all Immunization Card documents.

5.14.1 HL7 CDA Header Attributes Being Constrained for Immunization Card Documents

[CDAH-0501] An Immunization Card Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Immunization Card document SHALL also support the additional Clinical CDA Header attributes and constraints in Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

.Table 5.10-1 Additional constrained HL7 CDA Header Attributes for Immunization Cards

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Code	The code specifying the particular kind of document.	`./code`	See Below
Language Communication	Describes the primary and secondary languages of communication for a person.	`./languageCommunication/languageCode`	See Below
Employer and School Contacts	Employer and school informational contacts, including name, address, telephone numbers and other contact information.	`/participant/associatedEntity/scopingOrganization`	See Below
Patient Contacts	Contact information for person(s) responsible for the patient (e.g. parent, guardian).	`/patient/guardian`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0502] The `Clinical Document//code` **SHALL** contain 11369-6 History of Immunizations.

[CDAH-0503] The `Clinical Document//languageCommunication` **SHALL** contain one [1..n] languages codes indicating the primary language(s) of the patient/guardian to inform patient communications using the “Language” value set.

[CDAH-0504] The `Clinical Document//participant/associatedEntity/scopingOrganization` **MAY** contain one [0..1] **Employer or School contact**.

[CDAH-0505] The `Clinical Document//patient/guardian` **SHALL** contain one [0..1] guardian if one exists.

5.14.2 Additional Content Modules and Constraints for Immunization Card Documents

This section describes the additional specific constraints for Immunization Card documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and the IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0506] An Immunization Card Content Creator Actor creating a Saudi eHealth Immunization Summary document **SHALL** also support the additional content module attributes and constraints in Table 5.10-2 Content Modules for Immunization Card Documents.

TABLE 5.10-2 CONTENT MODULES FOR IMMUNIZATION CARD DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINTT REF.
Immunizations	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.23']	6.10
Immunization Recommendations	The Immunization Recommendations Section documents the schedule of vaccinations that are intended or proposed for the patient.	1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1	See Below
Comments	The Comments section allows for a comment to be supplied with each entry.	1.3.6.1.4.1.19376.1.5.3.1.4.2	See Below

The list below provides constraints on the content modules. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0507] An **Immunization Card Document SHALL** contain exactly one [1..1] **Immunizations Section** conforming to the requirements found in Section 6.10.

[CDAH-0508] An **Immunizations Section SHALL** provide human readable narrative both in Arabic and English for patient consumption.

[CDAH-0509] An Immunization Summary document **SHALL** exactly one [1..1] Immunization Recommendations Section, which SHALL include the schedule of vaccinations that are intended or proposed for the patient according to the Saudi Vaccination Schedule, reflecting Immunization entries using the "Saudi Vaccine Name" value set to indicate the vaccine due in intent, including the due date in effectiveTime, and reflecting the guideline or Campaign in in definition mood.

[CDAH-0510] An Immunization Card document **MAY** contain exactly one [0..1] Comments Section.HL7 CDA Constraints for clinical scanned documents

5.15 HL7 CDA CONSTRAINTS FOR CLINICAL SCANNED DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for clinical scanned documents (PDF or plaintext documents) as defined in this Supporting Interoperability Specification.

[CDAH-0550] Constraints in the IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option **SHALL** apply to all clinical scanned clinical documents.

5.15.1 HL7 CDA header attributes being constrained for Clinical Scanned Documents

No additional HL7 CDA header constraints are defined beyond those specified in IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document (XDS-SD) Profile and Section 4 of this specification.

5.15.2 Additional Content Modules and Constraints For Clinical Scanned Documents

This section describes the additional specific constraints for scanned clinical documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules is found in the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

[CDAH-0551] A Content Creator Actor creating the document body of a scanned clinical document **SHALL** support the IHE IT Infrastructure (ITI) Volume 3 (ITITF-3) Section 5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option.

5.16 HL7 CDA CONSTRAINTS FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral Request documents and Transfer Request documents as defined in this Supporting Interoperability Specification. The Referral Request document is used to request a referral. The Transfer Request document is used to request a Transfer. Within this section, constraints specific to the Referral Request or Transfer Request will specify the type of Request Document that the constraint applies to. Constraints that apply to both types of document will just refer to them as Request documents.

[CDAH-0960] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to Request documents.

5.16.1 HL7 CDA Header Attributes Being Constrained for Request Documents

[CDAH-0961] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Request document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.12-1 Additional constrained HL7 CDA Header Attributes for Referral Request and Transfer Request document.

TABLE 5.12-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		/ClinicalDocument/	

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	./patient/participant[@typeCode='IND']/associatedEntity [@classCode='NOK']	See Below
Requesting Healthcare Provider	The healthcare provider requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity	See Below
Requesting Healthcare Organization	The healthcare organization requesting the referral or transfer.	./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1101] The **Title** for the Referral Request Document **SHALL** be set to “Referral Request”.

[CDAH-1102] The **Title** for the Transfer Request Document **SHALL** be set to “Transfer Request”

[CDAH-0962] The **Code** for the Referral Request Document **SHALL** be set to '57133-1' Referral Note from LOINC.

[CDAH-0963] The **Code** for the Transfer Request Document **SHALL** be set to '18761-7' Transfer Summary Note from LOINC.

[CDAH-0964] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-0965] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-0966] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-0967] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-0968] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-0969] The **Next of Kin** should specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-0970] The **Next of Kin Relationship SHALL** come from the “***KSA Personal Relationship Role”*** Value Set.

[CDAH-0971] If the referral or transfer is for a new born baby there **SHALL** be a Next of Kin using code/@code='MTH' from the “***HL7 Personal Relationship Role Type”*** Value Set (2.16.840.1.113883.1.11.19563) to describe the mother if she is alive and known.

[CDAH-0972] The **Next of Kin** for the mother as described above **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID

[CDAH-0973] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Provider.**

[CDAH-0974] The **Requesting Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-0975] The **Requesting Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-0976] The **Requesting Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-0977] The **Clinical Document SHALL** contain exactly one [1..1] **Requesting Healthcare Organization.**

[CDAH-0978] The **Requesting Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

5.16.2 Additional Content Modules and Constraints for Request Documents

This section describes the additional specific constraints for Request documents. The IHE constraints on the content modules found below are specified in IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-0979] A Clinical Summary Content Creator Actor creating a Saudi eHealth Request document **SHALL** also support the additional content module attributes and constraints in Table 5.12-2 Additional Content Modules for Referral Request and Transfer Request document.

TABLE 5.12-2 ADDITIONAL CONTENT MODULES FOR REFERRAL REQUEST AND TRANSFER REQUEST DOCUMENT

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Coded Reason for Referral	Contains a narrative and coded description of the reason that the patient is being referred or transferred.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.2']	See Below
Care Plan Section	Contains information about the requested services.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Request document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-0980] The **Request document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-0981] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-0982] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set.

[CDAH-0983] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-0984] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-0985] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-0986] The **Request document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and **SHALL NOT** be empty.

[CDAH-0987] The **Request document SHALL** contain exactly one [1..1] **KSA Care Plan Section IF KNOWN**.

[CDAH-0988] The **Care Plan Section SHALL** contain [0..*] zero or more **Plan of Care Activity** entries conforming to the **HL7 Plan of Care Activity** template (2.16.840.1.113883.10.20.1.25) representing the desired services being requested in order by importance.

[CDAH-0990] The code/@code attribute of a **Plan of Care Activity** entry **SHALL** be present to indicate the service requested.

[CDAH-0991] The code/@code attribute of a **Plan of Care Activity** entry may be populated from the "***KSA Radiology Procedure"*** value set.

[CDAH-0992] The priorityCode/@code attribute of the **Plan of Care Activity SHALL** be populated from the "***KSA Referral and Transfer Priority"*** value set.

[CDAH-0993] The specialty of the performer of the requested service may be specified in performer/assignedEntity/code/@code attribute of the **Plan of Care Activity** entry.

[CDAH-0994] The specialty of the performer **SHALL** contain a value from the "***KSA Individual Provider Specialty"*** value set.

[CDAH-0995] The Receiving Organization **MAY** be specified in performer/assignedEntity/representedOrganization.

[CDAH-0996] The **Request document SHALL** contain exactly one [1..1] **Transport Section** IF KNOWN.

[CDAH-0997] The required **Transport Entry** in the **Transport Section SHALL** specify the **Intended Mode of Transport** in the Act/code/@code attribute.

[CDAH-0998] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-0999] The **effectiveTime MAY** be set to null flavor "UNK".

5.17 HL7 CDA CONSTRAINTS FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

This Section provides Saudi eHealth constraints to be implemented for Referral/Transfer Response documents as defined in this Supporting Interoperability Specification.

[CDAH-1000] Constraints in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) **SHALL** apply to all clinical Referral/Transfer Response documents.

5.17.1 HL7 CDA Header Attributes Being Constrained for Response Documents

[CDAH-1001] A Clinical Summary Content Creator Actor creating the HL7 CDA Release 2 document header for a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional Clinical CDA Header attributes and constraints in Table 5.13-1 Additional constrained HL7 CDA Header Attributes for Referral Response and Transfer Response document.

TABLE 5.13-1 ADDITIONAL CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	CROSS REF
Clinical Document		`/ClinicalDocument/`	
Title	The title of the document	/ClinicalDocument/title	See Below
Code	The code specifying the particular kind of document.	/ClinicalDocument/code	See Below
Next of KIN	Related family member(s) to the patient (e.g. mother, father, etc.)	`./patient/participant[@typeCode='IND']/associatedEntity[@classCode='NOK'`	See Below
Receiving Healthcare Provider	The healthcare provider receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity`	See Below
Receiving Healthcare Organization	The healthcare organization receiving the referral or transfer.	`./documentationOf/serviceEvent/performer/assignedEntity/representedOrganization`	See Below

See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1103] The **Title** for the Response Document **SHALL** be set to “Referral/Transfer Response Document”

[CDAH-1104] The **Code** for the Response Document **SHALL** be set to 'ReferralTransferResponseDocument' from the “KSA Referral and Transfer Document Type” Value Set.

[CDAH-1002] The **Clinical Document SHALL** contain one or more [1..*] **Next of Kin IF KNOWN**.

[CDAH-1003] The **Next of Kin SHALL** conform to the Patient Contacts template specified in IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) Section 6.3.2.4.

[CDAH-1004] The **Next of Kin SHALL** contain one or more [1..*] **Address IF KNOWN**

[CDAH-1005] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey phone/mobile number information.

[CDAH-1006] The **Next of Kin SHALL** contain one or more [1..*] **Telecom IF KNOWN** to convey e-mail information.

[CDAH-1007] The **Next of Kin SHOULD** specify the **Next of Kin Relationship** in the code/@code attribute.

[CDAH-1008] The **Next of Kin Relationship SHALL** come from the "***KSA Personal RelationshipRole"*** Value Set.

[CDAH-1009] If the referral or transfer is for a new born baby, there **SHALL** be a **Next of Kin** using code/@code='MTH' from the "***KSA Personal Relationship Role"*** Value Set to describe the mother, if she is alive and known.

[CDAH-0x59] The **Next of Kin** for the mother **SHALL** contain exactly one [1..1] **id** which contains the Mother's assigned MOH Health ID.

[CDAH-1010] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Provider.**

[CDAH-1011] The **Receiving Healthcare Provider SHALL** conform to Section 4.6 Performer Attributes and Constraints.

[CDAH-1012] The **Receiving Healthcare Provider SHALL** contain one or more [1..*] **Performer Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1013] The **Receiving Healthcare PROVIDER SHALL** contain one or more [1..*] **Performer Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1014] The **Clinical Document SHALL** contain exactly one [1..1] **Receiving Healthcare Organization.**

[CDAH-1015] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey phone/mobile number information **IF KNOWN**.

[CDAH-1016] The **Receiving Healthcare Organization SHALL** contain one or more [1..*] **Performer Organization Telecom** to convey e-mail information **IF KNOWN**.

[CDAH-1130] The standardIndustryClassCode in the **Requesting Healthcare Organization SHALL** be set to a value from the "KSA Organization Sector" value set.

5.17.2 Additional Content Modules and Constraints for Response Documents

This section describes the additional specific constraints for Referral/Transfer Response documents. The IHE constraints on the content modules found below are specified in the IHE Content Modules section within IHE Patient Care Coordination (PCC) Volume 2 (PCCTF-2) and IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Content Module.

[CDAH-1017] A Clinical Summary Content Creator Actor creating a Saudi eHealth Referral/Transfer Response document **SHALL** also support the additional content module attributes and constraints in Table 5.13-2 Additional Content Modules for Referral Response and Transfer Response document.

TABLE 5.13-2 ADDITIONAL CONTENT MODULES FOR REFERRAL RESPONSE AND TRANSFER RESPONSE DOCUMENTS

CONTENT MODULES	CONTENT MODULES DEFINITION	CDA LOCATION	CONSTRAINT REF.
Payers	The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 ']	See Below
Care Plan Section	Contains information about the requested services or the reason for aborting the transfer or referral.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.3.31']	See Below
Transport Section	Contains information about the mode of transport of the patient.	//section[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.1.10.3.2 ']	See Below

The list below provides the Saudi eHealth specific constraints on the content modules associated with a Response document. See the Preface section How to Read the Tables for more information on interpreting this table.

[CDAH-1018] The **Response Document SHALL** contain exactly one [1..1] **Payers Section IF KNOWN**.

[CDAH-1019] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the type of grantor program **SHALL** be specified in the act/code/@code attribute.

[CDAH-1020] When the performer in the Coverage Entry of the Payers Section is a Guarantor (act/performer[@typeCode='PRF' and assignedEntity/code/@code='GUAR'], the value of the act/code/@code attribute **SHALL** come from the "***KSA Grantors"*** value set .

[CDAH-1021] When the payer is an insurer, the **Payer Entry** in the **Payers Section SHALL** contain the identifier of the member or subscriber in the appropriate participantRole/id/@extension attribute.

[CDAH-1022] When the payer is an insurer and the value for the participantRole/id/@root attribute is unknown in a **Payer Entry**, participantRole/id/@nullFlavor **SHALL** be set to "NAV".

[CDAH-1023] When the payer is an insurer, the name of the insurer **SHALL** be present in performer/assignedEntity/representedOrganization/name.

[CDAH-1024] The **Response document SHALL** contain exactly one [1..1] **Coded Reason for Referral Section** and SHALL NOT be empty.

[CDAH-1025] The **Response document SHALL** contain exactly one [1..1] **KSA Care Plan Section**.

[CDAH-1026] The **Response document SHALL** contain exactly one [1..1] **Transport Section IF KNOWN.**

[CDAH-1027] The **Transport SHALL** specify the **Intended Mode of Transport** in the code/@code attribute.

[CDAH-1028] The **Intended Mode of Transport SHALL** come from the "***KSA Mode of Transport"*** value set.

[CDAH-1029] The **effectiveTime MAY** be set to null flavor "UNK".

6. CDA SECTION ATTRIBUTES AND CONSTRAINTS

This section describes the attributes of sections found in a CDA document and explains the constraints on those sections.

6.1 PROBLEMS SECTION ATTRIBUTES AND CONSTRAINTS

The Problems section is used to record current active and recently resolved problems.

[CDAH-0660] The **Problems Section SHALL** contain one or more [1..*] **Problem Entry** for each currently active or recently resolved problem.

[CDAH-0661] A **Problem Entry SHALL** conform to the constraints in Section 7.3.

6.2 ALLERGIES SECTION ATTRIBUTES AND CONSTRAINTS

The Allergies section is used to record both environmental and drug allergies, as well as the adverse reactions.

If the Allergy is to a drug:

[CDAH-0600] The **Allergies and Other Adverse Reactions Section SHALL** contain one or more [1..*] **Allergy and Intolerance Entry** for each drug allergy.

[CDAH-0601] The **Allergies and Other Adverse Reactions Section Allergy and Intolerance Entry SHALL** conform to the constraints in Section 7.12.

6.3 MEDICATIONS SECTION ATTRIBUTES AND CONSTRAINTS

The Medications section is used to record information on a patient's current and relevant medications during an Outpatient encounter.

[CDAH-0602] The **Medications Section SHALL** contain one or more [1..*] **Medication** entries with the additional constraints specified in Section 7.1.

6.4 ADMISSION MEDICATION HISTORY SECTION ATTRIBUTES AND CONSTRAINTS

The Admission Medications section is used to record information on a patient's current and relevant medications as part of the admission to the Hospital.

[CDAH-0603] The **ADMISSION MEDICATION Section SHALL** contain one or more [1..*] **Medication** entries with the additional constraints specified in Section 7.1.

6.5 MEDICATIONS ADMINISTERED SECTION ATTRIBUTES AND CONSTRAINTS

The Medications Administered section is used to record a selective list of the relevant medication administered during a patient's hospital stay.

[CDAH-0604] The **Medications Administered Section SHALL** contain one or more [1..*] **Medication** entries with the additional constraints specified in Section 7.1.

6.6 HOSPITAL DISCHARGE MEDICATIONS SECTION ATTRIBUTES AND CONSTRAINTS

The Discharge Medications section is used to record information on a patient's current and relevant medications as part of the discharge from the Hospital.

[CDAH-0605] The **Hospital Discharge Medications Section SHALL** contain one or more [1..*] **Medication** entries with the additional constraints specified in Section 7.1.

6.7 MEDICATION LIST SECTION ATTRIBUTES AND CONSTRAINTS

The Medications List section is a list of medications and associated information, pertaining to a specific patient, constructed for a specific purpose.

[CDAH-0606] The **Medication List Section MAY** contain one or more [0..*] **Medication** entries with the additional constraints specified in Section 7.1.

[CDAH-0269] Constraints in the IHE Pharmacy Medication List (PML) Supplement **SHALL** apply to this section.

6.8 DIAGNOSIS SECTION

The Diagnosis section is used to record the current problem list associated with a patient.

[CDAH-0609] The **Diagnosis Section Text SHALL** be present and **SHALLNOT** be null flavor.

[CDAH-0610] The **Diagnosis Section SHALL** contain one or more [1..*] **Problem Concern Entries IF KNOWN.**

[CDAH-0611] The **Diagnosis Section Problem Concern SHALL** contain one or more [1..*] **Problem Entries** and conform to the constraints in Section 7.3, **IF KNOWN.**

6.9 VITAL SIGNS SECTION ATTRIBUTES AND CONSTRAINTS

The Vital Signs section is used to record coded vital signs (e.g. blood pressure, weight) for a given patient.

[CDAH-0612] The **Coded Vital Signs Section MAY** contain zero or one [0..1] **Pain Score Observation Entries.**

6.10 IMMUNIZATION SECTION ATTRIBUTES AND CONSTRAINTS

The Immunization section is used to record immunizations that have been given to a patient.

[CDAH-0670] The **Immunizations Section SHALL** contain zero or more [0..*] **Immunizations Entries** with the additional constraints specified in Section 7.13.

6.11 SURGICAL DRAINS SECTION ATTRIBUTES AND CONSTRAINTS

The Surgical Drains section is used to record information about drains that have been surgically implanted during surgery.

[CDAH-0613] Constraints in IHE HL7 Health Story Consolidated CDA Section 4.59 **SHALL** apply to all **Surgical Drains Sections**.

6.12 CODED RESULTS SECTION ATTRIBUTES AND CONSTRAINTS

The Coded Results section is used to provide information on relevant diagnostic tests performed on a patient.

6.12.1 Blood Group Coded Results

The Blood Group Coded Results provides information on a patient's blood group.

[CDAH-0614] The **Coded Results Section SHALL** contain exactly one [1..1] **Blood Type Observation Entry IF KNOWN and SHALL** be populated with a value from the "**Blood Group"** value set.

6.12.2 Newborn Screening Coded Results

The Newborn Screening Coded Results provides newborn screening diagnostic test results.

[CDAH-0615] The **Coded Results Section** SHALL contain a description of all the Newborn Screening Results.

[CDAH-0616] The **Coded Results Section SHALL** contain exactly zero or more [0..*] **Simple Observation Entries** pertaining to the Newborn Screening Results.

[CDAH-0658] Simple Observation Entry Codes for the Newborn Screening Results **SHALL** use appropriate test codes from the "**Laboratory Orders and Results"** Value Set.

6.13 LABOR AND DELIVERY EVENTS: PROCEDURES AND INTERVENTIONS SECTION ATTRIBUTES AND CONSTRAINTS

The Labor and Delivery Events: Procedures and Interventions section provides relevant information about the labor and the type of delivery.

[CDAH-0617] The **Labor and Delivery Events: Procedures and Interventions Section SHALL** contain exactly one [1..1] **Procedure Entry** and conform to the constraints in Section 7.4, **IF KNOWN.**

6.14 DELIVERY EVENT OUTCOME SECTION ATTRIBUTES AND CONSTRAINTS

The Delivery Event Outcome section provides information about the outcome of the delivery including the number of live and still born births.

[CDAH-0619] The **Delivery Events: Outcome Section SHALL** contain exactly one [1..1] **Live Births Observation** and conform to the constraints in Section 7.6.

[CDAH-0620] The **Delivery Events: Outcome Section SHALL** contain exactly one [1..1] **Still Births Observation** and conform to the constraints in Section 7.6.

6.15 NEWBORN DELIVERY INFORMATION SECTION ATTRIBUTES AND CONSTRAINTS

The following Newborn Delivery information **SHALL** be included in the Newborn Delivery Information Section:

TABLE 6.15-1 CONTENT MODULES FOR NEWBORN DELIVERY INFORMATION

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Gestational Age Observation	The Gestational age (or menstrual age) is a measure of the age of a pregnancy (in weeks).	`Observation [code/@code='49051-6']/value`	7.5.1
Apgar after 1 min Observation	Apgar contains the values of the repeatable method used to quickly and summarily assess the health of newborn children immediately after birth.	`Observation [code/@code='9272-6']/value`	7.5.2
Apgar after 5 min Observation		`Observation [code/@code='9273-4']/value`	7.5.2
Apgar after 10 min Observation		`Observation [code/@code='9271-8']/value`	7.5.2

[CDAH-0622] The **Newborn Delivery Information Section SHALL** contain exactly one [1..1] **Gestational Age Code**.

[CDAH-0623] The **Newborn Delivery Information Section SHALL** contain exactly one [1..1] **1 min Apgar Code**.

[CDAH-0624] The **Newborn Delivery Information Section SHALL** contain exactly one [1..1] **5 min Apgar Code**.

[CDAH-0625] The **Newborn Delivery Information Section SHALL** contain exactly one [1..1] **10 min Apgar Code**.

6.16 ACUITY ASSESSMENT ATTRIBUTES AND CONSTRAINTS

The Acuity Assessment is used by a Surgeon to assess the severity of a patient's condition.

[CDAH-0626] Constraints in IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Modules Section 6.3.3.9.6 **SHALL** apply to all **Acuity Assessment Sections**.

6.17 DISCHARGE DISPOSITION ATTRIBUTES AND CONSTRAINTS

The Discharge Disposition provides information on where a patient will be going upon discharge from the hospital.

[CDAH-0627] The **Discharge Disposition Section SHALL** contain a narrative description of where the patient was discharged to (e.g., Home, Long Term Care).

- [CDAH-0628] When the **Discharge Disposition Section** is present, the `/ClinicalDocument/componentOf/encompassingEncounter/dischargeDispostionCode` element **SHALL** be populated with a value from the "**KSA Discharge Disposition"** value set.

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6.18 VISIBLE IMPLANTED MEDICAL DEVICES ATTRIBUTES AND CONSTRAINTS

The Visible Implanted Medical Devices provides information on medical devices implanted in a patient.

[CDAH-0630] Constraints in IHE Patient Care Coordination Technical Framework (PCCTF) Volume 2 Section 6.3.3.4.7 **SHALL** apply to all **Visible Implanted Medical Devices Sections.**

6.19 HISTORY OF TRANSFUSIONS ATTRIBUTES AND CONSTRAINTS

The History of Transfusions will provide a history about the transfusions given to a patient.

[CDAH-0631] Constraints in IHE Patient Care Coordination (PCC) Technical Framework Supplement CDA Modules Section 6.3.3.2.31 **SHALL** apply to all **History of Transfusions Sections**.

6.20 PLANNED PROCEDURE ATTRIBUTES AND CONSTRAINTS

The Planned Procedure section will provide information on the procedures to be performed on a patient.

- [CDAH-0632] The **Planned Procedure Section** `priorityCode` element **SHALL** be populated with a value from the "**KSA Planned Procedure Priority"** value set.

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6.21 PROCEDURE DESCRIPTION ATTRIBUTES AND CONSTRAINTS

The Procedure description will provide a detailed description of the operative course, including preparation and pertain information about the surgery.

[CDAH-0634] The **Procedure Description Section SHALL** contain a **Procedure Entry** which conforms to the constraints in Section 7.4.2, and specifies the duration of the surgery.

6.22 PRESCRIPTION CODED VITAL SIGNS SECTION ATTRIBUTES AND CONSTRAINTS

The Prescription Coded Vital Signs Section is used to record the patient's weight in a Prescription.

[CDAH-0650] The **Prescription Coded Vital Signs Section SHALL** contain **WEIGHT and SHALL** be populated with a value from the "**KSA Weight Units"** value set and **SHOULD NOT** include other coded vital signs.

6.23 PRESCRIPTION SECTION ATTRIBUTES AND CONSTRAINTS

The Prescription Section contains a description of the medications in a given prescription for the patient. It includes entries for each Prescription Item. The Prescription Section for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: PRE, Section 6.3.3.1 Prescription Section Content Module Specification.

[CDAH-0651] **Prescriber SHALL NOT** be present.

[CDAH-0652] The **Prescription Section SHALL** contain one or more [1..*] **Prescription Items** with the additional constraints specified in Section 7.8.

6.24 DISPENSE SECTION ATTRIBUTES AND CONSTRAINTS

The Dispense Section contains a description of a medication dispensed for the patient. It includes exactly one Dispense Item entry. The Dispense Section for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: DIS, Section 6.3.3.3 Dispense Section Content Module Specification.

[CDAH-0653] **Dispenser SHALL NOT** be present.

[CDAH-0654] The **Dispense** Section **SHALL** contain exactly one [1..1] **Dispense Item** with the additional constraints specified in Section 7.9.

6.25 PHARMACEUTICAL ADVICE SECTION ATTRIBUTES AND CONSTRAINTS

The Pharmaceutical Advice section contains a pharmaceutical advice to a medication prescribed or dispensed for the patient. It shall include exactly one Pharmaceutical Advice entry. The Pharmaceutical Advice Section for Saudi eHealth is a further constrained use of IHE-PHARM TF Supplement: PADV, Section 6.3.3.2 Pharmaceutical Advice Section Content Module Specification.

[CDAH-0655] **Pharmaceutical Adviser SHALL NOT** be present.

[CDAH-0656] The **Pharmaceutical Advice** Section **SHALL** contain exactly one [1..1] **Pharmaceutical Advice Item** with the additional constraints specified in Section 7.10.

7. CDA ENTRY ATTRIBUTES AND CONSTRAINTS

This section describes the attributes of entries found in sections of a CDA document and explains the constraints on those sections.

7.1 MEDICATIONS ENTRY

[CDAH-0700] **Product Code SHALL** be present.

[CDAH-0701] A **Product Code SHALL** contain the following information:

- **Product Code SHALL** contain a code that comes from the "**KSA Prescription Pharmacy Item Name"** or "**KSA Dispensation Pharmacy Item Name"** value set.
- In case of a Compound medicine:
- **Product Code SHALL** be null flavor "NA".

[CDAH-0702] **Product Name SHALL** be present and **SHALL NOT** be null flavor.

[CDAH-0703] The following data elements **SHALL** conform to the constraints specified in Section 7.8.1:

- Additional Template ID for identifying the `<entry>` as a particular type of medication event ("Normal Dosing", etc.)
- Effective Time (Duration of Treatment)
- Medication Frequency
- Route of Administration
- Approach Site Code
- Dose Quantity
- Rate Quantity
- Related Components

7.2 MEDICATIONS ALLERGY ENTRY

This entry is a specialization of the Allergies and Intolerances Entry, wherein the subject of the allergy is focused on recording a Medication Interaction Checking Issue.

[CDAH-0710] A **code SHALL** contain a Medication Interaction Checking Issue Code that comes from the "**KSA Medication Interaction Checking Issue Code"** value set.

[CDAH-0711] The `<reference>` element of **text SHALL** be set to null flavor "UNK".

[CDAH-0712] **effectiveTime SHALL** be present.

[CDAH-0713] The `<low>` element of **effectiveTime SHALL** be set to null flavor "UNK".
[CDAH-0714] The `<high>` element of **effectiveTime SHALL NOT** be present.

[CDAH-0715] A **value SHALL** be provided uncoded and contain a `<originalText>` sub-element, which contains a `</reference>` sub-element. The Uniform Resource Identifier (URI) given in the value attribute of the `<reference>` element **SHALL** point to an element in the narrative content that contains the complete text describing the Medication Interaction Checking Issue.

[CDAH-0716] **Substance (participant) SHALL NOT** be present.

[CDAH-0717] **Reactions SHALL NOT** be present.

[CDAH-0718] **Severity SHALL NOT** be present.

[CDAH-0719] **Clinical Status SHALL NOT** be present.

[CDAH-0720] **Comments SHALL NOT** be present.

7.3 PROBLEM ENTRY

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

[CDAH-0750] The **Problem value SHALL** contain exactly one [1..1] value.

[CDAH-0751] The **Problem value SHALL** be selected from the "**KSA Problem"** value set **IF KNOWN**.

[CDAH-0752] If the Diagnosis is unknown, the **Problem Value MAY** be empty

7.4 PROCEDURE ENTRY

7.4.1 Labor and Delivery Events Procedure Entry

The Labor and Delivery Events Procedure Entry will record the mode of delivery.

[CDAH-0753] The **Labor and Delivery Events: Procedures and Interventions Section Procedure Entry** `code` **SHALL** be populated with a value from the "**KSA Mode of Delivery"** value set.

7.4.2 Procedure Description Procedure Entry

The Procedure Description Procedure Entry will record the duration of the surgery.

[CDAH-0754] The **Procedure Description Section Procedure Entry** `effectiveTime/low` **SHALL** be populated with the start date and time of the surgery.

[CDAH-0755] The **Procedure Description Section Procedure Entry** `effectiveTime/width` **SHALL** be populated with the duration of the surgery.

7.5 NEWBORN DELIVERY INFORMATION ENTRIES

A pregnancy observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's current or historical pregnancies.

7.5.1 Gestational Age

The Gestational age is a measure of the age of a pregnancy (in weeks).

[CDAH-0756] **Observation Gestational Age code SHALL** be 49051-6 (Gestational Age) from the LOINC coding system (2.16.840.1.113883.6.1) and **SHALL NOT** be null.

[CDAH-0757] The **Observation Gestational Age value SHALL** contain exactly one [1..1] value and **SHALL** contain exactly one [1..1] unit and **SHALL NOT** be null.

[CDAH-0758] The **Observation Gestational Age value SHALL** contain exactly one [1..1] unit selected from the "KSA **Time Units"** value set.

7.5.2 Apgar

The Apgar contains the values of the repeatable method used to quickly and summarily assess the health of newborn children immediately after birth.

[CDAH-0759] **Observation 1 min Apgar** `code` **SHALL** be 9272-6 (Apgar after 1 min) from the LOINC coding system (2.16.840.1.113883.6.1).

[CDAH-0760] **Observation 5 min Apgar** `code` **SHALL** be 9273-4 (Apgar after 5 min) from the LOINC coding system (2.16.840.1.113883.6.1).

[CDAH-0761] **Observation 10 min Apgar** `code` **SHALL** be 9271-8 (Apgar after 10 min) from the LOINC coding system (2.16.840.1.113883.6.1).

[CDAH-0762] The **Observation Apgar value SHALL** contain exactly one [1..1] value and **SHALL NOT** be null.

7.6 DELIVERY OUTCOME ENTRIES

The delivery outcome observations are Simple Observations that record the number of still births and the number of live births.

[CDAH-0763] The **Observation live births** `code` **SHALL** be 11636-8 (Live Births) from the LOINC coding system (2.16.840.1.113883.6.1).

[CDAH-0764] The **Observation still births** `code` **SHALL** be 57062-2 (Stillborn Births) from the LOINC coding system (2.16.840.1.113883.6.1).

7.7 MEDICINE ENTRY

A Medicine entry describes a medicine and is used within Prescription or Dispensation Items. It describes a medicinal product, a generic/scientific name or a magistral preparation/compound medicine and contains information such as name, medication form, packaging information and active ingredients.

[CDAH-0800] **Name SHALL** be present and **SHALL NOT** be null flavor.

[CDAH-0801] **Form Code MAY** be present. If it is present it **SHALL** contain a pharmaceutical dose form that comes from the "**KSA Medication Pharmaceutical Dose Form" value set**.

[CDAH-0802] **Packaging MAY** be present. If it is present it **SHALL** contain a package form code that comes from the "**KSA Medication Package Form" value set**.

[CDAH-0902] If **Packaging** is present and contains a `<pharm:capacityQuantity>` element, it **SHALL** contain exactly one [1..1] unit that comes from the **KSA_Medication Quantity Unit"** value set.

[CDAH-0803] **Generic Equivalent SHALL NOT** be present.

[CDAH-0804] **Active Ingredients SHALL NOT** be present.

7.7.1 Additional Constraints for Medicine Entry Used in a Prescription Item

[CDAH-0805] A **Code SHALL** contain the following information:

- Prescribing of a medication item:
    - Code **SHALL** contain a code that comes from the "KSA Prescription Pharmacy Item Name" value set.
- Prescribing of a Compound medicine or an item not found in the IS0200 *Saudi eHealth Terminology Repository:*
    - Code **SHALL** be null flavor "NA".

[CDAH-0806] **Lot Number SHALL NOT** be present.

[CDAH-0807] **Expiration Date SHALL NOT** be present.

7.7.2 Additional Constraints for Medicine Entry Used in a Dispense Item

[CDAH-0808] A **Code SHALL** contain the following information:

- Dispensation of a medication item:
    - **Code SHALL** contain a code that comes from the "**KSA Dispensation Pharmacy Item Name"** value set.
- Dispensation of a Compound medicine or an item not found in the IS0200 *Saudi eHealth Terminology Repository:*
    - **Code SHALL** be null flavor "NA".

[CDAH-0809] **Lot Number SHALL** be present **IF KNOWN**.

[CDAH-0810] In case of Dispensation of a Compound medicine, **Lot Number SHALL NOT** be present.

[CDAH-0811] **Expiration Date SHALL** be present **IF KNOWN**.

7.8 PRESCRIPTION ITEM ENTRY

A Prescription Item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations. Prescription Item is the atomic entity for logistics, distribution and billing. It contains the prescribed medicine and dosage information as well as other information to the prescribed item such as patient and fulfillment instructions and substitution handling.

[CDAH-0820] **Prescription Item ID SHALL** contain a unique ID.

[CDAH-0821] The **Prescription Item ID SHALL** contain exactly one [1..1] id/@root that is set to an OID assigned by Health Information Exchange at deployment time to each system issuing Prescription Items to ensure a unique identifier.

[CDAH-0822] The **Code** element **SHALL NOT** be present in the **Prescription Item**.

[CDAH-0823] **Dosage Instructions SHALL** be present with the additional constraints specified in Section 7.8.1.

[CDAH-0824] In case structured dosage instructions are provided the following additional constraints apply to **Dosage Instructions**:

[CDAH-0956] The sub-elements of Effective Time (Duration of Treatment) **SHALL NOT** be null flavor.

[CDAH-0957] If the `<consumable>` element (Medicine entry) describes a Compound medicine, Route of Administration **SHALL** be present.

[CDAH-0825] In the case structured dosage instructions cannot be provided (e.g., tapered or conditional dosing, etc.), the dosage instructions SHALL be provided as narrative text. See also [CDAH-0828] and [CDAH-0829].

[CDAH-0826] **Consumable SHALL** contain exactly one [1..1] **Medicine entry** with the additional constraints specified in Section 7.7.

[CDAH-0827] One or more [1..*] **Reason MAY** be present and, if present, **SHALL** be internal references to diagnosis provided in the Diagnosis Section specified in Section 6.8.

[CDAH-0828] **Patient Medication Instructions SHALL** be present.

[CDAH-0829] The narrative portion of the document the **Patient Medication Instructions** point at **SHALL** contain human readable dosage instructions in narrative form, which may be in professional language including professional terms such as QID, etc.

[CDAH-0830] The narrative portion of the document the **Patient Medication Instructions** point at **MAY** contain general comments by the prescriber to the patient, e.g., additional instructions for taking the medicine, etc.

[CDAH-0831] In case the **Consumable** describes a Compound medicine, **Fulfillment Instructions SHALL** be present and the narrative portion of the document the **Fulfillment Instructions** point at **SHALL** contain "Information to the preparation of compound medicine". This information block **SHALL** be encompassed by a `<content>` element whose value in the @ID attribute starts with the prefix "compound_" (e.g., `<content ID='compound_1234'>`).

[CDAH-0832] The narrative portion of the document the **Fulfillment Instructions** point at **MAY** contain general comments by the prescriber to the dispenser, e.g., a proposal of a brand, information about substitution, etc.

[CDAH-0834] **Substitution Handling SHALL NOT** be present.

[CDAH-0835] **Precondition Criterion MAY** be present. If present it **SHALL** contain a `<criterion/code>` element containing a code that comes from the "**KSA Medication Frequency Precondition"** value set.

[CDAH-0903] A **Quantity** in **Amount of units of the consumable to dispense SHALL** contain exactly one [1..1] value and **SHALL NOT** be null.

[CDAH-0904] A **Quantity** in **Amount of units of the consumable to dispense SHALL** contain exactly one [1..1] unit that comes from the "**KSA Medication Quantity Unit"** value set.

7.8.1 Dosage Instructions

Dosage Instructions are a set of data elements which together represent the dosage instructions to a medication such as duration of treatment, medication frequency, dose quantity, route of administration, etc.

[CDAH-0836] Constraints in IHE Pharmacy Technical Framework Supplement "Pharmacy Prescription" (PHARM-TF Supplement: PRE) Volume 3 Section 6.3.4.5 **SHALL** apply to all Dosage Instructions.

[CDAH-0837] The **Dosage Instructions Additional Template ID SHALL** be set to either "NORMAL DOSING" (@root='1.3.6.1.4.1.19376.1.5.3.1.4.7.1') or "SPLIT DOSING" (@root='1.3.6.1.4.1.19376.1.5.3.1.4.9').

[CDAH-0908] In case structured dosage instructions are NOT provided the **Effective Time (Duration of Treatment)** element **SHALL** be nullFlavor="NA" (additionally to the sub-elements low/high, which **SHALL** be nullFlavor="UNK").

[CDAH-0838] A **Dose Quantity SHALL** contain exactly one [1..1] value and **SHALL NOT** be null.

[CDAH-0839] A **Dose Quantity SHALL** contain exactly one [1..1] unit that comes from the "**KSA Medication Quantity Unit"** value set.

[CDAH-0[CDAH-0840] A **Route of administration SHALL** contain a Route of administration code that comes from the "**KSA Medication Route of Administration"** value set.

[CDAH-0841] **Approach Site** Code **MAY** be present. If it is present it **SHALL** contain a body region code that comes from the "**KSA Medication Approach Site value set"**.

[CDAH-0842] **Rate Quantity SHALL NOT** be present.

[CDAH-0843] Duration units used in **Effective Time (Duration)** or **Medication Frequency** elements **SHALL** come from the "**KSA Medication Duration Unit"** value set.

7.9 DISPENSE ITEM ENTRY

A Dispense Item belongs to one Dispensation and represents one dispensed medication. It contains the dispensed medicinal product including information such as product code, brand name and packaging information.

[CDAH-0860] **Dispense Item ID SHALL** contain a unique ID.

[CDAH-0861] The **Dispense Item ID SHALL** contain exactly one [1..1] id/@root that is set to an OID assigned by Health Information Exchange at deployment time to each system issuing Dispense Items to ensure a unique identifier.

[CDAH-0872] A **Quantity SHALL** contain exactly one [1..1] value and **SHALL NOT** be null.

[CDAH-0873] A **Quantity SHALL** contain exactly one [1..1] unit that comes from the "**KSA Medication Quantity Unit"** value set.

[CDAH-0862] **Product SHALL** contain exactly one [1..1] **Medicine entry** with the additional constraints specified in Section 7.7.

[CDAH-0863] A **Reference to Prescription Item SHALL** contain the **Prescription Item ID** and **SHALL NOT** be a complete copy of the Prescription Item by which this dispense was performed.

[CDAH-0864] Reference to Pharmaceutical Advice Item **SHALL NOT** be present.

[CDAH-0865] If Human readable dosage instructions in narrative form are provided, **Patient Medication Instructions SHALL** be present.

[CDAH-0866] The narrative portion of the document the **Patient Medication Instructions** point at **SHALL** contain "Human readable dosage instructions in narrative form" **IF KNOWN**, which should be in language of the patient, without including professional terms such as QID, etc.

[CDAH-0867] The narrative portion of the document the **Patient Medication Instructions** point at **MAY** contain "General comments by the dispenser to the patient", e.g., additional instructions for taking the medicine, etc.

[CDAH-0868] **Dosage Instructions SHALL** be present **IF KNOWN** with the additional constraints specified in Section 7.8.1.

[CDAH-0869] In the case of (structured) dosage instructions are provided, the following additional constraints apply to **Dosage Instructions**:

[CDAH-0954] The sub-elements of Effective Time (Duration of Treatment) **SHALL NOT** be null flavor.

[CDAH-0955] Route of Administration **SHALL** be present and **SHALL** contain a Route of administration code that comes from the "**KSA Medication Route of Administration"** value set.

[CDAH-0905] **Precondition Criterion MAY** be present and conform to the IHE-PHARM TF Supplement: PRE, Section 6.3.4.2.3.18 Precondition Criterion Specification. If present it **SHALL** contain a `<criterion/code>` element containing a code that comes from the "**KSA Medication Frequency Precondition"** value set.

[CDAH-0870] In the case (structured) dosage instructions cannot be provided (e.g., tapered or conditional dosing, etc.), the dosage instructions SHALL be provided as narrative text. See also [CDAH-0865] and [CDAH-0866].

[CDAH-0871] Substitution act **SHALL NOT** be present.

7.10 PHARMACEUTICAL ADVICE ITEM ENTRY

A Pharmaceutical Advice Item belongs to one Pharmaceutical Advice and represents the validation outcome and management command (e.g., change, cancel, etc.) regarding the referenced Prescription- or Dispense Item.

It may be used for two purposes:

- Manage Prescription- and Dispense Items.
- Manage Medication Interaction Checking Issues.

[CDAH-0880] The **Pharmaceutical Advice Item** ID **SHALL** contain a unique ID.

[CDAH-0881] The **Pharmaceutical Advice Item ID SHALL** contain exactly one [1..1] id/@root that is set to an OID assigned by Health Information Exchange at deployment time to each system issuing Pharmaceutical Advice Items to ensure a unique identifier.

[CDAH-0882] A **Reference to Prescription Item SHALL** contain the **Prescription Item ID** and **SHALL NOT** be a complete copy of the Prescription Item by which this Pharmaceutical Advice was performed.

[CDAH-0883] A **Reference to Dispense Item SHALL** contain the **Dispense Item ID** and **SHALL NOT** be a complete copy of the Dispense Item by which this Pharmaceutical Advice was performed.

7.10.1 Additional Constraints for Pharmaceutical Advice Item Used to "Manage Prescription- or Dispense Items"

[CDAH-0884] An **Observation Code** SHALL be set to codes from "KSA Pharmaceutical Advice Observation Code" Value Set.

[CDAH-0885] **Pharmaceutical Advice Concern** entries **SHALL NOT** be present.

[CDAH-0886] **Changed or Recommended Prescription Items SHALL NOT** be present, if the status of the Pharmaceutical Advice (<code> Element) is set to "OK" and a reference to a Prescription Item is given.

[CDAH-0887] Prescription Items provided in **Changed or Recommended Prescription Items SHALL** conform to the additional constraints specified in Section 7.8.

[CDAH-0888] Dosage Instructions provided in **Changed Dosage Instructions SHALL** conform to the additional constraints specified in Section 7.8.1.

[CDAH-0889] In case **Changed Dosage Instructions** are provided, the following additional constraints apply to **Dosage Instructions**:

[CDAH-0952] The sub-elements of Effective Time (Duration of Treatment) **SHALL NOT** be null flavor.

[CDAH-0953] Route of Administration **SHALL** be present and **SHALL** contain a Route of administration code that comes from the "**KSA Medication Route of Administration"** value set.

[CDAH-0906] **Precondition Criterion MAY** be present and conform to the IHE-PHARM TF Supplement: PRE, Section 6.3.4.2.3.18 Precondition Criterion Specification. If present it **SHALL** contain a <criterion/code> element containing a code that comes from the "**KSA Medication Frequency Precondition"** value set.

[CDAH-0907] **Patient Medication Instructions MAY** be present and conform to the IHE-PHARM TF Supplement: PRE, Section 6.3.4.2.3.14 Patient Medication Instructions Specification. If present it **SHALL** contain "Human readable dosage instructions in narrative form" **IF KNOWN**, which should be in language of the patient, without including professional terms such as QID, etc. and **MAY** contain "General comments to the patient", e.g., additional instructions for taking the medicine, etc.

7.10.2 Additional Constraints for Pharmaceutical Advice Item Used to "Manage Medication Interaction Checking Issues"

[CDAH-0890] **Observation Code SHALL** be set to "OK".

[CDAH-0891] **Effective Time** (Date of becoming effective) **SHALL NOT** be present.

[CDAH-0892] One or more [1..*] **Pharmaceutical Advice Concern entries SHALL** be present with the additional constraints specified in Section 7.11.

[CDAH-0893] **Changed or Recommended Prescription Items SHALL NOT** be present.

7.11 PHARMACEUTICAL ADVICE CONCERN ITEM ENTRY

A Pharmaceutical Advice Concern Item belongs to one Pharmaceutical Advice Item and represents the information to concerns (e.g., problems, allergies, etc.) which the Prescription or Dispense Item referenced by the underlying Pharmaceutical Advice Item causes.

[CDAH-0894] The **Pharmaceutical Advice Concern Item ID SHALL** contain a unique ID.

[CDAH-0895] The **Pharmaceutical Advice Concern Item ID SHALL** contain exactly one [1..1] id/@root that is set to an Object Identifier (OID) assigned by Health Information Exchange at deployment time to each system issuing Pharmaceutical Advice Concern Items to ensure a unique identifier.

[CDAH-0896] The **Narrative description** of the **Concern SHALL NOT** be present.

[CDAH-0897] Exactly one [1..1] **Problems determined SHALL** be present with the additional constraints specified in Section 7.3.

[CDAH-0898] An **External Prescription or Dispense Item** triggering the **Concern SHALL NOT** be present.

[CDAH-0899] The **Severity of the concern SHALL** be present.

[CDAH-0900] The value of a **Severity of the concern SHALL** contain a `@code` and `@codeSystem` attribute.

[CDAH-0901] The value of a **Severity of the concern SHALL** contain a Medication Interaction Checking Issue Classification code that comes from the "**KSA Medication Interaction Checking Issue Classification"** value set.

7.12 ALLERGY AND INTOLERANCE ENTRY

[CDAH-0910] An **Allergy and Intolerance Entry SHALL** have exactly one [1..1] **Allergy and Intolerance Entry Cod**e and it **SHALL NOT** be null flavor.

[CDAH-0911] The **Allergy and Intolerance Entry Code SHALL** come from the HL7 Observation Intolerance Type Code System.

[CDAH-0912] An **Allergy and Intolerance Entry SHALL** have exactly one [1..1] **Allergy and Intolerance Entry Substance**.

[CDAH-0920] If the allergy is to a drug, the **Allergy and Intolerance Entry Substance SHALL** be coded using the "**KSA Prescription Pharmacy Item Name"** or "**KSA Dispensation Pharmacy Item Name"** value sets.

[CDAH-0921] If the allergy is to a food product, the **Allergy and Intolerance Entry Substance SHALL** be coded using the "**KSA Food Allergy"** value set.

[CDAH-0922] If the allergy is to a substance other than a drug or food product, the **Allergy and Intolerance Entry Substance SHALL** be coded using the "**KSA Substance Allergy"** value set.

7.13 IMMUNIZATION ENTRY

[CDAH-0932] The value for `@negationInd` on the **Immunization Entry SHALL** be "FALSE" to indicate that the vaccination was administered or "TRUE" if the vaccination was not administered.

[CDAH-1121] The `code` in an **Immunization** entry **SHALL** be set to 'IMMUNIZ' from the HL7 Act Code System.

[CDAH-0933] An **Immunization Entry SHALL** contain an **Immunization Substance** described in the substanceAdministration/consumable/manufacturedProduct element.

[CDAH-0934] The **Immunization Substance SHALL** contain the **Immunization Substance Code** in the manufacturedMaterial/code element indicating the vaccine and which **SHALL** be populated using the "KSA Vaccine Name" value set.

[CDAH-0935] The **Immunization Substance SHALL** contain the **Immunization Substance Name** in the manufacturedMaterial/name element indicating the vaccine.

[CDAH-0936] The **Immunization Substance SHALL** contain the **Immunization Substance Manufacturer** in the `manufacturerOrganization/id` element indicating manufacturer of the vaccine product administered **IF KNOWN** and which **SHALL** be populated using the "KSA Vaccine Manufacturer" value set for new immunization administrations, and for historical immunization information, **MAY** be populated.

[CDAH-0937] The **Immunization Substance SHALL** contain the **Immunization Product Code** in the manufacturedMaterial/ksa:formCode element to indicate the product used for the vaccination which **SHALL** be populated using the "KSA Vaccine Product" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0938] The **Immunization Substance SHALL** contain the **Immunization Substance Lot Number** in the id element indicating the batch number/lot number which **SHALL** be populated using the alphanumeric code assigned by the manufacturer for the product batch/lot used for the vaccine for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0939] The **Immunization Substance SHALL** contain the **Immunization Substance Expiration Date** in the manufacturedMaterial/ksa:expirationTime to indicate the expiration date of the product used for the vaccine which **SHALL** be populated for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0940] The **Immunization Entry SHALL** report the **Immunization Dose** in the substanceAdministration/doseQuantity element for provider-reported vaccinations,

and **SHALL** be submitted using UCUM Units for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0941] The **Immunization Entry SHALL** report the **Immunization Route of Administration** in the routeCode element for provider-sourced vaccination reports, and be **SHALL** populated using the "KSA Vaccine Route Administered" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0942] The **Immunization Entry SHALL** report the **Immunization Site** in the approachSiteCode element if known using the "KSA Vaccine Body Site of Administration" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0943] The **Immunization Entry SHALL** report the date and time that the vaccine was administered in the effective time element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0944] The **Immunization Entry SHOULD** report the reason for immunization given **IF KNOWN** in the `ksa:reasonCode/code` element, which **SHALL** be populated using the "KSA Vaccine Purpose" value set.

[CDAH-0958] The **Immunization Entry SHOULD** report the reason for immunization not given in the `ksa:reasonCode/code` element, which **SHALL** be populated using the "KSA Reason Vaccine Not Given" value set.

[CDAH-0945] The **Immunization Entry SHALL** report the **Immunization Campaign** in the entryRelationship[@typeCode='REFR']/act[@moodCode='DEF'] element if known.

[CDAH-0946] The **Immunization Entry SHALL** report any text description of an **Adverse Immunization Event** in the entryRelationship[@typeCode='CAUS']/observation/text element when there was an adverse event associated with the immunization. This element **SHALL** reference a narrative description of the event.

[CDAH-0946] The **Immunization Entry SHALL** report dose number **IF KNOWN** in the substanceAdministration/entryRelationship/observation/value element where substanceAdministration/entryRelationship/observation/code = '30973-2' codeSystemName='LOINC', using the HESN reported dose for Immunization Summary documents, and Immunization Card documents.

[CDAH-0947] The **Immunization Entry SHALL** report the responsible provider **IF KNOWN** using the author element.

[CDAH-0948] The **Immunization Entry SHALL** report the provider administering the vaccine using the performer element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0949] The **Immunization Entry SHALL** report, for patient supplied information, the informant using the informant element.

[CDAH-0950] The **Immunization Entry SHALL** report the identifier of the responsible provider using the Author Identifier element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0951] The **Immunization Entry SHALL** report the name of the responsible provider using the Author Name element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0520] The **Immunization Entry SHALL** report the specialty of the responsible provider using the Author Specialty element from the "KSA Individual Provider Specialty" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0521] The **Immunization Entry SHALL** report the profession of the responsible provider using the Author Functional Role element from the "KSA Individual Provider Type" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0522] The **Immunization Entry SHALL** report the identifier of the provider administering the vaccine using the Author Identifier element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0523] The **Immunization Entry SHALL** report the name of the provider administering the vaccine using the Author Name element for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0524] The **Immunization Entry SHALL** report the specialty of the provider administering the vaccine using the Author Specialty element from the "KSA Individual Provider Specialty" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

[CDAH-0525] The **Immunization Entry SHALL** report the profession of the responsible provider using the Author Functional Role element from the "KSA Individual Provider Type" value set for new immunization administrations, and for historical immunization information, **SHALL** be populated if known.

8. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this interoperability specification.

TABLE 8-1 INTERNAL REFERENCES

MOH DOCUMENT	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register laboratory orders for the correct patient.
IS0002 Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query	Documents the specification of the content and structure of the Saudi eHealth Healthcare Provider Directory services in support of the Healthcare Provider Directory Query Use Case. This service supports searches for providers and organizations and conveys authoritative attributes related to them. This information describes organizations that provide patient care, such as public and private hospitals, primary care centers, laboratories, pharmacies, etc. It is used by these organizations and by the MOH business applications.
IS0200 Saudi eHealth Terminology Repository.	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.

TABLE 8-2 EXTERNAL REFERENCES

STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	An XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 further builds upon the Version 3.0 Reference Information Model (RIM) Standard. For more information See www.hl7.org/implement/standards/product_brief.cfm?product_id=7
International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com
HL7 Implementation Guide for CDA Release 2 IHE Health Story, Consolidation, Release 1.1 – US Realm	The Consolidated Template implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). For more information See http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
IHE Patient Care Coordination (PCC) Technical Framework Supplement -- CDA Content Modules	This supplement defines a number of PCC content modules that are shared between various content documents. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc

STANDARD	DESCRIPTION
IHE Patient Care Coordination (PCC) Technical Framework – Volume 2 (IHE PCC TF-2) – Section 6 CDA Content Modules	This section defines a number of PCC content modules that are shared between various content documents. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Immunization Content (IC)– Section 6	Immunization Content describes the content and format of documents for exchange of immunization data, including support for reporting vaccinations to the immunization registry, and to communicate the immunization 'card' to the patient. This profile also supports the communication of vaccine forecast. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) Integration Profiles,– Final Text – Cross-Enterprise Sharing of Scanned Documents (Section 5.2 XDS-SD)	A variety of non-formatted healthcare reports, legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order, or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system. It is necessary to provide a mechanism that allows such source metadata to be stored with the document. This profile defines how such information captured can be represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information. Furthermore, this profile defines elements of the CDA R2 header necessary to minimally annotate these documents. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE Pharmacy Prescription (PRE) Content Profile	The Pharmacy Prescription Document Profile (PRE) describes the content and format of a prescription document generated during the process in which a healthcare professional (in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. A prescription is an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient. May be obtained at http://www.ihe.net/Technical_Frameworks/#pharmacy
IHE Pharmacy Dispense (DIS) Content Profile	The Pharmacy Dispense Document Profile (DIS) describes the content and format of a dispense document generated during the process in which a healthcare professional (in most cases, but not necessarily always, a pharmacist) hands out a medication to a patient. May be obtained at http://www.ihe.net/Technical_Frameworks/#pharmacy
IHE Pharmacy Pharmaceutical Advice Content Profile (PADV)	The Pharmacy Pharmaceutical Advice Document Profile (PADV) describes the content and format of a pharmaceutical advice generated during the process in which a healthcare professional (in most cases, but not necessarily always, a pharmacist) validates a Prescription Item of a prescription against pharmaceutical knowledge and regulations. The validation can be with regard to conflicts with other Prescription Items or current medication of the patient or other reasons which affect the further processing of the Prescription Item (may be dispensed with change, etc.). May be obtained at http://www.ihe.net/Technical_Frameworks/#pharmacy

STANDARD	DESCRIPTION
IHE Pharmacy Prescription (PRE) Content Profile	The Pharmacy Prescription Document Profile (PRE) describes the content and format of a prescription document generated during the process in which a healthcare professional (in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. A prescription is an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient. May be obtained at http://www.ihe.net/Technical_Frameworks/#pharmacy
Logical Observation Identifiers, Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC® database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC® database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org

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9. APPENDIX A – CONFORMING EXAMPLES

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.