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 Core Interoperability Specification for ePrescriptions

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Document Revision History

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PREFACE

DOCUMENT PURPOSE

The purpose of this document is to address the Saudi eHealth Core Interoperability Specification for the Prescription Use Case which is specified in UC0008 *Saudi eHealth Medication Interoperability Use Case*. It forms a set of requirements that complements the set of Integrating the Healthcare Enterprise (IHE) Profiles, Health Level 7 (HL7) and vocabulary Standards required by this specification with Saudi Health Information Exchange specific constraints. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

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

HOW TO READ THIS DOCUMENT

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

Section 1: Describes the Use Case, including design constraints and assumptions. Please refer to the UC0008 *Saudi eHealth Medication Interoperability Use Case* for workflows.

Section 2: Establishes the core interoperability requirements for the Interoperability Specification.

Section 3: Defines the conformance requirements for ePrescriptions Actors.

Section 4: Establishes the Saudi eHealth Constraints on ePrescriptions.

Section 5: Lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: illustrates sample documents and messages associated with ePrescriptions.

REFERENCES

The Saudi eHealth Core Interoperability Specification (IS) is the sole entry point for the technology developers, the compliance assessor/testers and certifiers, and the purchasers of IT systems in terms of technical requirements.

It references a number of Supporting Interoperability Specifications:

- IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*
- IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries*
- IS0009 *Saudi eHealth Core Interoperability Specification for eDispensation*
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification*
- *IS0200 Saudi eHealth Terminology Repository.*

The Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints. Further descriptions and references for the documents identified below are provided in Section 5 Referenced Documents and Standards.

This document fits into an overall specification framework described in Figure i-1: ePrescriptions Document Organization.

Implementations are required to conform to the requirements within this Interoperability Specification; all eHealth Information Exchange Platform referenced Interoperability Specifications and the standards and profiles they specify.

Figure Diagram

Related Core Interoperability Specifications	Related Core Interoperability Specifications	Interoperability Use Case
Saudi eHealth Core Interoperability Specification for eDispensation	*Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographics Query*	*Saudi eHealth Medication Use Case*

Related Core Interoperability Specifications
Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries

Core Interoperability Specifications
Saudi eHealth Core Interoperability Specification for ePrescriptions

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Interoperability Specifications
Saudi eHealth Clinical Documents Constrains

Interoperability Specifications
ISO200 Saudi eHealth Terminology Repository

Interoperability Specifications
Saudi eHealth Security and Privacy

Implementation Conformance
Products conform to Use Case Actors For ePrescriptions

Interoperability Specifications
Saudi eHealth Document Sharing

FIGURE I-1: EPRESCRIPTIONS DOCUMENT ORGANIZATION

DESCRIPTION

This Core Interoperability Specification describes the technical interface requirements for sharing electronic Prescriptions (ePrescriptions) through the Health Information Exchange (HIE). This capability is accessible to various "edge" applications including point of service systems and MOH business applications.

ePrescriptions enables Healthcare Providers to record a prescription in an outpatient environment. The prescription conveys information necessary to ensure dispensers have the proper data to fulfill the dispensation including dosing information and additional clinical information to document the rationale behind the prescription as well as to support drug interaction checking. This Interoperability Specification focuses only on the services that need to be standardized at the national level to support the ability to match the medication prescription information by the various "edge" applications connected to the eHealth Information Exchange Platform.

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.

Requirements Language

Throughout this document the following conventions[1] are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification. (Note: "SHALL ...... IF KNOWN" means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>).

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.

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.

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[1] Definitions based upon RFC 2119

METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences. Stakeholders included Physicians and Pharmacists and Saudi eHealth IT specialists.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers should review UC0008 *Saudi eHealth Medication Interoperability Use Case.*

1. USE CASE OVERVIEW

This section provides an overview of the Prescription Use Case. For full details of the Use Case, see UC0008 *Saudi eHealth Medication Interoperability Use Case*.

This section describes the underlying Use Case, including all design constraints and assumptions as well as the flows of information that will be specified in this specification. This section also introduces the scenarios that describe how the specified workflows may be used in the Saudi eHealth context.

1.1 SCOPE

In Scope:

The scope of this document is the specification of recording prescriptions including information relating to dosage, additional clinical information, and relevant drug interaction checking data.

Specification of the content of the ePrescriptions is found in the supporting document: IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specification*.

The following topics are in scope for this Interoperability Specification:

- Prescribing and its electronic documentation.
- Managing Prescriptions Records.
- Content definitions of Prescriptions Records.
- Out-patient prescribing and medication management.
- Medication prescription at in-patient discharge.

Out of Scope:

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

- Content definition of the physical prescription (might be different to the electronic Prescription Record).
- Content definition of the medication list section of the interoperable Electronic Health Record (iEHR) summary.
- In-patient prescribing and medication management.
- The reconciliation of temporary KSA-Wide Health IDs to a patient's permanent KSA-Wide Health ID.
- Requirements for the User Interface for querying and retrieving Prescriptions.
- Requirements for the User Interface for the display of the Prescriptions.
- Requirements for the internal documentation of prescription within a specific Healthcare Organization.

1.2 USE CASE ACTORS AND SERVICES

The Use Case Actors and the Services that are used by this Saudi eHealth ePrescriptions Core Interoperability Specification are described at a functional level in the Saudi eHealth

Interoperability Medication Use Case document. Readers who wish to understand the mapping of Use Case Actors to real world products are recommended to read UC0008 *Saudi eHealth Medication Interoperability Use Case*. A summary is provided in the following tables.

TABLE 1.2-1 USE CASE ACTORS

USE CASE ACTOR NAME	DESCRIPTION
Prescriber	Responsible for the creation of Prescription Records and publishing them to the HIE Document Repository.
HIE Document Repository	Stores Medication records (Prescription Records, Dispensation Records and updates to such records). It also provides access to related information about patients and their medical records (e.g. allergies, lab results, etc.).

How actual implementations support Use Case Actors may vary. For example, some implementations may support a Use Case Actor entirely by a single system design. While other implementations may support a Use Case Actor using a gateway system integrated with the point of service system.

The typical implementation architecture aligns the Use Case Actors capabilities as defined in this Core Interoperability Specification with a single system or integrated set of systems under the design and responsibility of one vendor.

In specific implementation situations the vendor boundary may not align with the Use Case Actor. For example, a point of service system is from one vendor, while a gateway system which converts the point of service system to the Use Case Actor is from a different vendor. The interface between the two systems is not specified by this Core Interoperability Specification and is the responsibility of the implementation project.

TABLE 1.2-2 USE CASE SERVICES

SERVICE NAME	DESCRIPTION
Create/Manage Prescription	Used to create a prescription and publish it to the HIE Document Repository as well to submit changes to a prescription (e.g. cancel Prescription Item, change Prescription Item, etc.).
Create/Manage Dispensation (See Note)	Creates a Dispensation Record and publishes it to the HIE Document Repository as well as to submit changes to a Dispensation Record (e.g. to stop intake of a Dispensation Item, to change dosage of a Dispensation Item, etc.).
Query/Retrieve Medication Records	Queries and Retrieves relevant Medication Records and all related records (e.g., updates) from the HIE Document Repository.

Note: Only Prescriber Use Case Actors are allowed to Manage Dispensation.

1.3   DESIGN CONSTRAINTS AND ASSUMPTIONS

The following design principles underlie this interoperability specification:

- It is expected that all services initiated or provided by these Actors operate in accordance to UC0303 *Saudi Health Information Exchange Polices*.
- Temporary KSA-Wide Health IDs can be created to enable the recording of Prescriptions.
- A permanent KSA-Wide Health ID can be created for a newborn.
- A KSA Healthcare Provider and/or Organization can synchronize with the iEHR On-Demand Summaries from the HIE Document Repository.
- Medication Interaction Checking is performed by the HIE Document Repository when receiving a submitted medication document.

2. CORE INTEROPERABILITY SPECIFICATION REQUIREMENTS

2.1 ACTOR MAPPING TO SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a Use Case Actor. A system may claim conformance to one or more Use Case Actors. Multiple systems may fulfill a single Use Case Actor.

The Use Case Actors and the Services they support are described at a functional level in the UC0008 *Saudi eHealth Medication Interoperability Use Case*. Services may be required, conditional or optional. The Use Case Actors, Service(s) and Optionality are conveyed in the first three columns of Interoperability Conformance Requirement tables shown below.

The second part of the table (columns 4-7) provides the mapping for the Use Case Actor to the detailed specifications (such as IHE Profiles, Technical Actors, Optionality) that systems shall implement to exchange healthcare information in the context of this Use Case.

For a selected Use Case Actor (a single row in the table), all the requirements listed in the second part of the table (columns 4-7) shall be implemented. This includes the referenced profiles and the standards specified (terminology or other).For each Technical Actor (whether required or optional), the last column references the detailed specification that constrain and extend of the implementation of this profile for KSA specific requirements. These specifications may be found in Sections in this core specification or in other referenced Saudi eHealth Interoperability Specifications (e.g. Saudi eHealth Security and Privacy Interoperability Specification, etc.).

TABLE 2.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR PRESCRIBER

SHARING IMAGES AND IMAGING REPORTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Prescriber	Create/Manage Prescriptions	R	Prescription Placer (grouped with a Medication Interaction Reporter Actor)	R	IHE Community Medication Prescription and Dispense (CMPD)	Sections 4.1.1 and 4.1.3 IS0200 Saudi eHealth Terminology Repository
			Content Creator	R	IHE Pharmacy Prescription (PRE)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Section 5.6 IS0200 Saudi eHealth Terminology Repository
			Pharmaceutical Adviser (grouped with a Medication Interaction Reporter Actor)	R	IHE - Community Medication Prescription and Dispense (CMPD)	Sections 4.1.2 and 4.1.3 IS0200 Saudi eHealth Terminology Repository

			Content Creator	R	IHE Pharmacy Pharmaceutical Advice (PADV)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Section 5.8
						IS0200 Saudi eHealth Terminology Repository
			Document Source (grouped with a Document Administrator Actor)	R	IHE Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2
						IS0200 Saudi eHealth Terminology Repository
						IS0200 Saudi eHealth Terminology Repository
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Query/Retrieve Medication Records	R	Prescription Placer	R	IHE - Community Medication Prescription and Dispense (CMPD)	IS0009 Saudi eHealth Core Interoperability Specification for eDispensation – Section 4.1.3
						IS0200 Saudi eHealth Terminology Repository
			Content Consumer	R	IHE Pharmacy Prescription (PRE)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Section 5.6
						IS0200 Saudi eHealth Terminology Repository
			Content Consumer	R	IHE Pharmacy Pharmaceutical Advice (PADV)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Section 5.8
						IS0200 Saudi eHealth Terminology Repository
			Content Consumer	R	IHE Pharmacy Dispense (DIS)	IS0106 Saudi Clinical Documents Constrains Interoperability Specifications – Section 5.7
						IS0200 Saudi eHealth Terminology Repository

			Document Consumer	R	IHE Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository
			X-Service User	R	IHE Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Create/Manage Dispensation (See Note)	R	Pharmaceutical Adviser (grouped with a Medication Interaction Reporter Actor)	R	IHE - Community Medication Prescription and Dispense (CMPD)	IS0009 Saudi eHealth Core Interoperability Specification for eDispensation - Sections 4.1.2 and 4.1.4 IS0200 Saudi eHealth Terminology Repository
			Content Creator	R	IHE Pharmacy Pharmaceutical Advice (PADV)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Section 5.8 IS0200 Saudi eHealth Terminology Repository
			Document Source (grouped with a Document Administrator Actor)	R	IHE Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

| Prescriber (grouped with Clinical Content Consumer) | iEHR On-demand summary | R | NA | NA | NA | IS0007 Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries – Section 3.4 and 4.1 |

R=Required, O = Optional, C= Conditional

Note: Only Prescriber Use Case Actors are allowed to Manage Dispensation.

TABLE 2.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR HIE DOCUMENT REPOSITORY

E-DISPENSATION			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
HIE Document Repository	Create/Manage Prescriptions	R	Document Repository (grouped with Medication Interaction Checking Actor)	R	IHE Cross-Enterprise Document Sharing (XDS.b)	Section 4.2.2 IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Query/Retrieve Medication Records	R	Community Pharmacy Manager	R	IHE - Community Medication Prescription and Dispense (CMPD)	Section 4.2.1 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository

E-DISPENSATION			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Document Registry and Document Repository	R	IHE Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository
			X-Service Provider	R	IHE Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Create/Manage Dispensations	R	Document Repository (grouped with Medication Interaction Checking Actor)	R	IHE Cross-Enterprise Document Sharing (XDS.b)	Section 4.2.2 IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4 IS0200 Saudi eHealth Terminology Repository IS0200 Saudi eHealth Terminology Repository
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

2.2 INTEROPERABILITY SEQUENCE DIAGRAMS

The following Sequence diagrams provide an overview of the combined flow of transactions resulting from the above selected profiles and standards. The Main Flow Sequence Diagram illustrates a very common (i.e., typical) workflow and other sequence diagrams are shown to provide an alternative or exception to the main flow. Other sequence diagrams are possible but they cover the same key transactions with only slight variants of information exchange between the Use Case Actors, therefore, have been omitted.

The ePrescriptions sequence diagrams provide a high level sequence of events for the exchange of information for recording a patient's prescription. It also illustrates typical security exchanges for authorized network communications and audit trail of patient information access.

There is one Main Flow Sequence Diagram, one Alternative, and two Exception Flow Sequence Diagrams. In addition, a number of pre-conditions and other requirements exist.

2.2.1   Sequence Diagram Pre-conditions

A number of pre-conditions must exist in order to enable the main, alternative and exception sequence diagrams.

1.   Prior to querying/retrieving documents from the HIE Document Repository or creating documents to share on the HIE Document Repository; the Healthcare Provider or Organization shall obtain the KSA-Wide Health ID. The requirements on how to obtain a patient's KSA-Wide Health ID and key patient demographics are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

2.   The Health ID and key patient demographics attributes are used to identify the patient for which the prescriptions and medications are shared. This ensures KSA-Wide identification of the patient in health records. This is not shown in any of the sequence diagrams, and the details to accomplish this are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

3.   The IHE XDS.b: [Register Document Set – b ITI-42] transaction is listed without first performing the authentication between the Document Repository and Registry systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that those two systems are implemented within the same system. If these Actors are implemented in separate systems, the authentication transaction would be required.

4.   When querying and retrieving medication documents, the [IHE CMPD Profile: Query Pharmacy Documents PHARM-1] and [IHE XDS-b: Retrieve Document Set ITI-43] transitions are listed without first performing the authentication between the two systems (e.g. an edge system and the HIE Document Repository) [IHE ATNA Profile: Authenticate Node ITI-19]. The IHE ATNA transaction is required to be performed.

The following transactions must occur prior to the start of the main, alternative or exception Sequences:

1.   Time synchronization shall occur at least once prior to communicating between the HIE Document Repository and the Prescriber.

2.   Before the information exchanges can take place, an authentication process takes place between the Prescriber/Secure Node Actor and the HIE Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

    Note: It is assumed that once a secure connection has been established, it will be maintained. If this is not the case, then an additional authentication transaction will need to occur before continuing any exchange transactions.

Figure 2.2-1 Pre-condition Sequence Diagram depicts the pre-condition in the case that the Prescriber is acting as a Prescription Placer.
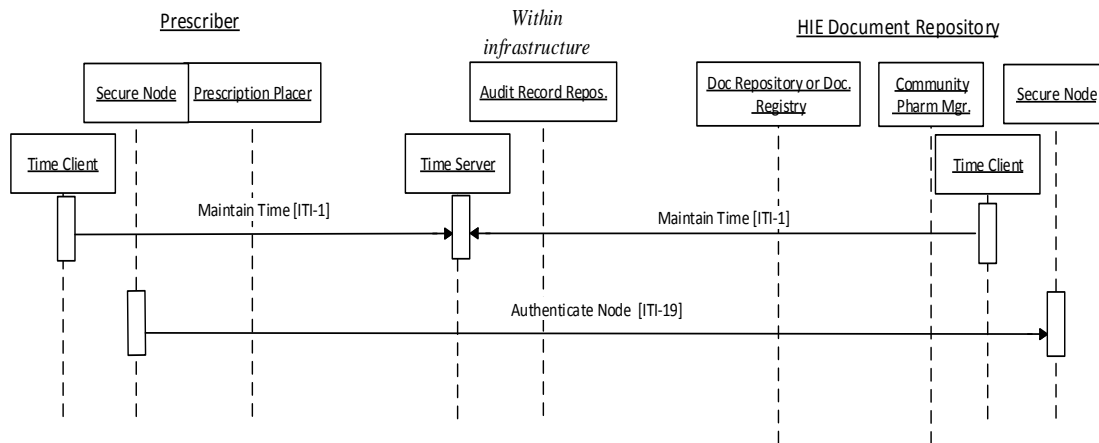

FIGURE 2.2-1 PRE-CONDITION SEQUENCE DIAGRAM

2.2.2   Other Sequence Diagram Requirements

In order to simplify the sequence diagrams, the following transaction pairing should be taken into account.

2.2.2.1   Publish Medication Document(s) to the HIE Document Repository

Figure 2.2-2 Transactions associated with Publish Medication Document and the text below depicts the transactions associated with storage of medication document(s) (i.e. Prescription Records, Dispensation Records, Update Records, and Medication Interaction Checking Issue Management Records) to the HIE Document Repository. When document(s) are stored to the Document Repository, the following transactions must all take place:

1.   The Prescriber/Document Source publishes the medication document to the HIE Document Repository/Document Repository using [IHE XDS.b: Provide & Register Document Set ITI-41].

2.   The Prescriber/Secure Node generates a local audit record of the release of patient health information [using the data content as defined by IHE ATNA and IHE XDS.b Profiles].

3.   The HIE Document Repository registers the medication document with the Document Registry [IHE XDS.b: Register Document Set – b ITI-42].

4. The HIE Document Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
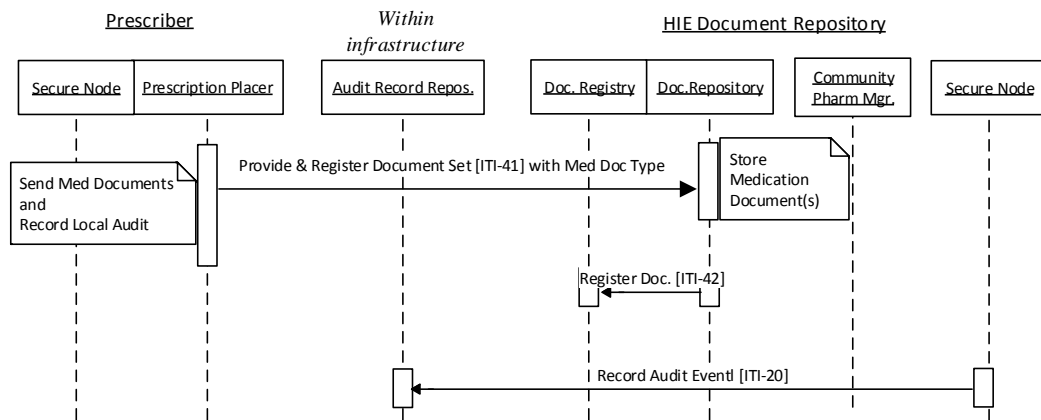

FIGURE 2.2-2 TRANSACTIONS ASSOCIATED WITH PUBLISH MEDICATION DOCUMENT

2.2.2.2   Query/Retrieve Medication Documents from the HIE Document Repository

In order to obtain a patient's medication records, the Prescription or Dispensation Records and all related records from the HIE Document Repository are queried and retrieved using the Prescriber Actor.

The Query/Retrieve Medication sequence flow diagram and the text depicting querying and retrieving Prescription and Dispensation Records and all related records (e.g., updates) from the HIE Document Repository are defined in the IS0009 *Saudi eHealth Core Interoperability Specification for eDispensation* document.

The main flows for querying and retrieving medication records are:

- Query Prescription or Dispensation Records from the HIE Document Repository.
- Identify the Prescription or Dispensation Records in the search result.
- Retrieve the Prescription or Dispensation Records and all related records from the HIE Document Repository and processing them (i.e., apply to each prescription or dispensation the updates from related pharmaceutical advices to present the most current view).

2.2.2.3   iEHR on-Demand Summary

In order to obtain the patient's summary record, the Interoperable Electronic Health Record (iEHR) summaries containing clinical data from all of the patient's visits since the last patient visit are queried and retrieved using the Clinical Content Consumer Actor. This is called iEHR on-demand summary.

The Prescriber Actor is grouped with the Clinical Content Consumer Actor to obtain the iEHR on-demand summary document. The requirements on how to obtain the iEHR summary are defined in the IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* document.

Example usage of the iEHR Summary:

- Review patient's current medication list.
- Use medication information of the iEHR summary to perform medication reconciliation (e.g. systematic evaluation of a patient's complete medication regime including information about Immunizations and Allergies).

2.2.3 Main Flow Sequence Diagram – Prescription Based upon a Patient's Encounter

The main flow sequence diagram and the text below depict documenting the prescription of medication to a patient. The patient is being given a prescription based upon the purpose of his/her encounter.

The main flows are:

- Obtain the patient's medication history and possibly perform medication reconciliation.
- Submit the Prescription Record to the HIE Document Repository.
- HIE Document Repository performs Medication Interaction Checking which does not determine errors, warnings or informational issues only.

Note: If issues are discovered during Medication Interaction Checking, the submission of the Prescription Record will be rejected and the issues found returned, this results either in a change of the Prescription or in the acceptance of the issues by the Healthcare Provider (this scenario will be addressed in the Exception flow sequence diagram).

Note: The Use Case Services are actually implemented using the underlying transaction(s) defined by the Profiles or Standards selected. Therefore, the Use Case Services are not depicted directly in the sequence diagrams.

Steps 1 – 5 related to the prescription of medication are shown in Figure 2.2-3Transactions associated with Prescribe Medication – Prescription Based upon the Purpose of a Patient's Encounter.

1. The patient visits a Healthcare Provider or Organization for an encounter and is prescribed medication. The patient's KSA-Wide Health ID is obtained to manage the patient's medical records. See pre-conditions described in Section 2.2.1.
2. The Prescriber/Clinical Content Consumer Actor queries and retrieves the patient's iEHR on-demand summary document from the HIE Document Repository. The Healthcare Provider may perform Medication Reconciliation. Obtaining the iEHR on-Demand Summary is described in Section 2.2.2.3 …
3. The prescription is recorded in the local Point of Service system and a Prescription Record is created. The Prescriber/Prescription Placer Actor publishes the Prescription Record(s) [IHE XDS.b: Provide & Register Document Set ITI-41] to the HIE Document Repository (see Section 2.2.2.1 Publish Medication Document(s) to the HIE Document Repository Publish Medication Document(s) to the HIE Document Repository for the full set of transactions).
4. The HIE Document Repository performs Medication Interaction Checking based upon the Prescription Record(s). No issues are found and the Prescription Record(s) are successfully published to the HIE Document Repository with no errors.
    Note: The Medication Interaction Checking service may also respond with "informational text". This does not change the sequence flow as it is considered a successful response.

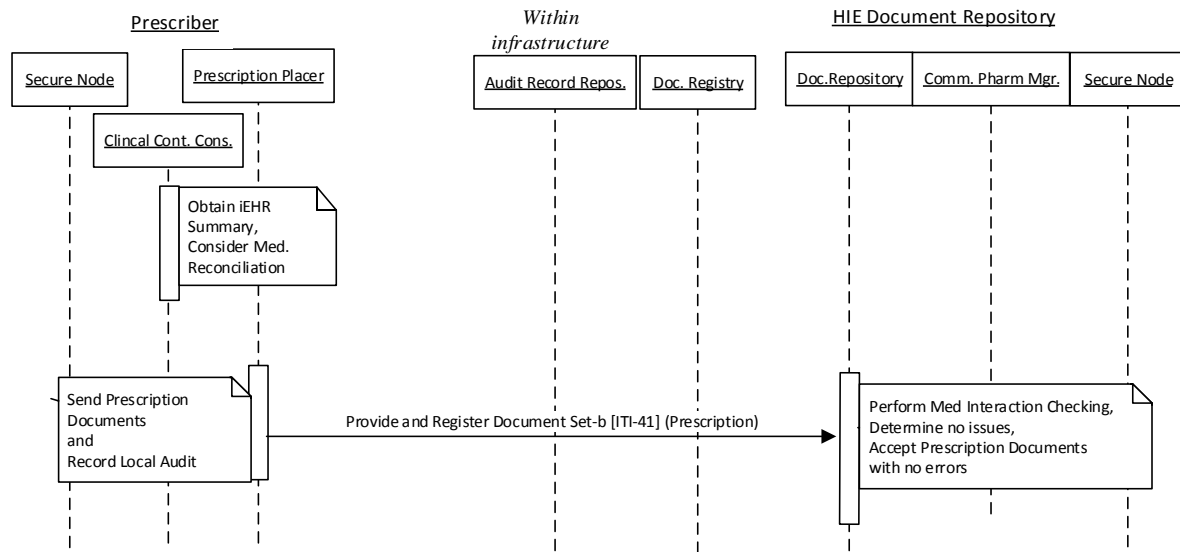5. The Healthcare Provider issues the prescription to the patient.

FIGURE 2.2-3TRANSACTIONS ASSOCIATED WITH PRESCRIBE MEDICATION – PRESCRIPTION BASED UPON A PATIENT'S ENCOUNTER

2.2.4   Alternate Flow Sequence Diagram – Manage Prescription Record

The alternate flow sequence diagram and the text below depict managing the Prescription Record by making changes such as:

- Change Prescription Item
- Cancel Prescription Item
- Set Prescription Item to suspended
- Set Prescription Item to active

The alternate flows are:

- Manage Prescription Item in local system
- Local Point of Service system creates the update to the Prescription Record
- Submit the update to the HIE Document Repository

Note: The Use Case Services are actually implemented using the underlying transaction(s) defined by the Profiles or Standards selected. Therefore, the Use Case Services are not depicted directly in the sequence diagrams.

Steps 1 – 2 related to the management of Prescription Records are shown in Figure 2.2-4 Transactions associated with managing the Prescription Record.

1. The update to the Prescription Record is recorded in the local Point of Service system and an Update Record (see *IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specification* – Section 5.8) is created containing a reference to the Prescription Record. The Prescriber/Prescription Placer Actor publishes the Update Record [IHE XDS.b: Provide & Register Document Set ITI-41] to the HIE Document Repository. See Section **Error! Reference source not found.** Publish Medication Document(s) to the HIE Document Repository for the full set of transactions.

2. The HIE Document Repository performs Medication Interaction Checking based upon the updated Prescription Record. No issues are found and the Update Record is successfully published to the HIE Document Repository with no errors.
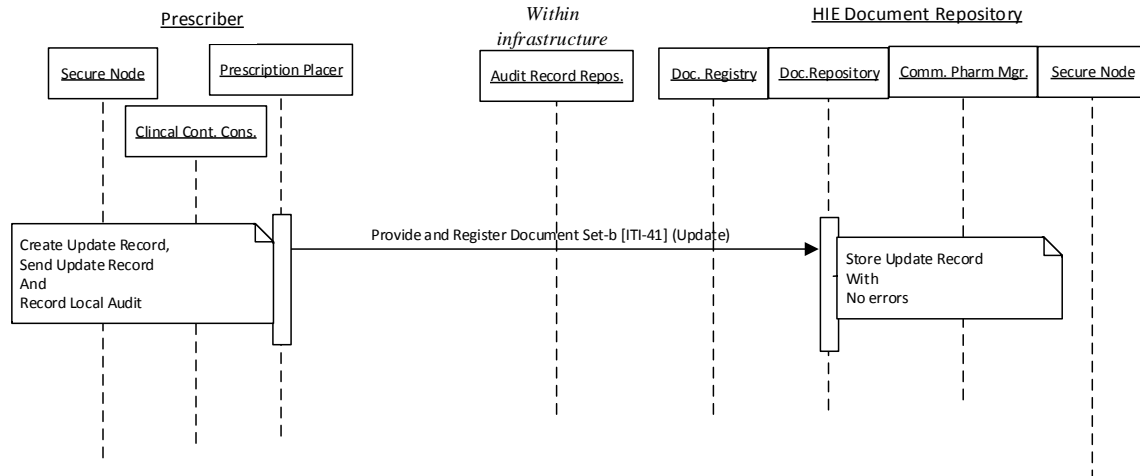

FIGURE 2.2-4 TRANSACTIONS ASSOCIATED WITH MANAGING THE PRESCRIPTION RECORD

2.2.5 Exception Flow Sequence Diagram – Medication Interaction Checking Determines Errors or Warnings

The exception flow sequence diagram and the text below depict the prescription of medication to a patient with the Medication Interaction Checking service finding errors.

The exception flows are based on the main flow with the following differences:

- At submission of the Prescription Record, the HIE Document Repository performs Medication Interaction Checking which determines errors or warnings.
- After the Healthcare Provider examines the issues, the Prescription is either changed or the issue is accepted. If the Healthcare Provider accepts the issues, Issue Management Record(s) are created to document the reason(s) why the issues are accepted.
- The same or updated Prescription Record is submitted with a Medication Interaction Checking Issue Management Record to document the reasons for the creating the prescription.
- The HIE Document Repository performs Medication Interaction Checking which determines errors or warnings, which the HIE Document Repository now identifies as accepted by the Healthcare Provider (via the Issue Management Records). Thus, the Prescription Record is successfully published to the HIE Document Repository with no errors.

Note: The Use Case Services are actually implemented using the underlying transaction(s) defined by the Profiles or Standards selected. Therefore, the Use Case Services are not depicted directly in the sequence diagrams.

Steps 1 – 3 are identical to Steps 1 – 3 of the main flow sequence (see Section 2.2.3 Main flow sequence diagram – Prescription based upon the purpose of a patient's encounter) and are not shown in this diagram.

Steps 4 – 7 related to the prescription of medication are shown in **Error! Reference source not found.**.

4. The HIE Document Repository performs Medication Interaction Checking based upon the Prescription Record. One or more issues of class "Error" or "Warning" are found and the Prescription Record is rejected with specified Medication Interaction Checking error codes returned for each issue found.
5. The Healthcare Provider reviews the Medication Interaction Checking Issues contained in the error code information and decides to accept the issues (i.e. medication should still be prescribed to the patient). The reasons for prescribing the medication are recorded in the local Point of Service system and Medication Interaction Checking Issue Management Record(s) are created (see *IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specification* – Section 5.8). The Prescriber/Prescription Placer Actor publishes the same or updated Prescription Record and the Medication Interaction Checking Issue Management Record together using [IHE XDS.b: Provide & Register Document Set ITI-41] to the HIE Document Repository. See Section 2.2.2.1 Publish Medication Document(s) to the HIE Document Repository for the full set of transactions.
6. The HIE Document Repository performs Medication Interaction Checking based upon the Prescription Record. One or more issues of class "Error" or "Warning" are found, which the HIE Document Repository now can successfully map to related Medication Interaction Checking Issue Management Records. Thus, the Prescription and all related Medication Interaction Checking Issue Management Records are successfully published to the HIE Document Repository with no errors.
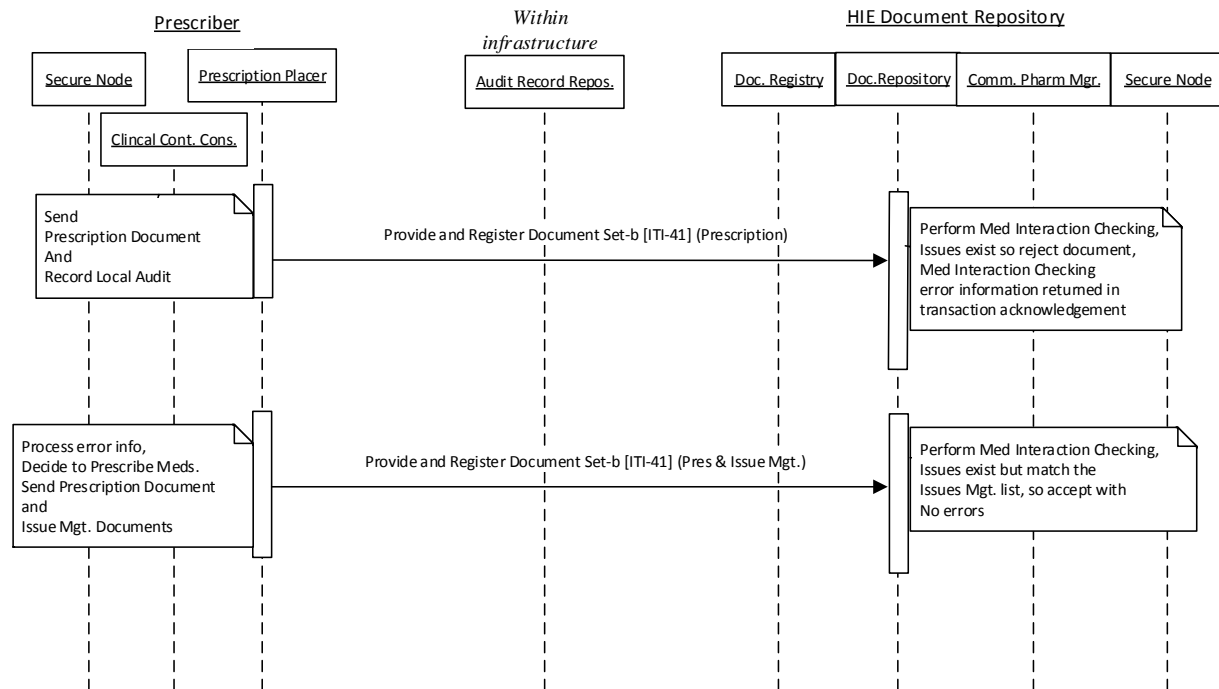7. The Healthcare Provider issues the prescription to the patient.

FIGURE 2.2-5 TRANSACTIONS ASSOCIATED WITH PRESCRIBE MEDICATION – MEDICATION INTERACTION CHECKING DETERMINES ERRORS OR WARNINGS

2.2.6   Exception Flow – Revoke Prescription Record

The exception flow sequence diagram and the text below depict revoking the prescription of medication already submitted to the HIE Document Repository (e.g., in case of error).

The exception flows are based on the main flow with the following differences:

- After submitting the Prescription Record to the HIE Document Repository, the Healthcare Provider decides to revoke the prescription in the local Point of Service system.
- The Healthcare Provider sends request to the HIE Document Repository to delete the Prescription Record in the HIE Document Repository.

Steps 1-3 are identical to Steps 1-3 of the main flow sequence (see Section **Error! Reference source not found.**) and are not shown in this diagram.

Steps 4-5 related to the revoking of prescriptions are shown in**Error! Reference source not found.**.

4. The Healthcare Provider decides to revoke a prescription in the local Point of Service system and HIE Document Repository due to an error. The Prescriber/Prescription Placer Actor sends request to the HIE Document Repository to delete the Prescription Record [IHE XDS.b Supplement: Metadata Update: Delete Document Set Request ITI-62] in the HIE Document Repository (see Section 4.1.1 for the constraints of deleting prescriptions).

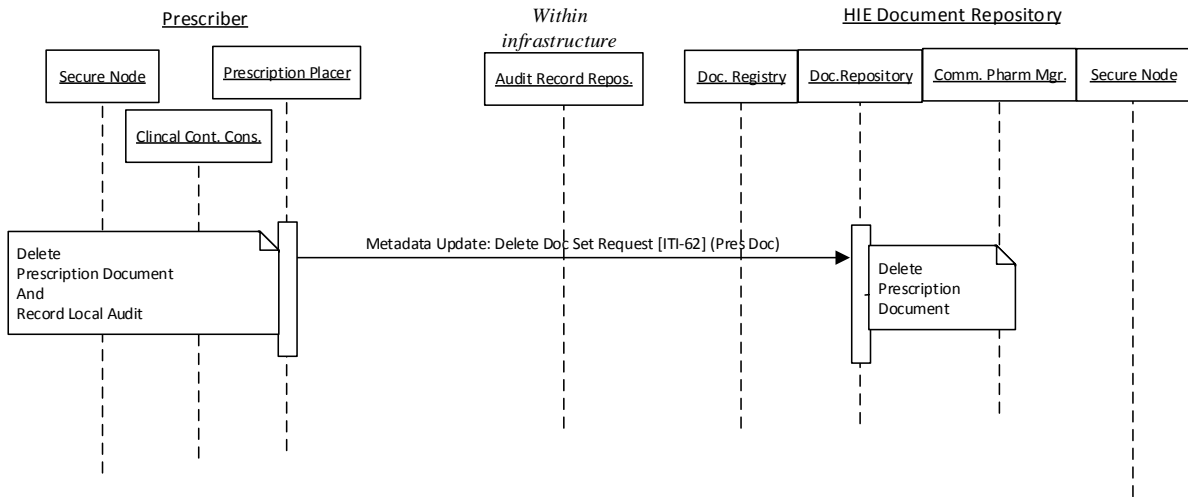5. The Healthcare Provider revokes the prescription.

FIGURE 2.2-6 TRANSACTIONS ASSOCIATED WITH REVOKING A PRESCRIPTION RECORD

3. ePrescriptions Actor Conformance

This section is designed to establish the Conformance Requirements for the Interoperability Specification.

It maps one to one, with the tables in section 2.1.

3.1 Prescriber Conformance

Systems may claim conformance to the IS0008 *Saudi eHealth Core Interoperability Specification for ePrescriptions* as a Prescriber as follows:

*"*ePrescriptions Prescriber Actor*"*

This requires:

➢ supporting the Create/Manage Prescriptions Service by conforming to:

[KPRE-001] – IHE Community Medication Pharmacy Prescription and Dispense (CMPD) as a Prescription Placer Actor (grouped with a Medication Interaction Reporter Actor) with the additional constraints specified in:

- Section 4.1.1 and 4.1.3
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-002] – IHE Pharmacy Prescription (PRE) as a Content Creator Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.6*
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-003] – IHE Community Medication Prescription and Dispense (CMPD) as a Pharmaceutical Adviser Actor (grouped with a Medication Interaction Checking Reporter Actor) with the additional constraints specified in:

- Sections 4.1.2 and 4.1.3
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-004] – IHE Pharmacy Pharmaceutical Advice (PADV) as a Content Creator Actor with additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.8*
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-005] – IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Source Actor (grouped with a Document Administrator Actor) with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-006] – IHE - Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.2

[KPRE-007] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ supporting the Query/Retrieve Medication Records Service by conforming to:

[KPRE-008] – IHE Community Medication Pharmacy Prescription and Dispense (CMPD) as a Prescription Placer Actor with the additional constraints specified in:

- IS0009 *Saudi eHealth Core Interoperability Specification for eDispensation* - Section 4.1.3
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-009] – IHE Pharmacy Prescription (PRE) as a Content Consumer Actor with the additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.6
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-010] – IHE Pharmacy Pharmaceutical Advice (PADV) as a Content Consumer Actor with additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.8
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-011] – IHE Pharmacy Dispense (DIS) as a Content Consumer Actor with additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* – Section 5.7
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-012] – IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.3
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-013] – IHE Cross-Enterprise User Assertion (XUA) Integration Profile as an X-Service User Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1

[KPRE-014] – IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.2

[KPRE-015] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ supporting the Create/Manage Dispensation Service by conforming to:

[KPRE-016] – IHE Community Medication Pharmacy Prescription and Dispense (CMPD) as a Pharmaceutical Adviser Actor (grouped with a Medication Interaction Reporter Actor) with the additional constraints specified in:

- Section 4.1.3
- IS0009 *Saudi eHealth Core Interoperability Specification for eDispensation* - Section 4.1.2
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-017] – IHE Pharmacy Pharmaceutical Advice (PADV) as a Content Creator Actor with additional constraints specified in:

- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.8
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-018] – IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Source Actor (grouped with a Document Administrator Actor) with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-019] – IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.2

[KPRE-020] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

Note: Only Prescriber Use Case Actors are allowed to Manage Dispensation.

➢ supporting the iEHR On-Demand Summary by conforming to:

[KPRE-021] – The Prescriber Actor is grouped with the Clinical Content Consumer Actor. IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* – Section 2.1 and 3.3.

3.2 HIE DOCUMENT REPOSITORY CONFORMANCE

Systems may claim conformance to the IS0008 *Saudi eHealth Core Interoperability Specification for ePrescriptions* as an HIE Document Repository as follows:

"ePrescriptions HIE Document Repository Actor"

This requires:

➢ supporting the Create/Manage Prescriptions Service by conforming to:

[KPRE-022] – IHE Cross-Enterprise Document Sharing (XDS.b) as a Document Repository Actor (grouped with a Medication Interaction Checking Actor) with additional constraints specified in:

- Section 4.2.2
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-023] – IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1

[KPRE-024] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ supporting the Query/Retrieve Medication Records Service by conforming to:

[KPRE-025] – IHE Community Medication Pharmacy Prescription and Dispense (CMPD) as a Community Pharmacy Manager Actor with the additional constraints specified in:

- Section 4.2.1
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-026] – IHE Cross-Enterprise Document Sharing (XDS.b) as a Document Registry and Document Repository Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-027] – IHE Cross-Enterprise User Assertion (XUA) Integration Profile as an X-Service Provider Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2

[KPRE-028] – IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1

[KPRE-029] – IHE - Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ supporting the Create/Manage Dispensations Service by conforming to:

[KPRE-030] – IHE Cross-Enterprise Document Sharing (XDS.b) as a Document Repository Actor (grouped with Medication Interaction Checking Actor) with additional constraints specified in:

- Section 4.2.2
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- *IS0200 Saudi eHealth Terminology Repository*

[KPRE-031] – IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1

[KPRE-032] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

4. SAUDI EHEALTH CONSTRAINTS ON EPRESCRIPTIONS

This section defines required behavior rules for Use Case Actors defined in this Core Interoperability Specification.

4.1 REQUIREMENTS FOR PRESCRIBER USE CASE ACTOR

[KPRE-033] – The Prescriber Actor is grouped with the Clinical Content Consumer Actor to query an iEHR on-demand Summaries Documents based upon IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries* – Sections 2.1 and 3.3.

[KPRE-034] –A Prescriber Actor/Document Consumer **SHALL** be able to process and display the iEHR on–demand Summaries Documents as specified in IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* – Section 5.5.

4.1.1 Prescription Placer Technical Actor

The following rules shall be supported for the conformance to the Prescriber Actor as a Prescription Placer Technical Actor (grouped with a Medication Interaction Reporter Actor):

[KPRE-035] – A Prescriber Actor **SHALL** publish Prescription Documents with content as specified in IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* – Section 5.6.

[KPRE-036] –The XDS Metadata associated with creating a Prescription Document is defined in two parts. The non-medication prescription specific metadata are specified in the document – IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 3.2.1. The medication prescription specific extensions **SHALL** meet the following additional constraints:

> [KPRE-037] – The classCode attribute **SHALL** contain one coded value which **SHALL** be "PRESCRIPTIONS".
> [KPRE-038] – The practiceSetting attribute **SHALL** contain one coded value from the "KSA Organization Specialty".
> [KPRE-039] – The typeCode Attribute **SHALL** be set to "57833-6, LOINC, Prescriptions".
> [KPRE-040] – The mimeType attribute **SHALL** contain one coded value which **SHALL** be "text/xml".
> [KPRE-041] – The formatCode attribute **SHALL** contain one coded value which **SHALL** be "urn:ihe:pharm:pre:2010" for the Pharmacy Prescription.

[KPRE-042] – If a Prescription Document has been published with an error (e.g. assigned to an incorrect patient, etc.), a Prescriber Actor (Document Source of the IHE-XDS Profile grouped with a Document Administrator Actor-See KXDS-072 in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*) **SHALL** correct the error by using the [IHE XDS.b Supplement: Metadata Update: Delete Document Set Request ITI-62] to delete the original Prescription Document.

[KPRE-060] – Prescription Documents **SHALL NOT** be deleted, if related Pharmaceutical Advice Documents and/or related Dispensation Documents exist.

[KPRE-043] – When generating Prescription Documents (as a Prescription Placer Actor) and Pharmaceutical Advice Documents (as a Pharmaceutical Adviser Actor) as a result of Medication Interaction Checking Issue Management, the Prescriber Actor **SHALL** publish the documents to the HIE Document Repository using the same [IHE XDS.b: Provide & Register Document Set ITI-41] transaction.

4.1.2   Pharmaceutical Adviser Technical Actor

The following rules shall be supported for the conformance to the Prescriber Actor as a Pharmaceutical Adviser Technical Actor (grouped with a Medication Interaction Reporter Actor):

[KPRE-044] – A Pharmaceutical Adviser Actor **SHALL** publish Pharmaceutical Advice Documents with content as specified in IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* – Section 5.8.

[KPRE-045] –The XDS Metadata associated with creating a Pharmaceutical Advice Document is defined in two parts. The non-pharmaceutical advice specific metadata are specified in the document – IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 3.2.1. The medication prescription specific extensions **SHALL** meet the following additional constraints:

> [KPRE-046] – The classCode attribute **SHALL** contain one coded value which **SHALL** be "PRESCRIPTIONS".
> [KPRE-047] – The practiceSetting attribute **SHALL** contain one coded value from the "KSA Organization Specialty".
> [KPRE-048] – The typeCode Attribute **SHALL** be set to "61356-2, LOINC, Medication Pharmaceutical Advice".
> [KPRE-049] – The mimeType attribute shall contain one coded value which **SHALL** be "text/xml".
> [KPRE-050] – The formatCode attribute **SHALL** contain one coded value which **SHALL** be "urn:ihe:pharm:padv:2010" for the Pharmacy Pharmaceutical Advice.

4.1.3   Medication Interaction Reporting

The Medication Interaction Reporter Technical Actor is grouped with the Prescription Placer and Pharmaceutical Adviser Technical Actors shown in Table 2.1-1 Interoperability conformance requirements for Prescriber. It uses the information returned by the [IHE XDS.b: Provide and Register Document Set-b ITI-41] transaction when present to inform the prescriber about the results of Medication Interaction Checking performed by the HIE Platform at the time of submission of the Prescription or Update Record.

[KPRE-051] – The Medication Interaction Reporter Technical Actor **SHALL** be grouped with the Prescription Placer and Pharmaceutical Adviser Technical Actors and use the information returned in the [IHE XDS.b: Provide and Register Document Set-b ITI-41] transaction response to report to its users zero or more medication interaction issues detected. The information contained in each <RegistryError> element **SHALL** be presented to the user for each Medication Interaction Checking Issue found (See [KDIS-080] for the format of the issues reported).

[KPRE-052] – The [IHE XDS.b: Provide and Register Document Set-b ITI-41] transaction may succeed or fail based on the outcome of the issues detected by medication interaction

checking. The Prescription Placer and Pharmaceutical Adviser **SHALL** implement all cases specified in Table 4.2-3 impact of medication interactions on the Provide and Register Transaction below.

[KPRE-053] – When a transaction [IHE XDS.b: Provide and Register Document Set-b ITI-41] has failed due to issues detected by Medication Interaction Checking, the Medication Interaction Reporter Actor grouped with the Prescription Placer Actor **SHALL** implement a means for the Healthcare Provider to examine the issues and decide either in a change of the Prescription or in the acceptance of the issues. In case the Healthcare Provider decides to accept the issues, the Healthcare Provider **SHALL** have a mean to document the reasons why the issues are accepted in Medication Interaction Checking Issue Management Records. The same or updated Prescription Record **MAY** be re-submitted together with all Medication Interaction Checking Issue Management Records related to it.

4.2   REQUIREMENTS FOR HIE DOCUMENT REPOSITORY USE CASE ACTOR

4.2.1   Community Pharmacy Manager Technical Actor

The following rules shall be supported for the conformance to the Community Pharmacy Manager Actor:

[KPRE-054] – When responding to a query, a Document Registry **SHALL** be able to support the return of several medication documents for the same patient.

[KPRE-055] – The following stored queries **SHALL** be supported by the Document Registry:

> FindPrescriptions
>
> FindDispenses
>
> FindPrescriptionsForDispense

4.2.2   Medication Interaction Checking

The Medication Interaction Checking Technical Actor is grouped with the Document Repository Technical Actor. It performs Medication Interaction Checking and communicates the results by the [IHE XDS.b: Provide and Register Document Set-b ITI-41] transaction when issues have been detected to inform the prescriber.

[KPRE-056]- The Medication Interaction Checking Technical Actor **SHALL** be grouped with the Document Repository Technical Actor and return in the [IHE XDS.b: Provide and Register Document Set-b ITI-41] medication to return zero or more medication interaction issues detected in the `<RegistryError>` element within the `<RegistryErrorList>`. Each `<RegistryError>` element **SHALL** contain the information about exactly one medication interaction issue found:

- errorCode: A supplemental ErrorCode value to those defined by IHE XDS, with the value: "MedicationInteractionCheckingIssue"

- severity: Based on the classification of the issue:

TABLE 4.2-1 ERROR SEVERITY

MEDICATION INTERACTION ISSUE SEVERITY	RESPONSE
Warning or Error	urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error
Information	urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Warning

- location: Source type (Prescription or Dispensation Item):

TABLE 4.2-2 SOURCE TYPE

SOURCE TYPE	RESPONSE
Prescription Item	PRE
Dispensation Item	DIS

- codeContext: the textual representation of the error, which includes four concatenated elements separated by an underscore delimiter:
    i. Medication Interaction Checking Issue Classification code (Error, Warning, Information). Values **SHALL** be out of the **KSA Medication Interaction Checking Issue Classification** value set.
    ii. Medication Interaction Checking Issue Sub-error code conveying a high-level issue code. Values **SHALL** be out of the **KSA Medication Interaction Checking Issue Code** value set.
    iii. Medication Interaction Checking Issue Location Reference to Prescription or Dispensation Item in the format: @root^@extension
    iv. Medication Interaction Checking Issue Text Message: Narrative Description of the Issue

Example of an ITI-41 transaction response with a `<RegistryErrorList>` including three `<RegistryError>` elements:

```
<RegistryResponse
xmlns="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Failure">
<RegistryErrorList
highestSeverity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error">
<RegistryError
errorCode="MedicationInteractionCheckingIssue"
codeContext="E_DOSE_OID^1234_Narrative description of the error"
location="PRE"
severity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error"/>
<RegistryError
errorCode="MedicationInteractionCheckingIssue"
codeContext="W_DOSE_ OID^7890_Narrative description of the warning"
location="PRE"
severity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error"/>
```

```
<RegistryError
errorCode="MedicationInteractionCheckingIssue"
codeContext="I_DOSE_ OID^7890_Narrative description of the info"
location="DIS"
severity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Warning"/>
:
</RegistryErrorList>
</RegistryResponse>
```

[KPRE-057]- The [IHE XDS.b: Provide and Register Document Set-b ITI-41] transaction may succeed or fail based on the outcome of the issues detected by medication interaction checking. Table 4.2-3 impact of medication interactions on the Provide and Register Transactionbelow **SHALL** be implemented by the Document Repository when responding to this transaction.

TABLE 4.2-3 IMPACT OF MEDICATION INTERACTIONS ON THE PROVIDE AND REGISTER TRANSACTION

SEVERITY	XDS REGISTRY ERROR ELEMENT VALUE	XDS TRANSACTION RESULT
Error	registry error Severity: Error	If one or more registry errors (transaction highest severity): Transaction Failure
Warning	registry error Severity: Error	If one or more registry errors (transaction highest severity): Transaction Failure
Information	registry error Severity: Warning	Registry warnings only (transaction highest severity): Transaction Success Prescription or Dispensation document(s) recorded
(No issue)	No registry error	Transaction Success Prescription or Dispensation document(s) recorded

[KPRE-058]- When the transaction [IHE XDS.b: Provide and Register Document Set-b ITI-41] fails due to issues detected by Medication Interaction Checking, the Medication Interaction Checking Actor grouped with the Document Repository **SHALL** support the resubmission of the same or updated Prescription Record with one or more Medication Interaction Checking Issue Management Records related to it. The Medication Interaction Checking Actor **SHALL** process the resubmitted Prescription Record along with the Medication Interaction Checking Issue Management.

5. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this interoperability specification.

TABLE 5-1 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.
IS0007 Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries	Documents the specifications required to provide a synopsis of an encounter and detailed information about a specific type of encounter (e.g., Operative Note) with a patient.
IS0009 Saudi eHealth Core Interoperability Specification for eDispensation	Documents the specifications required to record a medication dispensation to a patient in an outpatient environment or at the time of an in-patient discharge including active ingredient(s) as input for later drug interaction checking of new medication and lot/batch information needed for tracking purposes.
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0102 Saudi eHealth Document Sharing Interoperability Specification	Forms a "container" for set of requirements that complements the IHE XDS Profile with Saudi eHealth specific constraints when it is called upon by any of the Core Interoperability Specifications.
IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications	Specifies common constraints for clinical documents such as data elements of document headers that are common across the eHealth Information Exchange Project.
IS0200 Saudi eHealth Terminology Repository.	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.
IS0303 Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Information Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the eHealth Information Exchange managed health records, including those connected to the eHealth Information Exchange Platform, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the eHealth Information Exchange.

MOH DOCUMENT	DESCRIPTION
UC0008 Saudi eHealth Medications Interoperability Use Case	Provides for the recording of prescription and dispensation in an electronic form in order to improve patient care by Healthcare Provider access to the medication information of the patient. • The Prescription Use Case conveys information necessary to ensure dispensers have the proper data to fulfill the dispensation including dosing information and additional clinical information to document the rationale behind the prescription as well as to support drug interaction checking. • The Dispensation Use Case enables Healthcare Providers to record a medication dispensation to a patient in an outpatient environment or at the time of an in-patient discharge. The Dispensation Record contains all information for the medication dispensed including active ingredient(s) as input for later drug interaction checking of new medication and lot/batch information needed for tracking purposes

TABLE 5-2 EXTERNAL REFERENCES

STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 10 *Cross-Enterprise Document Sharing (XDS.b)*	The Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. *May be obtained at http://www.ihe.net/Technical_Frameworks/#iti*
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 13 Cross-Enterprise User Attestation (XUA) profile	Cross-Enterprise User Assertion Profile (XUA) - provides a means to communicate claims about the identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross-enterprise transactions there is a need to identify the requesting principal in a way that enables the receiver to make access decisions and generate the proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Final Text Section 7 – IHE Consistent Time (CT)	The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti

STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Final Text Section 9: Audit Trail and Node Authentication (ATNA)	The Audit Trail and Node Authentication (ATNA) Integration Profile establishes security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE Pharmacy - Community Medication Prescription and Dispense (CMPD) Integration Profile	The Community Medication Prescription and Dispense Integration Profile (CMPD) describes the process of prescription, validation and dispense of medication in the community domain. *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*
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, gastro endoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org.

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6. APPENDIX A – SAMPLE MESSAGES

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.