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Ministry of Health

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Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Medication Interoperability Use Case

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Document Revision History

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1.0	February 22, 2015	First Release	eHealth Strategy Management Office – eHealth Standards Department

PREFACE

HOW TO READ THIS DOCUMENT

Sections 1 and 2 provide a high level overview of the Use Cases being addressed by this document and the actors and services that support these Use Cases.

Sections 3 and 4 provide an overview of each of the Use Cases and the associated business scenarios and process flows.

Section 5 defines the reusable business processes that result from the Use Cases described in section 3 and 4.

Section 6 elaborates the business processes from section 5 into a service architecture.

KEY CONCEPTS

Key concepts used in this document are introduced below. Consult *IS0302 SeHE Project Glossary* for other terms used within this document.

Interoperability Use Case: In software engineering, a Use Case is a technique for capturing the requirements of a new or updated system. Each Use Case provides one or more business scenarios that convey how the system should interact with end-users or other systems to achieve a specific business goal. Interoperability Use Cases use language that end-users and domain experts can understand, rather than technical jargon. Use Cases are often co-authored or co-developed by business analysts and end-users.

Business Scenario: The business scenario is defined as a sequence of activities by one or more users (e.g. patients, clinicians, etc.) that describe a real-world story. A business scenario executes one or more business processes in a sequence of end-user interactions called a process flow. Business scenarios are the starting point of the analysis leading to the discovery of actors and services necessary to meet the requirements of the assigned Use Case.

Actors: In this specification, actors describe the interoperable software components which support interoperable exchanges of information between systems.

Services: Services describe the collections of capabilities of a system that enable communication and exchange through standards-based messages and information content. A capability within a service describes the smallest unit of useful work that facilitates information exchange between systems.

Process Flow: A process flow represents a possible sequence of business processes being executed to perform the work of the Use Case. Process flows are identified by analysis of business scenarios through the identification of common reusable sequences of business processes.

Main Flow: The main flow of a Use Case usually describes the simplest path through the smallest set of business processes necessary to complete the work of the Use Case. It describes the minimal skeleton of the Use Case which appears in common across the various business scenarios which explore the scope of the Use Case. The main flow is the sequence of business processes that is both common to and required to be executed in all normal business scenarios.

Alternative Flow: Alternative flows describe additional paths that can be taken to provide additional capabilities to the main workflow. Alternative flows are described as auxiliary paths that can be added-on to the main flow in one or more locations.

Exception Flow: Exception flows describe alterations to the main flow under exceptional or out of the ordinary circumstances. The existence of exception flows allows for alternative exit paths from the main flow that allow a work flow to complete under extreme situations, even though it deviates from the main flow.

Business Process: A business process is a reusable unit of interaction between an end-user and one or more information systems. Business processes perform work through the execution of services provided in the information system environment.

APPROACH

The approach used to develop this Use Case specification starts with the identification of a stakeholder group of end-users, beneficiaries and implementers of systems which may be affected by implementation of Interoperability Specifications supporting the Use Cases in the workstream described by this document. These stakeholders identify real-world scenarios in which users and other individuals (e.g., patients) interact with systems to perform or receive a service. The process used is as follows:

- Scenarios are identified by first identifying the simplest (but not necessarily the most common) case in which the Use Case can be completed. More complex scenarios are added which illustrate the range of complexity of the Use Case until essential requirements have been identified.

- Through analysis of these scenarios, a main flow, and often one or more alternative and exception flows are identified. These process flows identified need not match one-to-one with the real-world scenarios originally used to explore the Use Case; however, they are derived from them.

- The process flows are decomposed into business processes, where a business process is described as an end-user initiated interaction with one or more systems in order to complete some essential task in the Use Case.

- The systems and business processes are analyzed to identify the common system components (Actors) responsible for supporting the end-user in the work being done.

- The actors and business processes are further analyzed to identify the necessary services which support the requirements identified in the Use Case.

- The collection of actors and services forms the solution space for the Use Case, representing the systems components and the interoperability that is necessary to meet the requirements of the Use Case.

- From business scenarios implemented by systems and operated by users to actors and services, the derivation of the service model can be shown through a clear progress of analysis.

Lastly, stakeholders contribute candidate data elements to the use case that support the information exchanges identified in the business scenarios.

CONVENTIONS
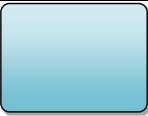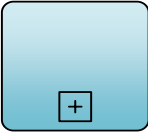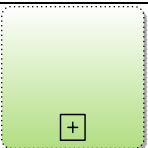
This document has adopted the following conventions for representing the Use Case concepts and information workflow.
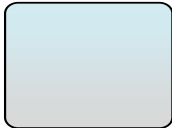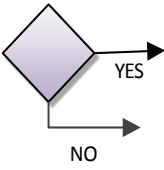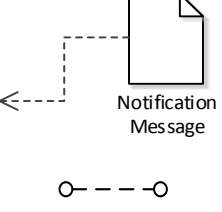
Process Flow Diagrams

The descriptions of Interoperability Use Cases that follow include process flow diagrams that illustrate a series of visual representation of related tasks that a person, business, and/or system executes to achieve a desired outcome of the Use Case. The process flow diagrams are created using the Business Process Modeling Notation (BPMN) format. The notations of the diagram represent different shapes such as an event (a circle shape denotes start/end of process), a process (a rectangle describes actions performed by the actor), a gateway (diamond shape determines forking and merging of paths depending on the conditions expressed), and a connector to show in which order the activities are performed and the intermingling of actions between actors and other systems. Complete explanations of the business process diagram elements used within this document are in the table below.

There are main process flows, followed by optional alternative or exception flows

TABLE 0-1SeHE BUSINESS PROCESS MODELING NOTATION CONVENTIONS

SHAPE	DESCRIPTION
Start	Start event acts as a trigger to launch the business process.
End	End event acts as a trigger to terminate the business process.
	Process that is represented with a rounded-corner rectangle which describes **systematic** action performed by the actor
+	Sub-process used to denote additional levels of business process by referring to an action that can be broken down to a finer level of detail or to another business process name.
	External process that represented with a rounded-corner rectangle and describes **systematic** action performed by the actor
+	External sub-process used to denote additional levels of business process by referring to an action that can be broken down to a finer level of details or to another business process name.

	Process that is represented with a light colored rectangle which describes **physical** action performed by the actor
YES NO	Gateway that determines forking and merging of paths depending on the conditions expressed
→	Sequence flow that shows in which order the activities are performed and the intermingling of actions between different actors or other systems.
Notification Message	Message flow that shows the flow of messages between two actors or systems that are prepared to send and receive messages.
Send Notification	Message event used to send a message and to invoke another Process within the business processes then the token will immediately move to the invoked flow of the process

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.

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

PROJECT PURPOSE

The National eHealth strategy has established a number of key business objectives for the Saudi eHealth program including the definition and implementation of healthcare applications to support critical business scenarios. This is further described in the National eHealth Strategy referenced in the section below.

Within this overarching strategy, an eHealth Standards-based Interoperability Specifications and Policy project has been identified, with scope defined to:

- Deliver the Interoperability Specifications (i.e. standards, profiles, terminologies, etc.)

- Deliver test plans, test tools, and testing and certification policies to support the associated conformance testing and certification for new and existing information systems (Hospital Information Systems (HIS), Primary Healthcare Systems (PHC), Laboratory Information Systems (LIS), Radiology Information Systems (RIS), Picture and Archiving Communication Systems (PACS), etc.). These test plans, test tools, and testing and certification policies will ensure that these systems connect to the a Saudi Health Information Exchange (HIE) platform and its internal Systems which includes patient identification management, provider directory, document and image repository, and access control, etc.

- Establish the policies for health information exchange in Saudi Arabia. These policies ensure trust relationships between the various healthcare organizations sharing information as well as the health professionals and patients in the Kingdom.

The project's goal is to enable interoperability and to mainly specify the external interfaces of the local edge systems (i.e. Point of Care HIS or PHC applications), without constraining:

- The local systems' internal design.
- The intra-organization interoperability policies or management processes used to implement such polices.

Figure 0-1 Scope of eHealth Standard based Interoperability Specifications and Policy Project depicts the general scope and focus of the project highlighted in red
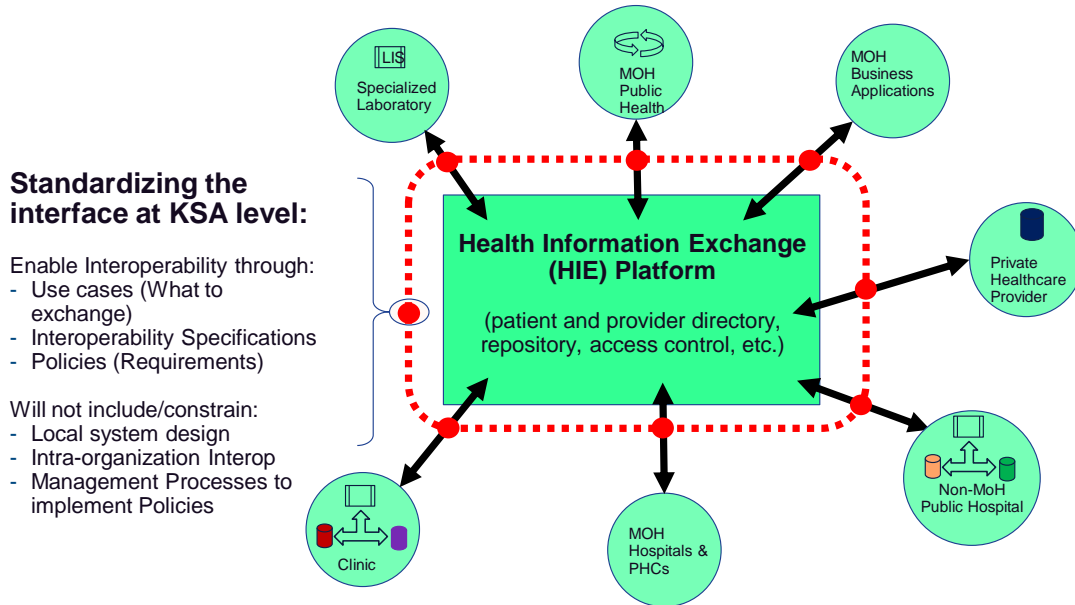
FIGURE 0-1 SCOPE OF eHEALTH STANDARD BASED INTEROPERABILITY SPECIFICATIONS AND POLICY PROJECT

REFERENCES

National eHealth Strategy

See the Saudi Ministry of Health Portal (Arabic: http://www.moh.gov.sa/Ministry/nehs/Pages/default.aspx English: http://www.moh.gov.sa/en/Ministry/nehs/Pages/default.aspx) for more information.

Saudi eHealth Interoperability Specification Document

A Saudi eHealth Interoperability Specification documents the selection of profiles and standards that support specific Saudi eHealth Interoperability Use Cases. Such Interoperability Specifications apply to new and existing information systems (HIS, PHC, LIS, etc.) and ensure their connection to the national Saudi Health Information Exchange (HIE) Platform.

Saudi Health Information Exchange Policy Document

IS0303 *Saudi Health Information Exchange Policies* is used to set the policies applicable to users and systems connected to the HIE Platform.

Examples of such policies are:

- Authentication Policy

- Consent and Access Control Policy
- Identity Management Policy
- Breach Notification Policy
- Others

The Use Cases specified in this document operate within the context of these Health Information Exchange policies.

MIDDLE-OUT METHODOLOGY

Like most eHealth programs around the world, the challenge to identify and document a large number of business Use Cases and variants is avoided by using a "middle-out" methodology. The core requirements start with the Interoperability Use Cases, especially when those are "classical Use Cases" that have been analyzed by the profiles and standards development organizations in their prior work.

Figure i-2 Methodology steps for the eHealth Standard based Interoperability Specification and Policy Project illustrates the main steps of this methodology, where the knowledge of the array of Business Scenarios come from the stakeholders and a validation performed through their experiences (i.e., issues and gaps corrected based on their feedback).
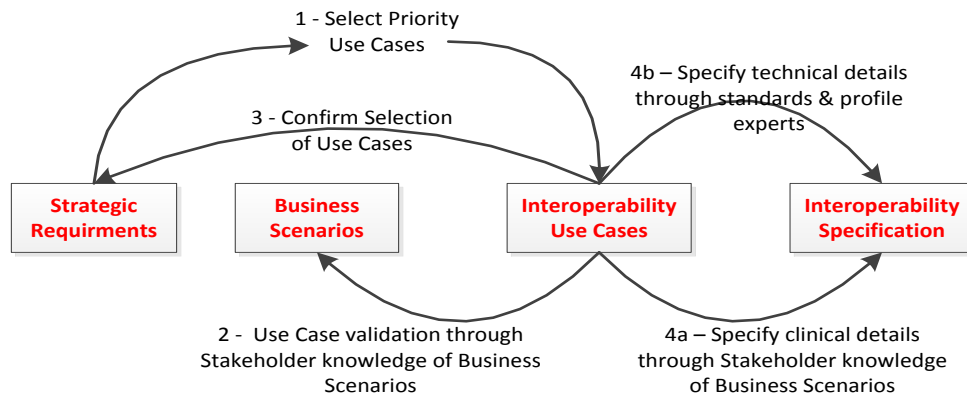
FIGURE 0-1 METHODOLOGY STEPS FOR THE EHEALTH STANDARDS BASED INTEROPERABILITY SPECIFICATIONS AND POLICY PROJECT

The Interoperability Use Cases provide a description of the workflows that need to be addressed and the main exception situations. They are not expected to cover all design details in term of error codes, data element specification and terminology code sets to be used.

This level of detail is appropriately addressed in the Interoperability Specification (See step 4a in the diagram methodology steps). It contains the detailed design specification against which implementations will be tested and certified. An Interoperability Use Case is a scoping document and is a stepping stone to the development of a Saudi eHealth Core Interoperability Specification and supporting Saudi eHealth Core Interoperability Specifications. Together these Interoperability Specifications cover five complementary aspects:

- The specification of the information transport running above the Internet TCP/IP layer.
- The specification of one or more data exchange services suitable for the workflow needed by the Use Case that runs over the above transport.
- The specification of one or more information content data structure enabling the structured representation of the health information data elements and their specific attributes to be conveyed.
- The specification of one set of coded values, each to be placed into a specific attribute of a selected data elements to be conveyed by the above data structure.
- The specification of the technical measures to ensure security and privacy of the information conveyed and accessed.

These Interoperability Specifications and the standards and profiles they reference are designed to form a complete specification covering all aspects necessary to achieve the standards-based exchange of information across the HIE Platform (except for interoperability policy matters that are addressed separately). The Saudi eHealth Interoperability Specifications are the authoritative documents for software implementers and system deployment teams.

As a consequence, rigorous but concise test plans (i.e., a set of test scripts) and test tools are used to provide a reasonable assurance of interoperability between successfully tested systems. Such testing for interoperability may be performed against test tools as well as between systems under test; a combination widely accepted as the most efficient testing process. These test plans and test tools provide closure against the Core Interoperability Specifications and Supporting Interoperability Specifications, thus bringing the necessary level of quality in interoperable IT systems development and deployment.

This is depicted in Figure i-3 Verification of Conformance to A Core Saudi eHealth Interoperability Specification.

5 - Test plans use Use Cases and are designed to structure the tests to validate conformance to the corresponding Core Interoperability Specification

6 – The test tools are designed to facilitate the execution of the test plans

Interoperability Use Cases

Interoperability Specification

Test Plans

Test Tools

8 – Test plans are executed to conduct repeatable quality controlled test sessions using the test tools

7 – Systems designed to support a use case shall implement their interfaces according to the corresponding Core Interoperability Specification

System Under Test

9 – Test tools are used to automate the validation of actual information exchange according to the corresponding Core Interoperability Specification

FIGURE 0-2 VERIFICATION OF CONFORMANCE TO A SAUDI EHEALTH CORE INTEROPERABILITY SPECIFICATION

1. MEDICATION USE CASE

1.1 SCOPE

In Scope:

The following topics are in scope for this Use Case:

- Prescribing and its electronic documentation in a local system.
- Dispensation Records and their electronic documentation in a local system.
- Managing prescriptions and Dispensation Records in a local system.
- Content definitions of prescriptions and Dispensation Records.
- Out-patient prescribing, dispensation and medication management.

Out of Scope:

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

- Content definition of the physical prescription which may be different from the electronic Prescription Record.
- Content definition of the Medication List section of the Interoperable Electronic Health Record (iEHR) summary.
- In-patient prescribing, dispensation and medication management.

2. WORKSTREAM

The purpose of the Medication Workstream is to provide necessary guidance and specification for the recording, review and modification of prescriptions and dispensations in an electronic form. This will result in enhanced patient safety through the sharing of consistent and standardized medication prescriptions and dispensations throughout the Kingdom.

2.1 CURRENT STATE

Currently, the act of prescribing and dispensing medication is not recorded electronically in a central location. The medication information of a patient is based either on information available in the local Health Information System or by verbal disclosure by the patient. Medication information from other facilities and organizations cannot be accessed, and more importantly, considered for Medication Reconciliation and Review, which may negatively impact patient safety, such as in cases where there may be risk of drug-drug interaction with medications not known to the clinician.

2.2 EXPECTED BENEFITS

- Provides a centralized prescription record which electronically supports Healthcare Providers to prescribe at one location and dispense at another.
- Introduces a national uniform and harmonized way to record prescription information and dispensation of medications to a patient, which enables a common definition to an electronic prescription that provides consistent interpretation and dispensing of prescriptions.
- Reduces errors in patient care related to misspelled or unclear medication information.
- Contributes valuable medication information to the patient's medication history which is usable as source for Medication Reconciliation and Review. Having this information in one location allows for more comprehensive drug interaction checking and enables centralized medication lot/batch information tracking in order to quickly and efficiently locate patients who may be taking specific drugs that may have adverse effects.
- Enables centralized medication lot/batch information tracking in order to quickly and efficiently locate patients who may be taking specific drugs that may have adverse effects.
- Centralizing medication data enables program planning and drug utilization activities at an aggregate level.

2.3 USE CASE OVERVIEWS

2.3.1 Prescription

The Prescription Use Case 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.

2.3.2 Dispensation

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.

2.4 ACTORS

The goal of an Interoperability Specification is to enable interoperability within a prescribed architecture. It does not explicitly define the Users and/or Information Systems in detail, as long as they are able to implement the underlying Interoperability Specification (i.e. able to record a prescription, etc.). The Actors defined for the Medication Workstream are described in Table 2.4-1 Actors.

TABLE 2.4-1 ACTORS

ACTOR NAME	DESCRIPTION	EXAMPLE REAL-WORLD IT SYSTEMS
Prescriber	Responsible for the creation of Prescription Records and publishing Prescription Records to the HIE Document Repository.	Point of Care (POC) Systems such as: • Primary Healthcare Center (PHC) Electronic Medical Record Systems • Hospital Information Systems (HIS) • Hospital Pharmacy IT Systems
Dispenser	Responsible for the creation of Dispensation Records and publishing the Dispensation Records to the HIE Document Repository.	Point of Care (POC) Systems such as: • Primary Healthcare Center (PHC) Electronic Medical Record Systems • Hospital Information Systems (HIS) (MOH, National Guard, Private) • Hospital Pharmacy IT Systems (MOH, National Guard, Private) • Community Pharmacy IT Systems
HIE Document Repository	Stores Medication records (Prescription Records, Dispensation Records and updates to such records) and performs Medication Interaction Checking. It also provides access to related information about the patient and their medical record (e.g. allergies, lab results, etc.).	• HIE Document Registry/Repository

2.5 HIGH LEVEL SERVICES OVERVIEW

For the purpose of Interoperability, Services provide an abstract for the communication between Actors through standards-based messages and information content.

2.5.1   Service Descriptions

The Services defined in this Use Case are described in Table 2.5-1 Overview of Medication Services.

TABLE 2.5-1 OVERVIEW OF MEDICATION SERVICES

SERVICE NAME	SERVICE USE
Create/Manage Prescription	Create/Manage Prescription is 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	Create/Manage Dispensation is used to create a Dispensation Record and publish 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	Query and Retrieve Medication Records and all related records (e.g., Prescription Records, Dispensation Records, updates) from the HIE Document Repository.

2.5.2   Service Model

The service model for the Medications Use Cases appears in the diagram below.
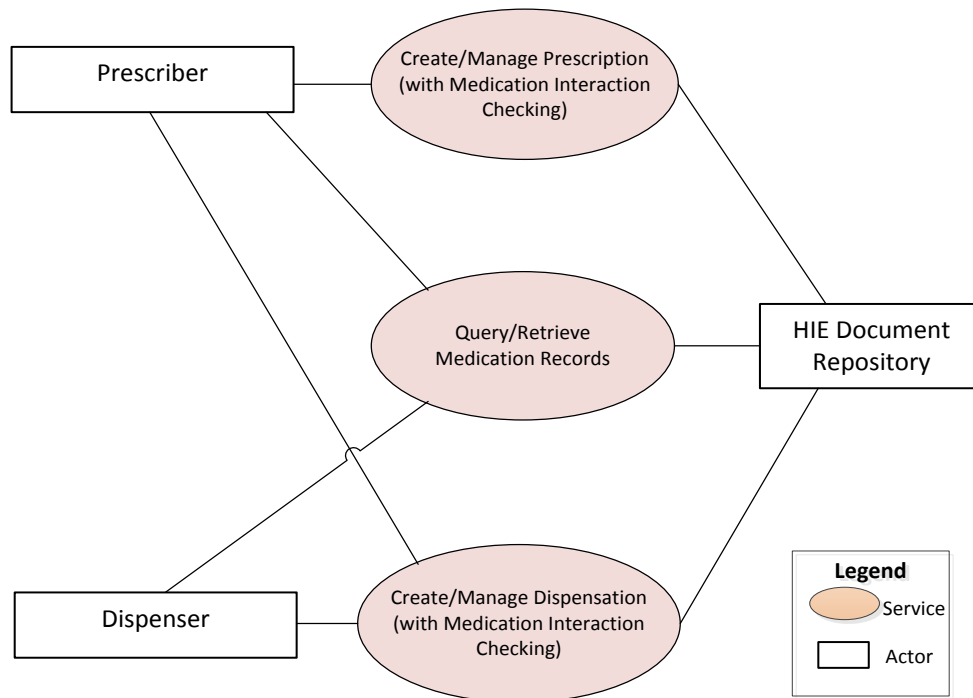
FIGURE 2.5-1 MEDICATION SERVICE MODEL

3. PRESCRIPTION USE CASE

The Prescription Use Case 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.

3.1 PRESCRIPTION SCOPE

The Prescription Use Case is applicable to KSA Healthcare Organizations, including Primary Healthcare Centers (PHC), Hospitals, Medical Cities, Specialty Centers, etc. This includes MOH facilities, other governmental organizations (e.g., the National Guard and Military) and private healthcare sector organizations.

3.2 PRESCRIPTION EXPECTED BENEFITS

- Provides a centralized prescription record which electronically supports Healthcare Providers to prescribe at one location and dispense at another.
- Enables a common definition to an electronic Prescription Record which will provide consistent interpretation and dispensing of prescriptions.
- Reduces errors in patient care resulting from misspelled or unclear medication information.
- Enables Dispensers to access prescriptions in an electronic form to allow for machine processing of drug interaction checking.

3.3 PRESCRIPTION BUSINESS SCENARIOS

This section provides an analysis leading to refining the scope of a specific Use Case within the domain of interest.

The Use Cases considered in this document are focused on interoperability between facilities of distinct organizations and their Health Information Systems that need to communicate at the national level. These Use Cases support the interactions needed to interface with the Saudi Health Information Exchange (HIE) Platform and support cross-facility data sharing and workflow.

The scope of each Use Case is defined to support a wide number of Business Scenarios relevant to the health information domain being considered. This is generally done in a flow-down discovery analysis, especially for Use Cases that are not well established.

The following section illustrates typical Business Scenarios that involve the prescription of medication.

The following Users are associated with these Business Scenarios:

TABLE 3.3-1 SCENARIO USERS

USER	USER ROLE
Patient	The person visiting a Healthcare Provider

USER	USER ROLE
Administrative Staff	The person(s) registering the patient in the Information System for the encounter
Physician	The Healthcare Provider responsible for examination and treatment of the patient

The following Information Systems are associated with these business scenarios:

TABLE 3.3-2 SCENARIO INFORMATION SYSTEMS

INFORMATION SYSTEM	SYSTEM ROLE
EMR	The Electronic Medical Records System used by a Healthcare Provider
HIS	The Electronic Healthcare Information System used within hospitals

3.3.1   Prescription Business Scenario 1: Patient Gets Prescription at PHC

A patient visits a PHC with flu-like symptoms. The patient is identified by the reception clerk and his Health ID is obtained [1] from the HIE Platform. The clinical data of the local POC system will be updated with information of the HIE Platform by performing Retrieve and Reconcile Clinical Data [2].

After entering the treatment room, the physician performs a physical examination of the patient. The physician considers prescribing medication and performs a Medication Reconciliation and Review [3].

He decides to prescribe Penicillin (generic "phenoxymethylpenicillin") in tablet form with a dosage of 1000mg once a day for one week. Additionally he prescribes generic "Paracetamol" in tablet form with a dosage of 500mg once a day for one week.

He prepares the prescription (containing two Prescription Items) in his local Information System and performs local Medication Interaction Checking.

After a successful check, the medication is prescribed [4], by recording the prescription in his local Information System, submitting the Prescription Record to the HIE Document Repository (which performs central Medication Interaction Checking), performing Medication Interaction Checking Issue Management [5] if needed and giving the prescription to the patient on paper.

> Note: The Business Scenario workflow will not change if PHC is replaced by another prescribing facility (e.g. hospital outpatient care or discharge prescriptions (either MOH or other Government), private hospital discharge, outpatient clinic (private), or home healthcare (part of Government Hospitals)).

TABLE 3.3-3BUSINESS SCENARIO breakdown

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1	Main Flow	Obtain Patient Health Identifier	Section 5.2.1

STEP	FLOW	BUSINESS PROCESS	REFERENCE
2	Main Flow	Retrieve and Reconcile Clinical Data	Section 5.2.2
3	Main Flow	Medication Reconciliation and Review	Section 5.1.1
4	Main Flow	Prescribe medication	Section 5.1.2
5	Main Flow	Medication Interaction Checking Issue Management	Section 5.1.10

3.3.2   Prescription Business Scenario 2: Healthcare Provider Manages a Prescription Item

There are three variants describing the act of managing a Prescription Item. All variants are extensions of Business Scenario 1.

3.3.2.1   Variant 1: Cancel a Prescription Item

After getting a medication prescribed by a physician, the patient does not get the prescribed medication from the pharmacy, but instead, re-visits the physician the next day and through the visit, determines that the prescription item is no longer required. The patient is again identified from the HIE Platform by the reception clerk and the clinical data of the local POC system is again being updated with information of the HIE Platform. The physician performs another physical examination to confirm that the prescription is no longer needed. For the patient's safety, the physician performs another Medication Reconciliation and Review.

In case the prescription is not available locally, the Physician queries and retrieves the prescription from the HIE Document Repository [6] and decides to cancel the Penicillin because the current course of the illness no longer requires an antibiotic. He manages the Prescription Item [7] by recording the cancel order in his local Information System and submitting the cancellation of the Penicillin Prescription Item to the HIE Document Repository.

> Note: In case of cancelling a Prescription Item the HIE Document Repository does not perform central Medication Interaction Checking, so performing Medication Interaction Checking Issue Management [8] is not needed.

3.3.2.2   Variant 2: Change a Prescription Item

After getting a medication prescribed by a physician, the patient does not get the prescribed medication from the pharmacy but re-visits the physician the next day because the illness worsened overnight. The patient is again identified from the HIE Platform by the reception clerk and the clinical data of the local POC system is again being updated with information of the HIE Platform. The physician performs another physical examination to confirm the change in health status. For the patient's safety, the physician performs another Medication Reconciliation and Review.

In case the prescription is not available locally the Physician queries and retrieves the prescription from the HIE Document Repository [6], and increases the dosage of the Penicillin from 1000mg once a day to 1000 mg twice a day. He performs local Medication Interaction Checking and manages the Prescription Item [7] by recording the change in his local Information System, submitting the change in dosage of the Penicillin Prescription Item to the HIE Document

Repository (which performs central Medication Interaction Checking), performing <u>Medication Interaction Checking Issue Management [8]</u> if needed and giving the changed physical prescription to the patient.

3.3.2.3   Variant 3: Set Prescription Item to "suspended" and "active"

After getting a medication prescribed by a physician, the patient does not get the prescribed medication from the pharmacy, but was taken to the hospital the next day because the illness became critical overnight. At admission, the clerk identifies the patient from the HIE Platform and the clinical data of the local POC system is again being updated with information of the HIE Platform. After entering the treatment room, the physician performs the admission examination. The hospital physician performs a Medication Reconciliation and Review.

The physician recognizes the prescription of Penicillin 1000mg from the day before and, in case the prescription is not available locally, <u>queries and retrieves the prescription from the HIE Document Repository [6]</u>. He decides to change this Prescription Item to "suspended" during the patient's hospital stay because other medications will be given to the patient in this situation. He <u>manages the Prescription Item [7]</u> by recording the change in his local Information System and submitting the status change to the HIE Document Repository.

> Note: In case of suspending a Prescription Item, the HIE Document Repository does not perform central Medication Interaction Checking, so performing <u>Medication Interaction Checking Issue Management [8]</u> is not needed.

Upon discharge of the patient, the physician decides to resume the previous drug treatment of the patient and prepares to change the Prescription Item to "active". He performs local Medication Interaction Checking and <u>manages the Prescription Item [7]</u> by recording the status change in his local Information System. The status change is then submitted to the HIE Document Repository (which performs central Medication Interaction Checking) which performs <u>Medication Interaction Checking Issue Management [8]</u>, if needed. The physician instructs the patient that the prescribed medication is now allowed to be dispensed.

TABLE 3.3-4 BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1-5	Main Flow	Same as in Business Scenario 1	
6	Alternative Flow	Query/Retrieve Prescription	Section 5.1.3
7	Alternative Flow	Manage Prescription Item	Section 5.1.4
8	Main Flow	Medication Interaction Checking Issue Management	Section 5.1.10

3.3.3   Prescription Business Scenario 3: Revoke a Prescription

This Business Scenario is an extension of Business Scenario 1. This differs from Business Scenario 2, Variant 1 "Cancel a Prescription Item" in that the complete/full prescription is being stopped in this business scenario whereas the variant noted above is stopping only one Prescription Item within a prescription.

Immediately after the patient receives the prescription he hands it back to the physician and announces that he has decided not to take medication.

Following the wish of the patient, the physician revokes the prescription [6] in his local Information System and disposes the paper prescription. The whole prescription is also revoked in the HIE Document Repository by the Information System.

TABLE 3.3-5BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1-5	Main Flow	Same as in Business Scenario 1	
6	Exceptional Flow	Revoke Prescription	Section 5.1.5

3.3.4   Prescription Business Scenario 4: Prescription Item Expired

This Business Scenario is an extension of Business Scenario 1. It describes the situation where either the patient never shows up to have the Prescription Item dispensed or in case of partial Dispensations do not complete the determined series of Dispensations to satisfy the treatment duration.

In both situations, the Prescription Item expires within the HIE Document Repository according to the following policies:

- The Prescription Item expires **after the validity end date** has passed, if no Dispensation has been taken place within the validity date range of the Prescription

  o Formula: Expiration date = Validity end date

  o Example: Validity date range of the Prescription is from the date of creation until 7 days later. The patient does not show up in the pharmacy for Dispensation within the 7 days, so the Prescription Item expires 7 days after creation.

- The Prescription Item expires **after the validity end date plus the duration of the treatment period** have passed, if at least one partial Dispensation has been taken place, within the validity date range of the Prescription, but the complete Dispensation of the Prescription Item has not been accomplished within the duration of treatment period prescribed for this Prescription Item.

  o Formula: Expiration date = Validity end date + Duration of treatment

  o Example: Validity date range of the Prescription is from the date of creation until 7 days later. The duration of treatment period of this Prescription Item is 6 months (intended to be dispensed partially every month). The patient shows up in the pharmacy for Dispensation of the first tranche within the 7 days and gets the medication for 1 month. The patient shows up as planned to receive the next 2 tranches but then ceased to get the rest of the tranches. The Prescription Item expires 6 months and 7 days after creation.

TABLE 3.3-6 BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1-5	Main Flow	Same as in Business Scenario 1	
Prescription Item expires in HIE Document Repository according to expiration policy.			

Note: This Business Scenario does not exist in IS0008 *Saudi eHealth Core IS for ePrescriptions* nor in IS0009 *Saudi eHealth Core IS for eDispensation*, but is documented in the Discussions on Domain Specific Rules document. This is due to the requirement that the determination of Prescription expiry must be performed locally by the Point of Care system.

3.4 PRESCRIPTION PROCESS FLOWS

3.4.1 Prescription Process Overview

The Prescription Business Process Model shown in the figure below is a composite of all of the process flows developed for this Use Case. It has been developed based on analysis of all of the process flows and identified from the Use Case scenarios described above. The diagram below depicts the user roles and the associated activities.

* These business process are required steps in this flow of event
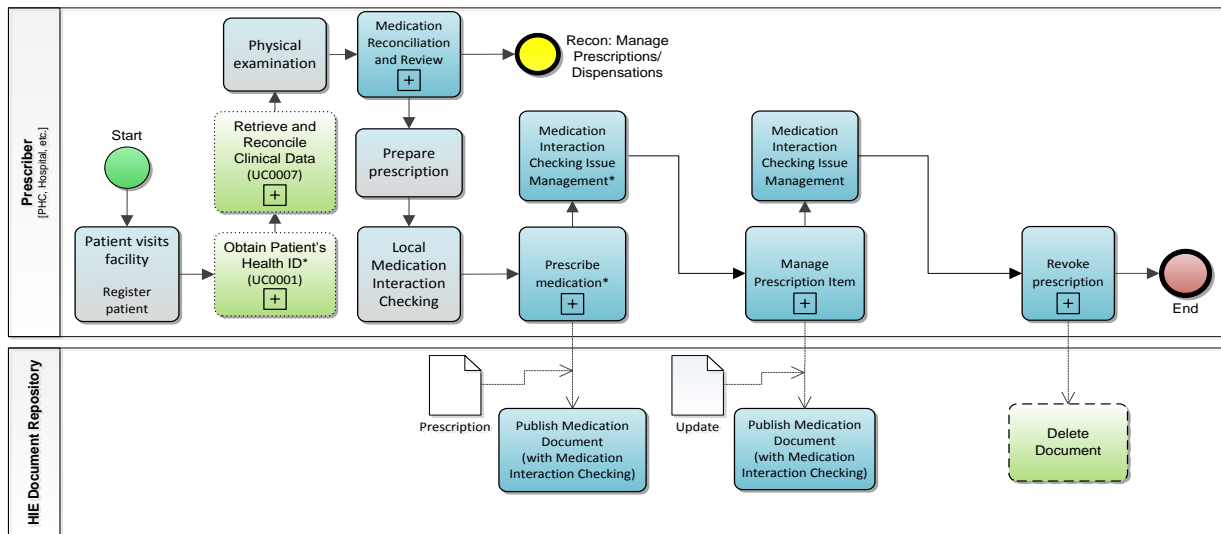
FIGURE 3.4-1 PRESCRIPTION FLOW OVERVIEW DIAGRAM

3.4.2 Prescription Main Flow of Events

A prescriber prescribes medication based upon the purpose of a patient's encounter. The main flow of events of the prescription Use Case is the following:

1. Upon arrival of the patient, the Healthcare Provider uses the Patient Demographic Consumer Actor (e.g. EMR or HIS) to **obtain the Patient Health Identifier** and associated patient demographics from the HIE Platform.

2. The clinical data of the local POC system is updated with information of the HIE Platform by performing **Retrieve and Reconcile Clinical Data**.

3. The Healthcare Provider performs a physical examination of the patient.

4. In order to get an overview of the patient's medication status, the Healthcare Provider performs a **Medication Reconciliation and Review**.

5. After preparing the prescription in the local Point of Care system, local Medication Interaction Checking is performed.

6. The Healthcare Provider uses the Prescriber Actor to **Prescribe Medication** and submits the prescription to the HIE Document Repository, which performs Medication Interaction Checking.

7. In case Medication Interaction Checking determined issues, **Medication Interaction Checking Issue Management** is performed using the Prescriber actor.
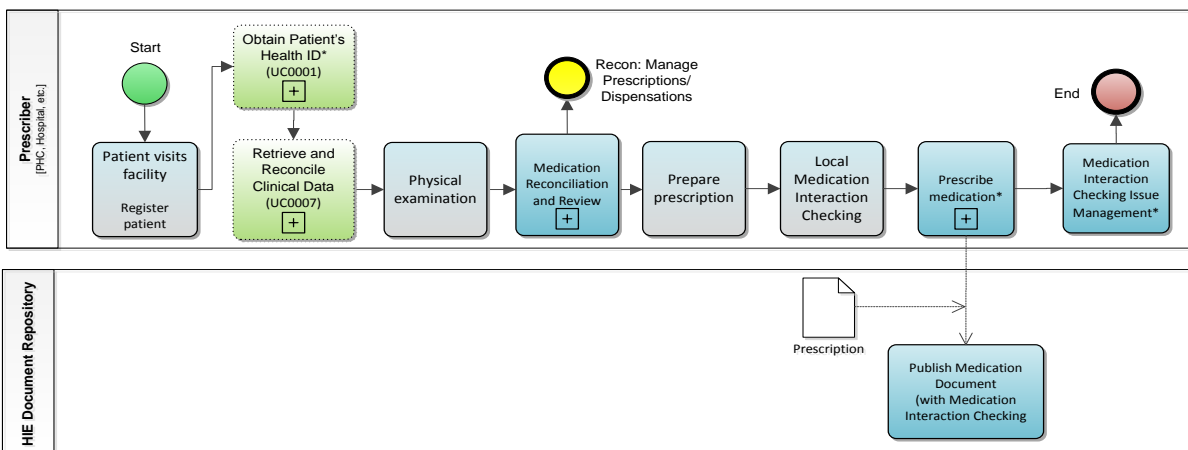
* These business process are required steps in this flow of event

FIGURE 3.4-2 PRESCRIPTION MAIN FLOW DIAGRAM

3.4.3 Prescription Alternative Flow of Events

3.4.3.1 Manage a Prescription Item

This alternative flow of events extends the Prescription Main Flow. Following the Prescription Main Flow, the patient has a prescription with one or more Prescription Items. Provided that the prescription has not yet been dispensed, a Prescription Item on that prescription may be managed in the following ways:

- A Prescription Item of the prescription may be "canceled" (removed from the prescription)

- A Prescription Item of the prescription may be "changed" (either partially e.g. the dosing information or completely)

- A Prescription Item of the prescription may be set to "suspended"

- A Prescription Item of the prescription may be set to "active" (after it has been set to "suspended")

The managing of a Prescription Item extends the Prescription Main Flow where the patient possesses a prescription, **which has not yet been dispensed**, by continuing with the following:

8. Upon return of the patient to the Healthcare Provider, the alternative flow begins with the same steps as the Prescription Main Flow (Obtain Patient's Health ID, Physical examination, Medication Reconciliation and Review). During this flow, the Healthcare Provider decides that the prescription the patient possesses needs to be managed.

9. In case the prescription is not available locally the Healthcare Provider **queries and retrieves the prescription** from the HIE Document Repository using the Prescriber Actor.

10. After preparing the update to the prescription in the local Point of Care system, local Medication Interaction Checking is performed.

11. The Healthcare Provider uses the Prescriber Actor to **manage a Prescription Item** and submits the update to the HIE Document Repository, which performs Medication Interaction Checking in case of changing or activating a Prescription Item.

12. In case Medication Interaction Checking determined issues, **Medication Interaction Checking Issue Management** is performed using the Prescriber actor.

* These business process are required steps in this flow of event
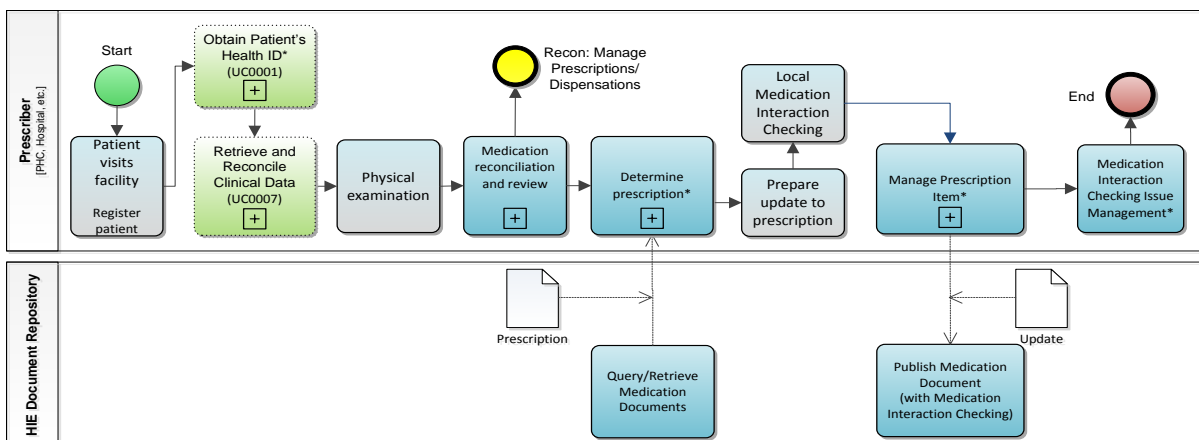
FIGURE 3.4-3 PRESCRIPTION ALTERNATIVE FLOW DIAGRAM

3.4.4   Prescription Exception Workflows

3.4.4.1   Revoke a Prescription

This exception flow of events extends the Prescription Main Flow. Upon completion of the Prescription Main Flow where the patient has an unfilled prescription, the prescription may be revoked entirely (e.g., in case of error).

The revocation of a prescription extends the Prescription Main Flow by continuing with the following:

8. The Healthcare Provider uses the Prescriber Actor to **revoke the prescription**.
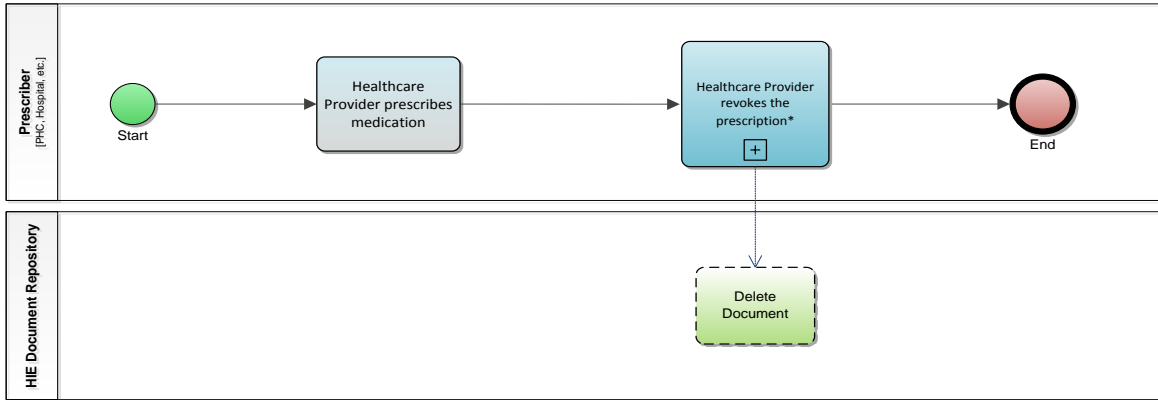
FIGURE 3.4-4 PRESCRIPTION EXCEPTION FLOW DIAGRAM

3.5 PRESCRIPTION INFORMATION REQUIREMENTS

This section defines the general scope of the type of data needed for this Use Case. However, it does not define the entire detailed data set as this will be discussed in IS0106 Saudi eHealth Common Constraints for Clinical Documents IS.

TABLE 3.5-1 PRESCRIPTION DATA CONTENT

PRESCRIPTION CONCEPTS	DESCRIPTION	TEXT/ CODED
Source and context information of the prescription		
Patient Demographics	Data elements which identify the patient and provide additional important information to the Medication Use Case. The following attributes have been identified as important: • Health ID • Name • Date of birth • Gender	Text and Coded
Healthcare Provider Information (Person)	Data elements which describe the Healthcare Professional performing the prescription including: • Healthcare Professional identifier • Healthcare Professional name • Healthcare Professional specialty	Text and Coded
Healthcare Provider Information (Organization)	Data elements which describe the Healthcare Organization of the Healthcare Professional creating the prescription including: • Organization identifier • Organization name • Organization address • Organization contact information	Text

PRESCRIPTION CONCEPTS		DESCRIPTION	TEXT/ CODED
Prescription information		Data elements which describe information about the prescription including: • Prescription ID • Prescription date • Prescription type (Controlled / Uncontrolled)	Text and Coded
Prescription Items		Prescription Items each contain the following information:	
Prescription Item	Prescription Item ID	This data element contains the ID of the Prescription Item. This identifier is used to link all following events happening to this prescribed item, such as managing acts (cancel, change, etc.) or Dispensations.	Text
	Medicine prescribed	A group of data elements which describe information to the medicine prescribed in this Prescription Item, including: Prescribed Pharmacy Item (Name/Code) or Compound Medicine description Pharmaceutical Dose form	Text and Coded
	Dosing information	A group of data elements which describe the dosing information of the medicine prescribed in this Prescription Item, including • Duration • Frequency and preconditions • Dose quantity • Route of administration • Approach Site	Text and Coded
	Patient Medication Instructions	Comments by the Prescriber to the patient, (e.g., special dosage information, information how to use/prepare the medication).	Text
	Fulfillment Instructions (aka Dispenser instructions)	Comments by the Prescriber to the Dispenser, (e.g., proposals of brands, instructions about substitutions, compound medicine information).	Text
	Clinical Data of the Patient	A group of data elements which describe clinical information of about the patient relevant for this Prescription Item, including: • Active problems (Diagnosis) • Vital signs (including "weight")	Text and Coded

4. DISPENSATION USE CASE

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.

4.1 DISPENSATION SCOPE

The Dispensation Use Case is applicable to KSA Healthcare Organizations, including Primary Healthcare Centers (PHC), Hospitals, Medical Cities, Community Pharmacies, etc. This includes MOH facilities, other governmental organizations (e.g., the National Guard and Military) and private healthcare sectors.

4.2 DISPENSATION EXPECTED BENEFITS

- Enables a common definition to an electronic Dispensation Record which will provide consistent interpretation of dispensations.
- Contributes valuable medication information to the patient's medication history usable as source for Medication Reconciliation and Review.
- Enables centralized medication lot/batch information tracking in order to quickly and efficiently locate patients who are taking specific drugs that may have adverse effects.

4.3 DISPENSATION BUSINESS SCENARIOS

This section provides an analysis leading to refining the scope of a specific Use Case within the domain of interest.

The Use Cases considered in this document are focused on interoperability between facilities of distinct organizations and their Health Information Systems that need to communicate at the national level. These Use Cases support the interactions needed to interface with the Saudi Health Information Exchange (HIE) Platform and support of cross-facility data sharing and workflow.

The scope of each Use Case is defined to support a wide number of Business Scenarios relevant to the health information domain being considered. This is generally done in a flow-down discovery analysis, especially for Use Cases that are not well established.

The following section illustrates typical Business Scenarios that involve the dispensation of medication.

The following Users are associated with these Business Scenarios:

TABLE 4.3-1 DISPENSATION USERS

USER	USER ROLE
Patient	The person visiting a PHC or Private Physician.

USER	USER ROLE
Pharmacist	The Healthcare Provider person responsible for dispensing medication to the patient.

The following Information Systems are associated with these Business Scenarios:

TABLE 4.3-2 DISPENSATION INFORMATION SYSTEMS

INFORMATION SYSTEM	SYSTEM ROLE
EMR	The Electronic Medical Records System used by a PHC or a Private. Physician
HIS	The Electronic Healthcare Information System used within hospitals.
Community Pharmacy IT system	The Electronic System used in Community Pharmacies.

4.3.1 Dispensation Business Scenario 1: Outpatient gets Prescribed Medication Dispensed through a Hospital Pharmacy

4.3.1.1 Variant 1: Full Dispensation

A patient visits Hospital Pharmacy as an outpatient to get a prescribed medication dispensed. The pharmacist identifies the patient and his Health ID is obtained [1] from the HIE Platform. The clinical data of the local POC system will be updated with information of the HIE Platform by performing Retrieve and Reconcile Clinical Data [2].The pharmacist determines the medication to be dispensed by, for example, reviewing the paper prescription.

For patient's safety, the pharmacist performs a Medication Reconciliation and Review [3].

The pharmacist prepares the Dispensation Record in his local Information System and performs local Medication Interaction Checking.

After successful check, the pharmacist dispenses the medication [4], by recording the dispensation in his local Information System, submitting the Dispensation Record to the HIE Document Repository (which performs central Medication Interaction Checking), performing Medication Interaction Checking Issue Management [5] if needed and giving the medication to the patient.

4.3.1.2 Variant 2: Partial Dispensation

A patient with high blood pressure has a mild heart attack and gets treated during a hospital stay. At discharge, the physician issues a long-term prescription for blood pressure medication. The prescription indicates the drug to be given in a specific dosage for three months. After that, the patient is instructed to re-visit the PHC or hospital for an examination and possible repetition of the previously held prescription for continuation of treatment.

The patient enters the hospital pharmacy as an outpatient to get the medication dispensed. The pharmacist identifies the patient and his Health ID is obtained [1] from the HIE Platform. The

clinical data of the local POC system will be updated with information of the HIE Platform by performing <u>Retrieve and Reconcile Clinical Data [2]</u>.

The pharmacist determines the medication to be dispensed by, for example, reviewing the paper prescription.

For patient's safety, the pharmacist performs a <u>Medication Reconciliation and Review [3]</u>.

The pharmacist prepares the Dispensation Record in his local Information System and performs local Medication Interaction Checking.

After successful check, the pharmacist <u>dispenses the medication [4]</u>, by recording the partial dispensation in his local Information System, submitting the Dispensation Record to the HIE Document Repository (which performs central Medication Interaction Checking), performing <u>Medication Interaction Checking Issue Management [5]</u> if needed and giving a one month supply to the patient.

After that, the patient is instructed to re-visit the pharmacy to get the medication for the next month dispensed.

> Note: The Business Scenario workflow will not change if Hospital Pharmacy is replaced by another prescribing facility (e.g., Primary Health Center (either MOH or other Government), private hospital pharmacy or community pharmacy).

TABLE 4.3-3 BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1	Main Flow	Obtain Patient Health Identifier	Section 5.2.1
2	Main Flow	Retrieve and Reconcile Clinical Data	Section 5.2.2
3	Main Flow	Medication Reconciliation and Review	Section 5.1.1
4	Main Flow	Dispense Medication	Section 5.1.6
5	Main Flow	Medication Interaction Checking Issue Management	Section 5.1.10

4.3.2 Dispensation Business Scenario 2: Patient gets Over-The-Counter (OTC) Medication Dispensed by a Community Pharmacy

A patient enters a Community Pharmacy and requests an OTC medication.

The pharmacist identifies the patient and her <u>Health ID is obtained [1]</u> from the HIE Platform. The clinical data of the local POC system will be updated with information of the HIE Platform by performing <u>Retrieve and Reconcile Clinical Data [2]</u>.

For patient's safety, the pharmacist performs a <u>Medication Reconciliation and Review [3]</u>.

The pharmacist prepares the Dispensation Record in his local Information System and performs local Medication Interaction Checking.

After successful check, the pharmacist <u>dispenses the medication [4]</u>, by recording the dispensation in his local Information System, submitting the Dispensation Record to the HIE Document Repository (which performs central Medication Interaction Checking), performing <u>Medication Interaction Checking Issue Management [5]</u> if needed and giving the medication to the patient.

TABLE 4.3-4 BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1	Main Flow	Obtain Patient Health Identifier	Section 5.2.1
2	Main Flow	Retrieve and Reconcile Clinical Data	Section 5.2.2
3	Main Flow	Medication Reconciliation and Review	Section 5.1.1
4	Main Flow	Dispense Medication	Section 5.1.6
5	Main Flow	Medication Interaction Checking Issue Management	Section 5.1.10

4.3.3   Dispensation Business Scenario 3: Healthcare Provider Manages a Dispensation Item

There are three variants describing the act of managing a Dispensation Item. All variants are extensions of Business Scenario 1.

4.3.3.1   Variant 1: Stop a Dispensation Item

After getting a medication prescribed by a physician, the patient retrieves the prescribed medication from the pharmacy and takes it for three days. He then re-visits the physician because the illness had improved. The patient is again identified from the HIE Platform by the reception clerk and the clinical data of the local POC system is again being updated with information of the HIE Platform. The physician performs another physical examination to confirm the improved health status. For patient's safety, the physician performs another Medication Reconciliation and Review.

> The Physician <u>queries and retrieves the Dispensation Record from the HIE Document Repository [6]</u> and decides to discontinue the Penicillin because the illness no longer requires an antibiotic. He <u>manages the Dispensation Item [7]</u> by recording the discontinuation in his local Information System and submitting the discontinuation of the Penicillin Prescription Item to the HIE Document Repository and instructing the patient to stop intake. Note: When stopping a Dispensation Item the HIE Document Repository does not perform central Medication Interaction Checking, so performing <u>Medication Interaction Checking Issue Management [8]</u> is not needed.

4.3.3.2   Variant 2: Change a Dispensation Item

After getting a medication prescribed by a physician, the patient retrieves the prescribed medication from the pharmacy and takes it for three days. He then re-visits the physician the next day because the illness had worsened. The patient is again identified in the HIE Platform by the reception clerk and the clinical data of the local POC system is again being updated with information of the HIE Platform. The physician performs another physical examination to confirm the worsened health status. For patient's safety, the physician performs another Medication Reconciliation and Review.

The Physician <u>queries and retrieves the Dispensation Record from the HIE Document Repository [6]</u> and decides to increase the dosage of the Penicillin from 1000mg once a day to 1000mg twice a day. He performs local Medication Interaction Checking and <u>manages the Dispensation Item [7]</u> by recording the change in his local Information System, submitting the change in dosage of the Penicillin Item to the HIE Document Repository (which performs central Medication Interaction Checking), performing <u>Medication Interaction Checking Issue Management [8]</u> if needed and instructing the patient about the new dosage.

4.3.3.3   Variant 3: Set Dispensation Item to "suspended" and "active"

After getting a medication prescribed by a physician, the patient retrieves the prescribed medication from the Pharmacy and takes it for three days. After that, he was taken to the hospital because the illness became critical. At admission, the clerk identifies the patient in the HIE Platform and the clinical data of the local POC system is again being updated with information of the HIE Platform. After entering the treatment room, the physician performs the admission examination. The hospital physician performs a Medication Reconciliation and Review.

The physician recognizes the dispensation of the 1000mg of Penicillin from three days earlier, and <u>queries and retrieves the Dispensation Record from the HIE Document Repository [6]</u>. He decides to change this Dispensation Item to "suspended" during the patient's hospital stay because other antibiotics will be given to the patient. He <u>manages the Dispensation Item [7]</u> by recording the status change to the Dispensation Item in his local Information System and submitting the status change to the HIE Document Repository.

> Note: When suspending a Dispensation Item the HIE Document Repository does not perform central Medication Interaction Checking, so performing <u>Medication Interaction Checking Issue Management [8]</u> is not needed.

Upon discharge of the patient, the physician decides to continue the treatment of the patient with the formerly dispensed medication and changes the Dispensation Item to "active". He performs local Medication Interaction Checking and <u>manages the Dispensation Item [7]</u> by recording the status change in his local Information System, submitting the status change to the HIE Document Repository (which performs central Medication Interaction Checking), performing <u>Medication Interaction Checking Issue Management [8]</u> if needed and instructing the patient to continue with the medication.

TABLE 4.3-5 BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1-5	Main Flow	Same as in Business Scenario 1	
6	Alternative Flow	Query/Retrieve Dispensation	Section 5.1.7
7	Alternative Flow	Manage Dispensation Item	Section 5.1.8
8	Main Flow	Medication Interaction Checking Issue Management	Section 5.1.10

4.3.4   Dispensation Business Scenario 4: Revoke a Dispensation

This Business Scenario is a continuation of Business Scenario 1. After the pharmacist has recorded the Dispensation Record in the HIE Platform; the patient returns the medication and announces that he refuses to take it.

The pharmacist revokes the Dispensation Record [6] in his local Information System, and withdraws the medication from the patient. The Dispensation Record is also revoked in the HIE Document Repository by the Information System.

TABLE 4.3-6BUSINESS SCENARIO BREAKDOWN

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1-5	Main Flow	Same as in Business Scenario 1	
6	Exceptional Flow	Revoke Dispensation	Section **Error! Reference source not found.**

4.4   DISPENSATION PROCESS FLOWS

4.4.1   Dispensation Process Overview

The Dispensation Business Process Model shown in the figure below is a composite of all of the process flows developed for this Use Case. It has been developed based on analysis of all of the process flows and identified from the Use Case scenarios described above. The diagram below depicts the user roles and the associated activities.
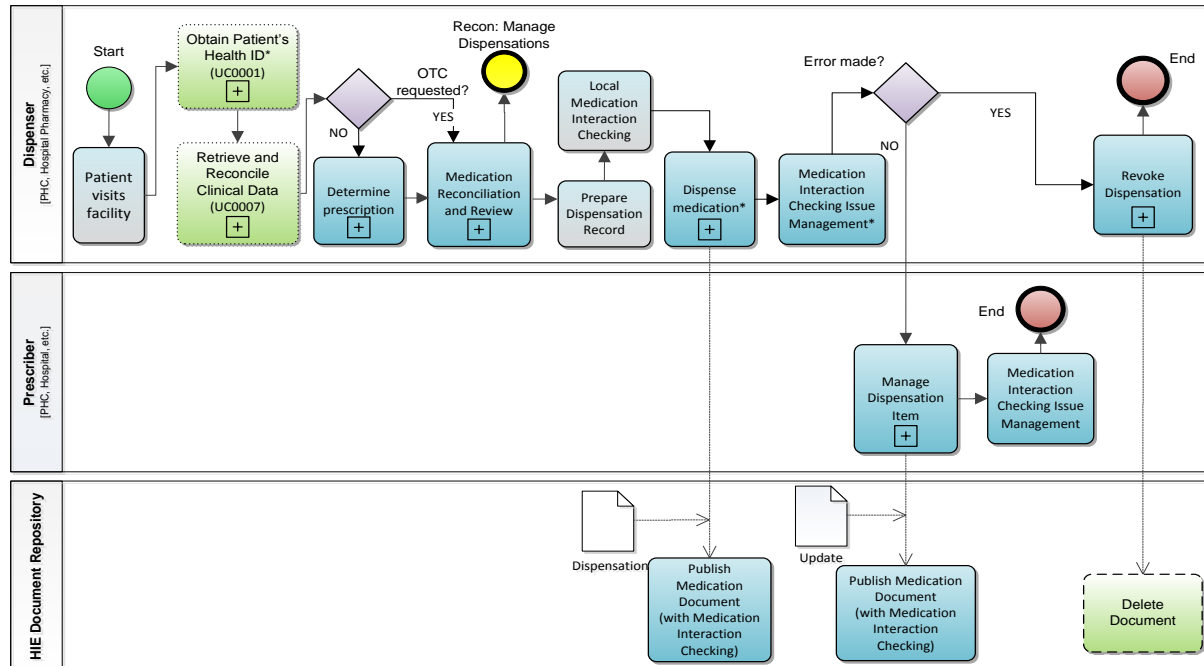
FIGURE 4.4-1 DISPENSATION FLOW OVERVIEW DIAGRAM

4.4.2 Dispensation Main Flow of Events

A Dispenser dispenses medication specified by a prescription or upon request for an OTC.

The main flow of events of the Dispensation Use Case is the following:

1. Upon arrival of the patient, the Healthcare Provider uses the Patient Demographic Consumer Actor (e.g. EMR, HIS or Pharmacy IT System) to **obtain the Patient Health Identifier** and associated patient demographics.

2. The clinical data of the local POC system is updated with information of the HIE Platform by performing **Retrieve and Reconcile Clinical Data**.

3. In case of dispensation specified by a prescription: The Dispenser determines the prescription to be dispensed by, for example, reviewing the paper prescription.

4. The Healthcare Provider performs a **Medication Reconciliation and Review to understand the patient's medication history**.

5. After preparing the Dispensation Record in the local Point of Care system, Local Medication Interaction Checking is performed.

6. The Healthcare Provider uses the Dispenser Actor to **Dispense Medication** and submits the Dispensation Record to the HIE Document Repository, which performs Medication Interaction Checking.

7. In case Medication Interaction Checking determined issues, **Medication Interaction Checking Issue Management** is performed using the Dispenser actor.
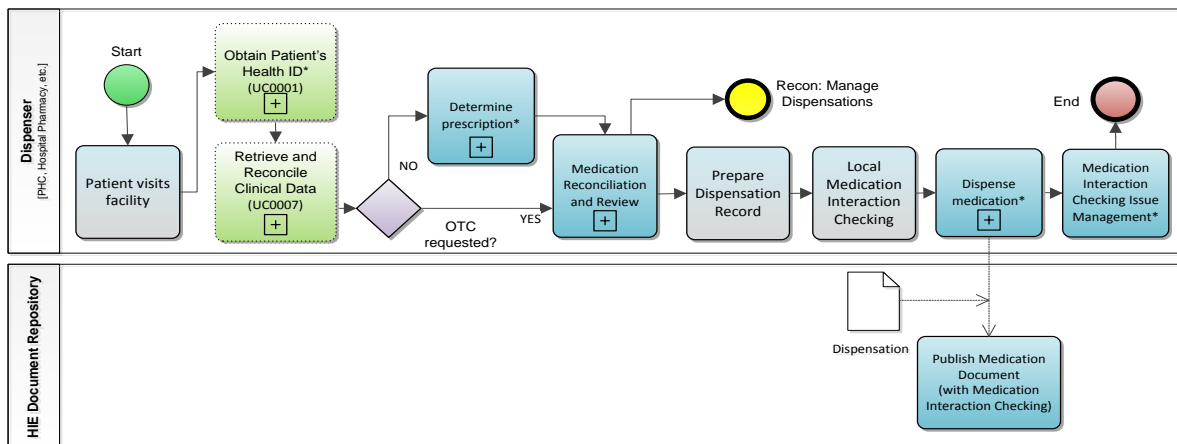
FIGURE 4.4-2DISPENSATION MAIN FLOW DIAGRAM

4.4.3 Dispensation Alternative Flow of Events

4.4.3.1 Manage a Dispensation Item

This alternative flow of events extends the Dispensation main flow. At the end of the Dispensation main flow, the patient has received medication which corresponds to the Dispensation Item (which records the dispensation). Those Dispensation Items may be managed in the following ways:

- A Dispensation Item may be "stopped" (stop intake)

- A Dispensation Item may be "changed" (dosage information)

- A Dispensation Item may be set to "suspended"

- A Dispensation Item may be set to "active" (after it has been set to suspended)

The managing of a Dispensation Item extends the Dispensation main flow, where the patient possesses the medication corresponding to the Dispensation Item, by continuing with the following:

8. At return of the patient to the Healthcare Provider, the alternative flow begins with the same steps as the Prescription main flow (Obtain Patient's Health ID, Physical examination, Medication Reconciliation and Review). The Healthcare Provider then decides that the Dispensation Record of the patient has to be changed.

9. In case the prescription is not available locally the Healthcare Provider **queries and retrieves the Dispensation Record** from the HIE Document Repository using the Dispenser Actor.

10. After preparing the update to the Dispensation Record in the local Point of Care system Local Medication Interaction Checking is performed.

11. The Healthcare Provider uses the Dispenser Actor to **manage a Dispensation Item** and submit the update to the HIE Document Repository, which performs Medication Interaction Checking in case of changing or activating a Dispensation Item.

12. In case Medication Interaction Checking determined issues, **Medication Interaction Checking Issue Management** is performed using the Dispenser actor.
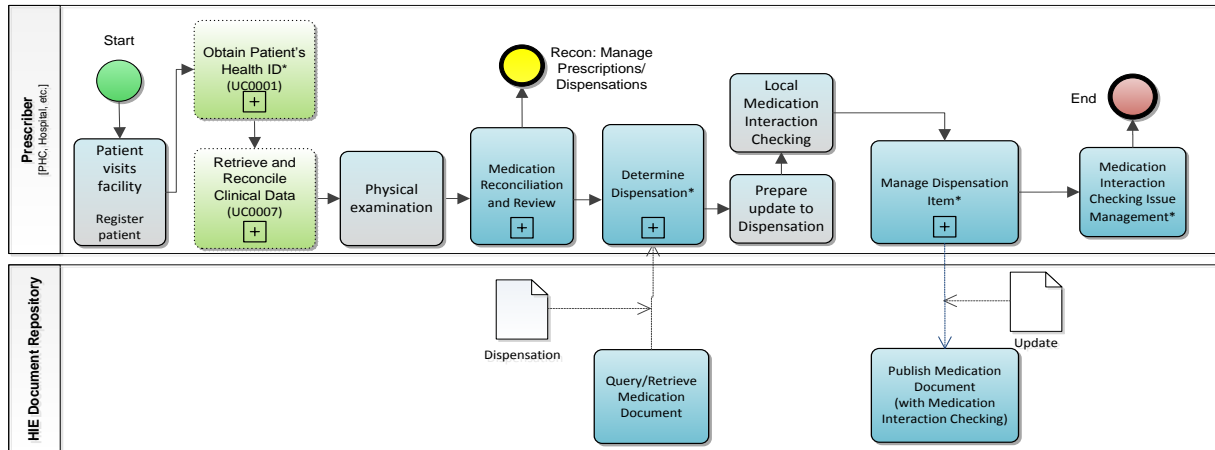
* These business process are required steps in this flow of event

FIGURE 4.4-3 DISPENSATION ALTERNATIVE FLOW DIAGRAM

4.4.4 Dispensation Exceptions Workflow

4.4.4.1 Revoke a Dispensation

This exceptional flow of events extends the Dispensation main flow. At the end of the Dispensation Main Flow, the patient has received medication which corresponds to the Dispensation Item which records the dispensation. This Dispensation Record and dispensation may be revoked entirely (e.g., in case of error).

The revocation of a Dispensation Record extends the Dispensation Main Flow, where the patient possesses a medication corresponding to the according Dispensation Item by continuing with the following:

8. The Healthcare Provider uses the Dispenser Actor to **revoke the Dispensation**.
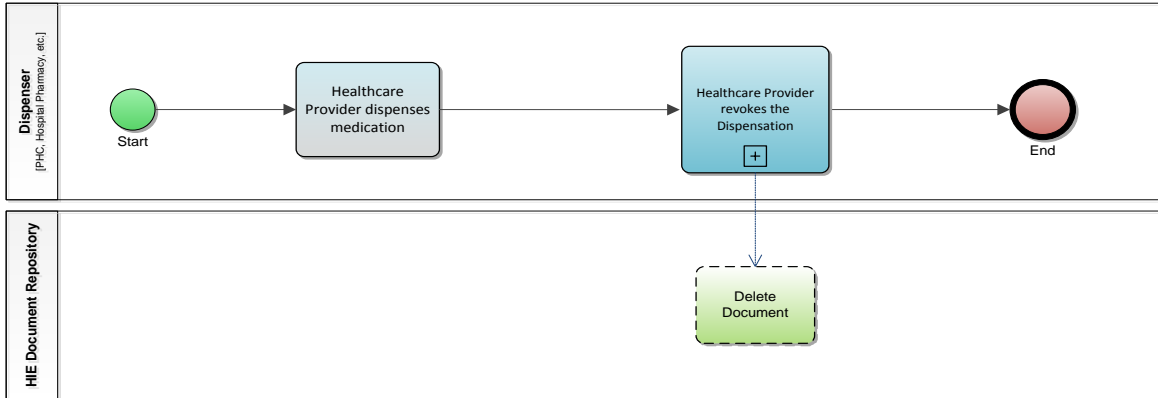
FIGURE 4.4-4 DISPENSATION EXCEPTION FLOW DIAGRAM

4.5 DISPENSATION INFORMATION REQUIREMENTS

This section defines the general scope of the type of data needed for this Use Case. However, it does not define the entire detailed data set as this will be discussed in IS0106 Saudi eHealth Common Constraints for Clinical Documents IS.

TABLE 4.5-1 DISPENSATION DATA CONTENT

DISPENSATION CONCEPTS	DESCRIPTION	TEXT/ CODED
Source and context information of the Outpatient Encounter Summary		
Patient Demographics	Data elements which identify the patient and provide additional important information to the Medication Use Case. The following are attributes which have been identified as important: • Health ID • Name • Date of birth • Gender	Text and Coded
Healthcare Provider Information (Person)	Data elements which describe the Healthcare Provider performing the Dispensation including: • Healthcare professional identifier • Healthcare professional name • Healthcare professional specialty	Text and Coded
Healthcare Provider Information (Organization)	Data elements which describe the Healthcare Organization of the person performing the dispensation including • Organization identifier • Organization name • Organization address • Organization contact information	Text

DISPENSATION CONCEPTS		DESCRIPTION	TEXT/ CODED
Dispensation information		Data elements which describe common information to the Dispensation including: • Dispensation ID • Dispensation date	Text and Coded
Dispensation Item		One Dispensation Items containing the following information	
Dispensation Item	Dispensation Item ID	This data element contains the ID of the Dispensation Item. This identifier is used to link all following events happening to this Dispensation Item, such as status changes (stop, change, etc.).	Text
	Reference to Prescription Item	This data element contains the reference to the Prescription Item on behalf of which this medication has been dispensed (if applicable).	Text
	Medicine dispensed	Data elements which describe information to the medicine dispensed, including: • Dispensed Pharmacy Item (Name/Code) or Compound Medicine description • Pharmaceutical dose form • Packaging information (e.g., Package form, lot number, expiration date)	Text and Coded
	Dosing information	A group of data elements which describe the dosing information of the medicine dispensed, including • Duration • Frequency and preconditions • Dose quantity • Route of administration	Text and Coded
	Patient Medication Instructions	Comments by the Dispenser to the patient (e.g., special dosage information, approach site, information how to use/prepare the medication).	Text
	Fulfillment Instructions (aka Dispenser instructions)	Comments by the Dispenser regarding the dispensation (e.g., warnings given to patient, etc.)	Text

5. DETAILED BUSINESS PROCESSES

These are comprised of a number of Business Processes, some of which are defined in this document and others which are defined in documents external to this Use Case.

5.1 MEDICATION BUSINESS PROCESSES

These business processes aggregate several processes from the Use Cases described in this workstream of the health standard-based Interoperability Specification and Policy Project.

5.1.1 Medication Reconciliation and Review

The Medication Reconciliation and Review business process assumes that the initial step of getting the most recent medication information has been performed during the updating the clinical data of the local POC system with information of the HIE Platform by the **Retrieve and Reconcile Clinical Data** business process.

Medication reconciliation is a formal process of obtaining and verifying a complete and accurate list of each patient's current medicines, and matching the medicines the patient <u>should</u> be prescribed to those that are <u>actually</u> prescribed. Discrepancies are discussed with the Prescriber and the reasons for changes to the medication regimen are documented. To let the knowledge gained during the reconciliation act flow back into the HIE Platform, **Manage Prescription Item** and **Manage Dispensation Item** business processes may be triggered to update the medication record of the patient (e.g., to record a stop of a Dispensation Item if the patient says that he doesn't take a medicine which he was expected to be taken, etc.).

A medication review is performed after reconciliation and is a critical clinical review of all prescribed, OTC and complementary medications undertaken to optimize therapy and minimize medication-related issues. It is a systematic evaluation of a patient's complete medication regime including information about Immunizations and Allergies.

Figure 5.1-1 Medication Reconciliation and Review process depicts the process associated with the **Medication Reconciliation and Review**, while Table 5.1-1: Medication Reconciliation and Review Business Processes lists all of the Business Processes associated with the **Medication Reconciliation and Review** Business Process.
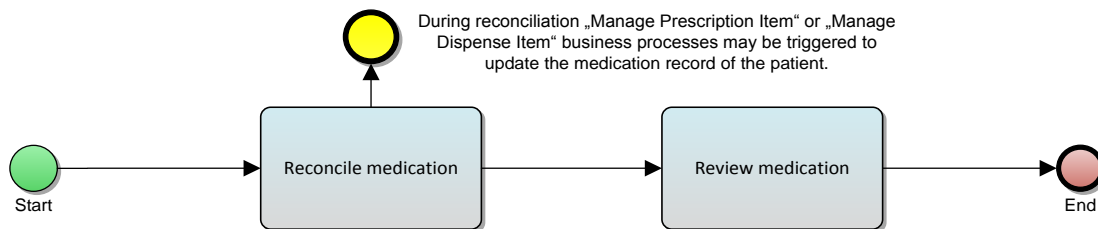

FIGURE 5.1-1 MEDICATION RECONCILIATION AND REVIEW PROCESS

TABLE 5.1-1: MEDICATION RECONCILIATION AND REVIEW BUSINESS PROCESSES

BUSINESS PROCESS	REFERENCE
Retrieve and Reconcile Clinical Data	UC0007 eHealth Interoperability Use Case for Clinical Notes and Summaries

5.1.2 Prescribe Medication

The Prescribe Medication Business process covers the act of prescribing medication to a patient. It includes the prescription of the medication in the local Point of Care system followed by the submission of the prescription to the HIE Document Repository. The submission succeeds in case the central Medication Interaction Checking service discovers no issues but fails if issues are discovered. If issues are discovered Medication Interaction Checking Issue Management is performed. The process ends with the delivery of the physical prescription to the patient.

The process steps for prescribing medication are:

1. Create Prescription in local Point of Care system.
2. Local Point of Care system creates the Prescription Record.
3. Submit the Prescription Record to the HIE Document Repository.
4. In case the submission fails because the central Medication Interaction Checking service reports issues, Medication Interaction Checking Issue Management is performed.
5. Hand out the physical prescription to the patient.

Figure 5.1-2 Prescribe Medication process depicts the process for **Prescribe Medication**.
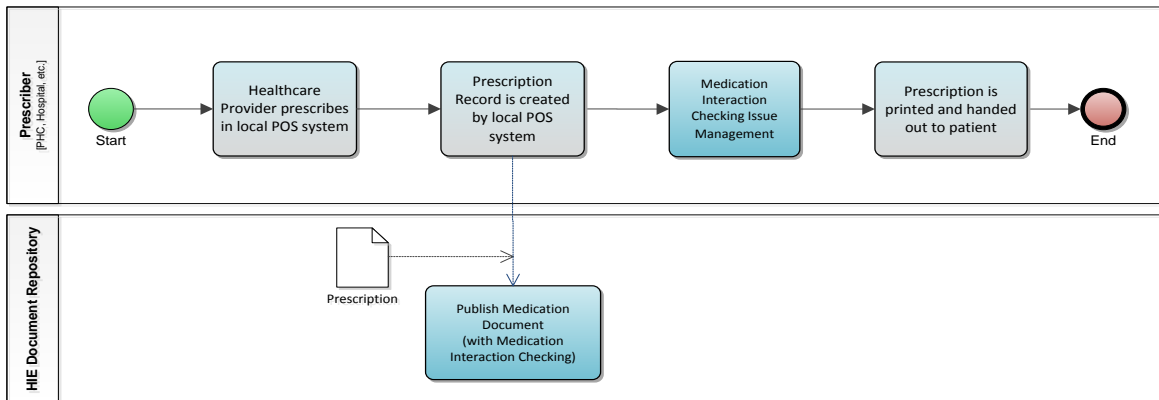

FIGURE 5.1-2 PRESCRIBE MEDICATION PROCESS

5.1.3 Query/Retrieve Prescription

The Query/Retrieve Prescription Business Process covers querying and retrieving a prescription and all related records (e.g., updates) from the HIE Document Repository.

The process steps for querying and retrieving prescriptions are:

1. Query prescriptions from the HIE Document Repository
2. Identifying the prescription in the search result

3. Retrieving the prescription and all related records from the HIE Document Repository and processing them (i.e., apply to each prescription the updates from related pharmaceutical advices and link performed dispensations to underlying prescriptions to present the most current view of the prescription)

Figure 5.1-3 Query/Retrieve Prescription process depicts the process for **Query/Retrieve Prescription**.
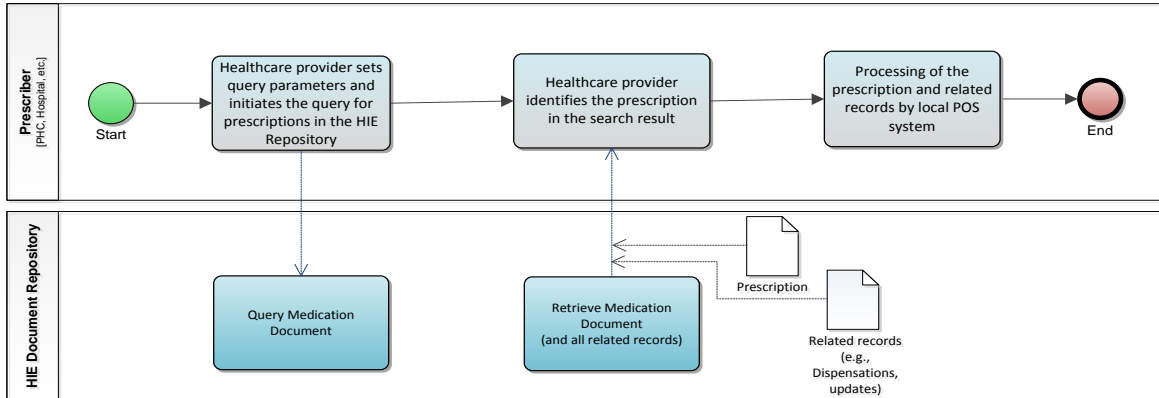

FIGURE 5.1-3 QUERY/RETRIEVE PRESCRIPTION PROCESS

5.1.4   Manage Prescription Item

The Manage Prescription Item business process covers the act of managing a single Prescription Item.

The process steps for managing a Prescription Item are:

1. Manage Prescription Item in local system
2. Local Point of Care system creates the update document
3. Submit the update to the HIE Document Repository

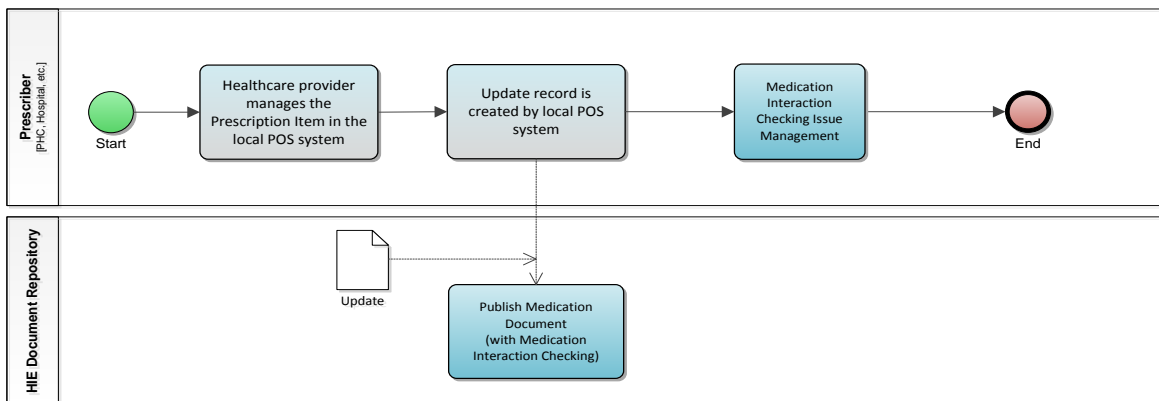Figure 5.1-4 Manage Prescription Item process depicts the process for **Manage Prescription Item**.

FIGURE 5.1-4 MANAGE PRESCRIPTION ITEM PROCESS

5.1.5   Revoke Prescription

The Revoke Prescription business process covers revoking a prescription already submitted to the HIE Document Repository. It includes the revocation of the prescription in the local Point of Care system followed by deleting the document. The process ends with the disposal of the physical prescription.

The process steps for revoking a prescription are:

1. Revoke the prescription in the local Point of Care system
2. Delete the prescription in the HIE Document Repository
3. Disposal of the physical prescription

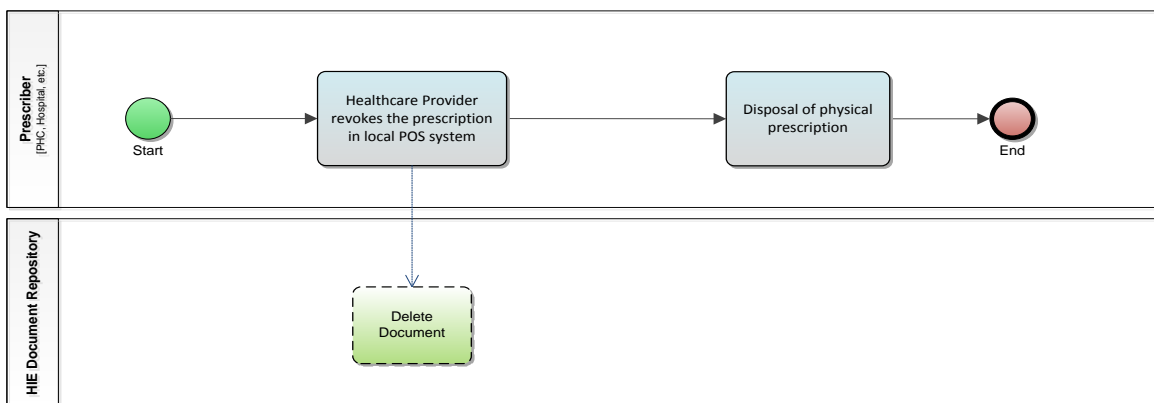Figure 5.1-5 Revoke Prescription process depicts the process for **Revoke Prescription**.

FIGURE 5.1-5 REVOKE PRESCRIPTION PROCESS

5.1.6   Dispense Medication

The Dispense Medication Business Process covers the act of dispensing medication to a patient. It includes the recording of the Dispensation Record in the local Point of Care system followed by the submission of the Dispensation Record to the HIE Document Repository. The submission succeeds in case the central Medication Interaction Checking service discovers no issues but fails if issues are discovered. If issues are discovered Medication Interaction Checking Issue Management is performed. The process ends with the delivery of the medication to the patient.

The process steps for dispensing medication are:

1. Record Dispensation Record in the local Point of Care system
2. Local Point of Care system creates the Dispensation Record
3. Submit the Dispensation Record to the HIE Document Repository
4. In case the submission fails because the central Medication Interaction Checking service reports issues, Medication Interaction Checking Issue Management is performed
5. Dispense medication to the patient

Figure 5.1-6 Dispense Medication process depicts the process for **Dispense Medication**.
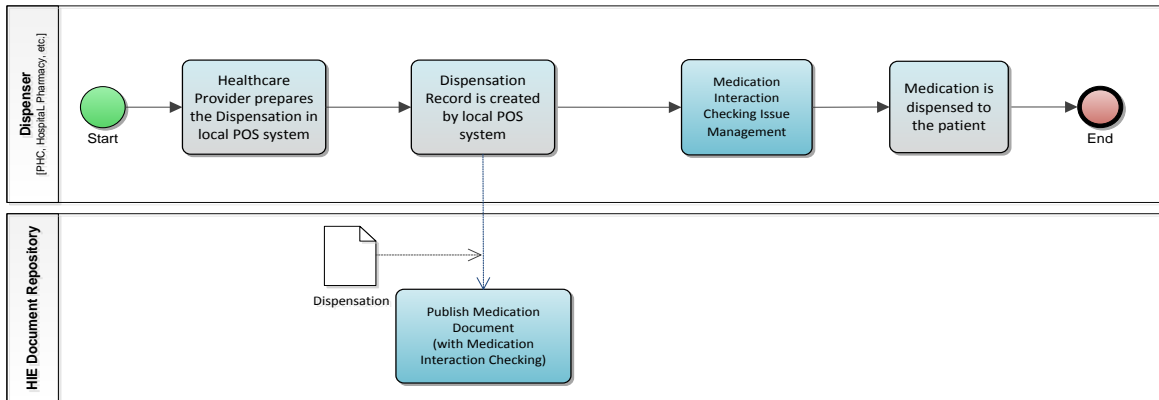
FIGURE 5.1-6 DISPENSE MEDICATION PROCESS

5.1.7   Query/Retrieve Dispensation

The Query/Retrieve Dispensation business process covers the act of querying and retrieving a Dispensation Record and all related records (e.g., updates) from the HIE Document Repository.

The process steps for querying and retrieving Dispensation Records are:

1. Query Dispensation Records from the HIE Document Repository
2. Identifying the Dispensation Records in the search result
3. Retrieving the Dispensation Record and all related records from the HIE Document Repository and processing them (i.e., apply to each dispensation the updates from related pharmaceutical advices to present the most current view of the dispensation)

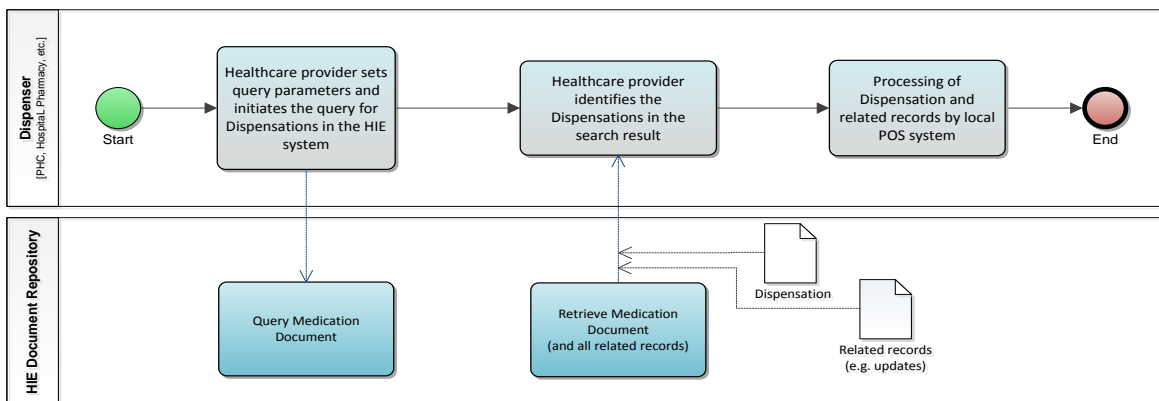Figure 5.1-7 Query/Retrieve Dispensation process depicts the process for **Query/Retrieve Dispensation**.

FIGURE 5.1-7 QUERY/RETRIEVE DISPENSATION PROCESS

5.1.8   Manage Dispensation Item

The Manage Dispensation Item business process covers the act of managing a single Dispensation Item.

The process steps for managing a Dispensation Item are:

1. Manage Dispensation Item in the local system.
2. Local Point of Care system creates the updated Dispensation Record.
3. Submit the update to the HIE Document Repository.

Figure 5.1-8 Manage Dispensation Item process depicts the process for **Manage Dispensation Item**.
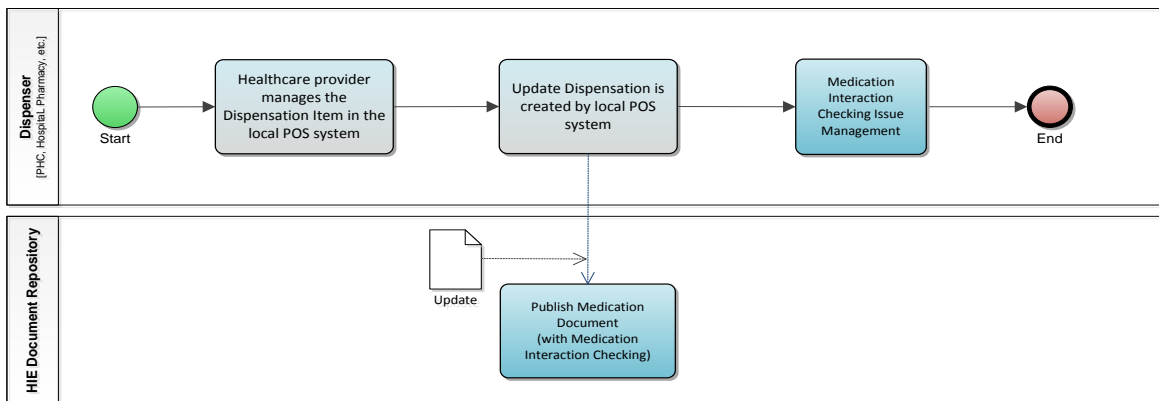
FIGURE 5.1-8 MANAGE DISPENSATION ITEM PROCESS

5.1.9   Revoke Dispensation

The Revoke Dispensation Business Process covers revoking a dispensation already submitted to the HIE Document Repository. It starts with the cancellation of the dispensation in the local Point of Care system followed by deleting the dispensation from the HIE Document Registry. The process ends with the retrieval of the medication from the patient.

The process steps for revoking a Dispensation Record are:

1. Retrieve medication from the patient.
2. Revoke the Dispensation Record in the local Point of Care system.
3. Delete the Dispensation Record entry in the HIE Document Repository.

Figure 5.1-9 Revoke Dispensation process depicts the process for **Revoke Dispensation**.

FIGURE 5.1-9 REVOKE DISPENSATION PROCESS
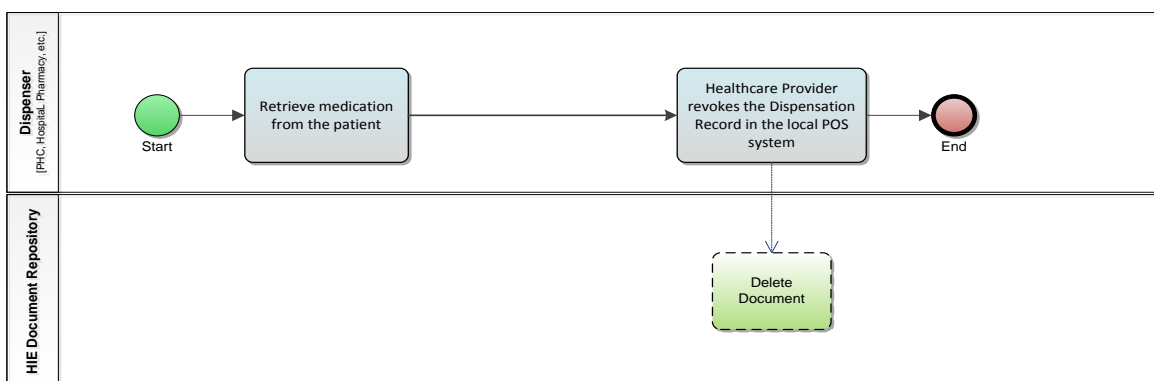
5.1.10 Medication Interaction Checking Issue Management

The Medication Interaction Checking Issue Management Business Process covers the act of the management of all Medication Interaction Checking issues determined during the Medication Interaction Checking process performed at submission of a record (Prescription-, Dispensation-, Update Records). Issues may be raised by:

- Medication-Allergy interactions.
- Medication-Medication interactions.
- Medication dosing problems.
- Problems of the Medication related to the diagnosis.
- etc.

Analyzing the determined issues may result in the following choices following a system alert to the Healthcare Provider:

(1) In case no issues have been determined, no issue management is required and the process ends.
(2) In case issues have been determined and the Healthcare Provider decides to change the original record following acknowledgement of the alert, the process starts again at submission of the changed record.
(3) In case issues have been determined and the Healthcare Provider decides to accept the issues, Medication Interaction Checking Issue Management records are created for each issue to document the decision and rational along with the Healthcare Provider's acknowledgement of the alert. The original record together with all management records is resubmitted to the HIE Document Repository.

The process steps for Medication Interaction Checking are:

1. Creation of Medication Interaction Checking Issue Management records.
2. Store original record and all issue management records.

Figure 5.1-10 Medication Interaction Checking Issue Management process depicts the process for **Medication Interaction Checking Issue Management**.
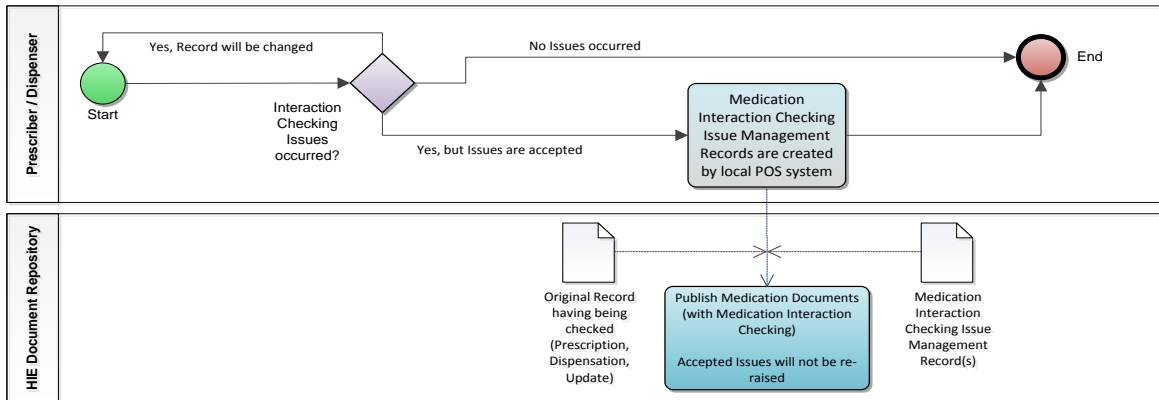
FIGURE 5.1-10 MEDICATION INTERACTION CHECKING ISSUE MANAGEMENT PROCESS

5.2 EXTERNAL BUSINESS PROCESSES

The following Business Processes are referenced in the Medication Use Cases, but are defined in other Use Cases.

5.2.1 Obtain Patient Health Identifier

This Business Process is initiated to retrieve a patient's Health ID from the HIE Platform. In order to query/retrieve any information (e.g. documents, images) for a patient from the HIE Platform it is first necessary to **Obtain Patient Health Identifier** using Patient Demographic Consumer Actor.

TABLE 5.2-1 OBTAIN PATIENT HEALTH IDENTIFIER

BUSINESS PROCESS	REFERENCE
Obtain Health Identifier	*UC0001 Saudi eHealth Use Cases – Phase 1A*: Patient and Provider Identification Use Cases

5.2.2 Retrieve and Reconcile Clinical Data

This Business Process is initiated to **Retrieve and Reconcile Clinical Data** for a given patient. In order to ensure that the Healthcare Provider's local clinical data are synchronized with the HIE Document Repository at the beginning of a patient's visit (e.g. outpatient encounter, inpatient stay). The iEHR summaries containing clinical data from all of the patient's visits since the last local patient visit are queried and retrieved using the Clinical Content Consumer Actor. The Healthcare Provider then uses these iEHR summaries along with the local clinical data to reconcile and update the patient's record with information occurring from the outside of the local system.

TABLE 5.2-2 RETRIEVE AND RECONCILE CLINICAL DATA

BUSINESS PROCESS	REFERENCE
Retrieve and Reconcile Clinical Data	UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries

6. SERVICES

6.1 SERVICE DESCRIPTIONS

The Services defined in this Use Case are described in Table 6.1-1 Services.

TABLE 6.1-1 SERVICES

SERVICE NAME	SERVICE USE
Create/Manage Prescription	Create/Manage Prescription is used to create a prescription and publish it to the HIE Document Repository as well as submitting changes to a prescription (e.g. cancel Prescription Item, change Prescription Item, etc.).
Create/Manage Dispensation	Create/Manage Dispensation is used to create a Dispensation Record and publish it to the HIE Document Repository as well as submitting changes to a Dispensation Record (e.g. stop intake of a Dispensation Item, change dosage of Dispensation Item, etc.).
Query/Retrieve Medication Records	Query and Retrieve Medication Records and all related records (e.g., Prescription Records, Dispensation Records, updates) from the HIE Document Repository.

6.1.1 Pre-Conditions

Table 6.1-2 Pre-Conditions identifies pre-conditions for this Use Case.

TABLE 6.1-2 PRE-CONDITIONS

ACTOR NAME	SERVICES	DESCRIPTION
Actor	All Services	It is expected that all services initiated or provided by this actor operate in accordance with the Saudi eHealth Interoperability Polices and Interoperability Specifications.
		The patient's Health ID has been obtained and is used for all medical records for the patient.
Prescriber	Create/Manage Prescription	A KSA authorized Healthcare Provider and/or Organization determines that one or more prescriptions need to be issued for a patient.
		A KSA authorized Healthcare Provider and/or Organization determines that one or more Prescription Items are required to be managed for a patient and the Prescription Items managed have not yet been dispensed or partially dispensed (e.g. changed).
		A KSA Healthcare Provider and/or Organization determines that the entire prescription is to be revoked.
		A KSA Healthcare Provider and/or Organization has been synchronized with the iEHR On-Demand Summaries from the HIE Document Repository.
	Create/Manage Dispensation	A KSA Healthcare Provider and/or Organization determines that one or more Dispensation Items are required to be managed for a patient (e.g., stopped).
		A KSA Healthcare Provider and/or Organization has been synchronized with the iEHR On-Demand Summaries from the HIE Document Repository.

	Query/Retrieve Medication Records	A KSA Healthcare Provider and/or Organization determines that one or more Prescription- or Dispensation Records (and related records such as updates) are required to be queried and retrieved from the HIE Document Repository.
Dispenser	Create/Manage Dispensation	The medication requested is ready to be dispensed (e.g. "in stock", etc.).
		A KSA authorized Healthcare Provider and/or Organization determines that one or more Dispensation Items are required to be managed for a patient (e.g., stopped).
		A KSA authorized Healthcare Provider and/or Organization determines that the entire Dispensation Record is to be revoked.
		A KSA Healthcare Provider and/or Organization has been synchronized with the iEHR On-Demand Summaries from the HIE Document Repository.
	Query/Retrieve Medication Records	A KSA Healthcare Provider and/or Organization determines that one or more Prescription- or Dispensation Records (and related records such as updates) are required to be queried and retrieved from the HIE Document Repository.

6.1.2   Post-Conditions

Table 6.1-3 Post-Conditions identify post-conditions for this Use Case.

TABLE 6.1-3 POST-CONDITIONS

ACTOR NAME	SERVICES	DESCRIPTION
Prescriber/ Dispenser	Query/Retrieve Medication Records	The requested Prescription- or Dispensation Record has been transferred to the requesting actor including all related records (e.g. Dispensation Records related to a prescription).

6.1.3   Assumptions and Dependencies

Table 6.1-4 Use Case Dependencies identifies and describes Use Cases which this Use Case depends upon for information workflow.

TABLE 6.1-4 USE CASE DEPENDENCIES

USE CASE NAME	DEPENDENCY ASSUMPTIONS
KSA-Wide Patient Demographic Query	The KSA-Wide Patient Demographic Query Use Case is used to obtain a Health ID and demographic attributes for the patient that the referral and/or transfer is being performed.
Healthcare Provider Directory Query	The Healthcare Provider Directory Query Use Case is used to obtain provider and organizational information. It may be used to identify requesting physicians and organizations and also receiver personal and organization information.
iEHR On-Demand Summary	The iEHR On-Demand Summary Use Case is used to retrieve and reconcile patient clinical data from past patient encounters (outpatient or inpatient).

6.1.4   Special Requirements

NA

7. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this Use Case.

TABLE 7-1 REFERENCED DOCUMENTS

MOH DOCUMENT	DESCRIPTION
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 Saudi Health Information Exchange managed health records, including those connected to the Saudi Health Information Exchange, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the Saudi Health Information Exchange. May be found at [PENDING Saudi Publication Location]
UC0001 Saudi eHealth Patient Identification Interoperability Use Case	This Use Case describes the capability to match a patient with his/her identity. This capability is accessible to various "edge" applications including point of care systems and MOH business applications. It uses a set of patient demographic attributes (name, birth date, gender, etc.) and a unique nation-wide identifier called a Health ID. A Health ID is registered for Saudi citizens, residents, displaced people, GCC nationals and visitors/pilgrims. This Health ID is used for the unique identification of a patient and his/her health records. This Health ID and associated demographic attributes are managed centrally by a "patient client registry" system so that the information may be widely accessed via queries against such a registry.
UC0002 Saudi eHealth Provider Identification Interoperability Use Case	This Use Case describes the ability to access information about health professionals and the organizations where they practice. This information is centrally managed by a national healthcare provider directory; the directory which 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.
UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries	The Clinical Notes and Summaries Use Case address improvement of patient care through increased healthcare provider access to information during a transition of patient care. These Use Cases provide one or more technical scenarios that convey how the system should interact with the end user, or another system, to achieve a specific business goal. These Use Cases provide a set of high-level functional requirements. Standards and Profiles supporting these Use Cases are documented in the Saudi Interoperability Specification and Interoperability Policies.