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eHEALTH DIGITAL SERVICES INFRASTRUCTURE OPEN NATIONAL CONTACT POINT IMPLEMENTATION AND TEST PLATFORM SERVICES

Core Interoperability Specification for Sharing ePrescription and eDispensation

Author	Anne-Gaëlle BERGE
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IHE-Europe – Bluepoint Building – 80, boulevard A. Ryers, 1030 Brussels Belgium

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Eamon Coyne		

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Name	Date	Contact	Purpose*
Eamon Coyne			V
Caitriona Wray			V
Peter Connolly			V

* A: for action / V: for Approval / C: for comments/ I: for information

Reference documents

This section gathers the documents which are referenced in this document. In the body of this document, any reference to an external document is formatted using [KEYWORD] from the first column.

Keyword	Name and reference
[S&P]	*Security and Privacy Interoperability Specification* HSE9100-LOT2-IS-SECURITY_PRIVACY
[ITERM]	*General Terminology Interoperability Specification* HSE9100-LOT2-IS-TERMINOLOGY
[UC_ANALYSIS]	*ePrescription and Patient Summary use cases analysis* HSE9100-LOT2-UC-DELIVERABLE-1A
[IPIM]	*Patient Identification Management Interoperability Specification* HSE9100-LOT2-IS-PAT_ID_MGT
[IXDS]	*Core Interoperability Specification for sharing documents* HSE9100-LOT2-IS-DOC_SHARING
[IPD]	*ePrescription and eDispensation Content Interoperability Specification* HSE9100-LOT2-IS-eP_eD_CONTENT

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1 Preface

Ireland as a European country is becoming involved in the eHDSI(eHealth Digital Services Infrastructure) project led by the European Commission under the CEF (Connecting European Facilities) program and will participate to the deployment in the wave 3 (2020). To prepare the deployment of the NCPeH (National Contact Point for eHealth) in Ireland, the HSE (Health Service Executive) procured in 2018 the support services that will facilitate the implementation of the NCPeH and its connection to central Irish services. The first step of the project is to define the needed use cases to support and to design the architecture for connecting the Irish NCPeH. These tasks will be followed by the design of the architecture within Ireland, the corresponding Interoperability Specifications, the testing strategy including test plans and the implementation of Gazelle test platform that includes test cases, test tools and test data.

1.1 Context

Directive 2011/24/EU provides rules for facilitating access to safe and high quality cross border healthcare and promotes cooperation on healthcare between member states. The aims of implementing the Irish NCPeH exchange of Patient Summaries and ePrescription are in line with the principles of cross-border care. The NCPeH and cross border exchange implementations are all key building blocks that will interact with the national data dictionary (single source of trust for clinical data definitions across the enterprise) and the Patient Summary and ePrescribing documents and associated will be stored there as minimum data sets.

The main goals are to design the platform based on the needs that will be developed in the first steps of the project that includes

- Use Cases for ePrescription and Patient Summary
- Corresponding Interoperability specifications and architecture orchestration
- Validated version of IHE Gazelle. The test harness will provide to the authority the ability to test prospective vendors and products against the above interoperability specifications.

1.2 Glossary

ePrescription: means a medicinal prescription issued and transmitted electronically, as elaborated in point 3 (f) of Commission Recommendation 2008/594/EC on cross-border interoperability of electronic health records. [PS/eP guidelines]

eDispensation: is defined as the act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format. [PS/eP guidelines]

IHE profile: provides a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. A Profile is a guideline for implementation of a specific process, by providing precise definitions of how standards can be implemented to meet specific clinical needs. [eHealth Interoperability Conformity Assessment Scheme for Europe (EURO-CAS)]

Interoperability use case: description of a specific use of HIT (Health Information Technology) that includes depiction of both humans (business actors) and systems (technical actors), scope, workflows of tasks performed by healthcare professionals and associated data flows. It should be written in natural language and may include several scenarios. One or more use cases are derived from one business case [IHE taskforce]

Realisation scenario: description of human activities (business actors), systems (technical actors) roles (i.e., IHE actors) and transactions related to a set of technical use cases that support the interoperability infrastructure for use cases (implementable infrastructure). [IHE taskforce]

1.3 Document purpose

An Interoperability Specification provides a detailed set of requirements (including references to specific profiles and standards) that enable health information exchange in an e-health deployment (national, regional, cross-border, intra institution) for a specific topic.

When covering the requirements related to the realization of an interoperability use case, the corresponding interoperability specification is called a Core Interoperability Specification. A (Core) Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

When covering a subset of the interoperability requirements for one or more use cases, the corresponding interoperability specification is called a Supporting Interoperability Specification. Indeed, it is intended to be referenced by one of more Core Interoperability Specifications

The present document is a Supporting Interoperability Specification for the sharing of documents in a nation-wide distributed environment organized around a document registry and one or more document repositories to which connect sources and consumers of documents.

1.4 How to read this document

This document contains three normative sections (3, 4, and 5), as well as informative appendices for the reader convenience. The document is structured as follows:

- **Section 3**: Gives the requirements in term of actor grouping
- **Section4**: Establishes the Conformance Requirements for the Interoperability Specification.
- **Sections 5**: Establishes the Constraints on the Cross-Enterprise Document Sharing (XDS.b) profile in the context of the Irish Cross-Border project.
- **AppendixA**: Illustrates the designed workflow with sequence diagrams.

1.5 References

A (Core) Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing and possibly certification, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

From this (Core) Interoperability Specification a number of supporting Interoperability Specifications are referenced:

- ePrescription and eDispensation Content Interoperability Specification [IPD]
- Interoperability Specification for Sharing Documents [IXDS]
- Patient Identification Management Interoperability Specification [IPIM]
- Security and Privacy Interoperability Specification [S&P]
- General Terminology Interoperability Specification [ITERM]

The above Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Irish specific constraints.

Implementations are required to conform to the requirements within this (Core) Interoperability Specification; all referenced Interoperability Specifications, and the standards and profiles they specify.

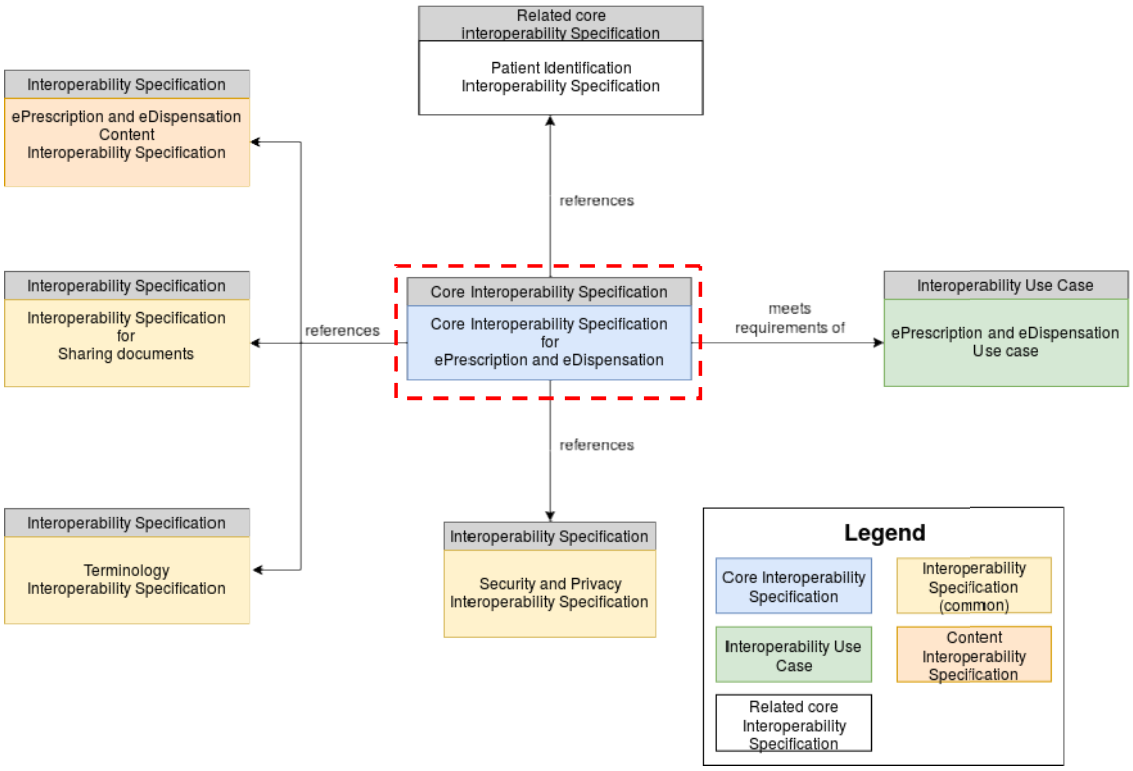

FIGURE 1-1 SHARING OF EPRESCRIPTION AND EDISPENSATION DOCUMENT ORGANIZATION

1.6 Description

This Interoperability Specification describes the technical interface requirements for sharing ePrescription and eDispensation in the cross-border context.

1.7 Document convention

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.

These numbered requirements are the elements of the Interoperability Specification that the system conforms 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 numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.7.1 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.

1.8 Methodology

This Interoperability Specification has been developed with input from various Irish stakeholders collected during several months through workshops and teleconferences.Stakeholders included Physicians from many different disciplines and Irish 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 may consider reviewing the related Use Case document.

1.8.1 Introduction of the use case driven approach

This methodology[2] has the objective to

[1] Definitions based upon IETF RFC 2119

[2] Bourquard,Karima and Berler, Alexander. Use case driven approach for a pragmatic implementation of interoperability in eHealth. IGI Global Journal

- Define Use cases and their prioritization to answer the eHealth strategy objectives of nation/region;
- From use cases to design the interoperability specifications and infrastructure based on IHE profiles;
- To define the testing strategy and identify test plan and test methods (test cases, test tools and test data);
- To support Project teams to procure products or solutions for their eHealth Project (Telemedicine, national/regional EHR, replacement of product in hospitals, …);

The methodology is based on experiences and good practices in other countries or regions. It is further described in [UC_ANALYSIS].

2 ePrescriptionUse case overview

2.1 Scope

The ePrescription and eDispensation use case is further defined and analyzed in [UC_ANALYSIS].

2.2 Not in scope

This Core Interoperability Specification does not define how the ePrescription source gets the data to fill out the ePrescription CDA document.

This first version of the Core Interoperability Specification does not specify the eDispensation Use case actors and requirements. It is expected in a next release of the document.

2.3 Use case actors and services

The Use Case Actors and the Services that are used by this Core Interoperability Specification for Sharing Patient Summaries are described at a functional level in [UC_ANALYSIS].Readers who wish to understand the mapping of Use Case Actors to real world products are recommended to read [UC_ANALYSIS]. A summary is provided in the following tables:

TABLE 2-1 USE CASE ACTORS

ACTOR NAME	DESCRIPTION
ePrescription Source	Responsible for the creation of ePrescription and publishing them to the Shared Document Repository.
Shared Document Repository	Stores records (ePrescription Records, eDispensation Records) and makes them available to consumers.
National Document Registry	Stores references to the documents published in the Shared Document Repository.
ePrescription Consumer	Consumes ePrescription documents.

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. 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 Actor's 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 does 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 2-2 USE CASE SERVICES

SERVICE NAME	DESCRIPTION
Publish Document(s)	Used to publish documents (ePrescription and eDispensation) to the National Shared Record as well as to submit changes to a record.
Register Document Entry	Used to register a document in the registry. This document might not exist at the time of the registration but the registry shall be notified that the Integrated Document Source/Repository is able to assemble it if needed.
Retrieve Document Set	Used to retrieve a document knowing its reference. Shall be preceded by a Query for Documents transaction.
Query for Documents	Query for relevant records. The result will be a list of references to the actual documents
Update Document Metadata	Fill the registry with the updated metadata of the document once it has been assembled.

2.4 Design constraints and assumptions

2.4.1 ePrescription Source

The ePrescription Source shall be aware of the patient's demographics and identifiers to fill correctly the CDA document section related to the patient identity. It might also be a source of identities for the National Document Registry.

> *[ISPD-001]* The ePrescription Source actor shall be grouped with the **Patient Identity Source and Identifier Cross-Reference Consumer** Use Case actor defined in the National Patient Identification Management Core Interoperability Specifications.

3 Core Interoperability Specification Requirements

3.1 Actor mapping to Interoperability Specifications

The Use Case Actors and the Services they support are described at a functional level in the **ePrescription and Patient Summary Use Case analysis** document [UC_ANALYSIS]. Services may be required, conditional or optional. The Use Case Actor, Service(s) and optionality are conveyed in the first three columns of Table 3-1 Interoperability Conformance Requirements.

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, Profile 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), the **system shall implement all the requirements** (some optionality when allowed) **listed in the second part of the table** (columns 4-7). This includes the referenced healthcare profiles, the standards specified and terminology standards. For each Profile Actor (whether required or optional), the last column references the detailed specification that constrains and extends the implementation of this profile for Irish specific requirements. These specifications may be found in Appendices to this (core) specification or in other referenced Interoperability Specifications.

Readers who wish to understand the mapping of Use Case Actors to real world products are recommended to read the ePrescription and Patient Summary Use Cases analysis document [UC_ANALYSIS].

TABLE 3-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR EPRESCRIPTION USE CASE

EPRESCRIPTION SHARING USE CASE			MAPPING TO SECTIONS FROM THIS AND REFERENCED INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
ePrescription Source	Publish document(s)	R	Content Creator	R	HL7 CDA Rel. 2.0	ePrescription & eDispensation Content Interoperability Specifications – ePrescription - Section 6
	Retrieve document Set	R	Content Creator	R	IHE Cross-Document Sharing of Scanned Document (XDS-SD)	IHE ITI TF Volume 1 – Section 20
			Integrated Document Source/Repository	R	IHE Cross-Enterprise Document Sharing (XDS.b)	Interoperability Specification for sharing documents – Section 3.2 Integration Profile Option to be supported: • Delayed Document Assembly • Document Replacement • Document Transformation

EPRESCRIPTION SHARING USE CASE			MAPPING TO SECTIONS FROM THIS AND REFERENCED INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Document Administrator	R	IHE Cross-Enterprise Document Sharing Metadata Update (XDS-MU)	Interoperability Specification for sharing documents – Section 3.6
			Authorization Decisions Verifier	R	IHE Secure Retrieve SeR	Security and Privacy Interoperability Specification – Section3.6.2 Systems shall implement either the SeR profile either an adHoc interface
			X-Service User	R	IHE Cross-Enterprise User Authorization (XUA)	Security and Privacy Interoperability Specification – Sections 11
			X-Service Provider	R	IHE Cross-Enterprise User Authorization (XUA)	Security and Privacy Interoperability Specification – Sections 12
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	Security and Privacy Interoperability Specification – Sections 9
			Time Client	R	IHE Consistent Time (CT)	Security and Privacy Interoperability Specification- Section 3.1.2
National Document Registry	Query for documents	R	Document Registry	R	IHE Cross-Enterprise Document Sharing (IHE XDS.b)	Interoperability Specification for sharing documents – Section 3.4 Integration Profile Option to be supported: • Document Metadata Update
			X-Service Provider	R	IHE Cross-Enterprise User Authorization XUA	Security and Privacy Interoperability Specification – Section12
			Authorization Decisions Manager	R	IHE Secure Retrieve SeR	Security and Privacy Interoperability Specification – Section3.6.2 Systems shall implement either the SeR profile either an adHoc interface

EPRESCRIPTION SHARING USE CASE			MAPPING TO SECTIONS FROM THIS AND REFERENCED INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	Security and Privacy Interoperability Specification – Section 9
			Time Client	R	IHE Consistent Time (CT)	Security and Privacy Interoperability Specification – Sections 3.1.2
ePrescription consumer	Query for Documents	R	Content Consumer	R	HL7 CDA Rel. 2.0	ePrescription & eDispensation Content Interoperability Specification – ePrescription – Section 6
			Content Consumer	R	IHE Cross-Document Sharing of Scanned Document (XDS-SD)	IHE ITI TF Volume 1 – Section 20
	Retrieve Document Set	R	Document consumer	R	IHE Cross-Enterprise Document Sharing (XDS.b)	Interoperability Specification for sharing documents – Section 3.3 Integration Profile Option to be supported: • Delayed Document Assembly
			X-Service User	R	IHE Cross Enterprise User Authorization (XUA)	Security and Privacy Interoperability Specification- Section 11
			Secure Node	R	IHE Audit Trail and Node Authentication	Security and Privacy Interoperability Specification- Section 9
			Time Client	R	IHE Consistent Time (CT)	Security and Privacy Interoperability Specification- Section 3.1.2

4 ePrescription actors conformance

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a **Use Case Actor (**first columns of Table 3-1 Interoperability Conformance Requirements**Erreur ! Source du renvoi introuvable.**). A system may claim conformance to one or more Use Case Actors among:

- ePrescription Source
- ePrescription Consumer
- National Document Registry
- Shared Document Repository

5 Constraints on ePrescription Use Case actors

5.1.1 Document Replacement

*[ISPD-002]*The ePrescription Source Use Case actor is required to implement the Document Replacement option.

The ePrescription Source shall maintain a record of the prescription items which have been used as inputs of an ePrescription document published in the Shared Document Repository. In case the prescription is modified at the ePrescription Source, the system shall update the ePrescription document at the Shared Document Repository by publishing a new version of the document using the RPLC association.

5.1.1 Document Transformation

*[ISPD-003]*The ePrescription Source Use Case actor shall implement the Document Transformation option.

Each ePrescription document shall be sent along with its PDF version embedded in XDS-SD document.

5.1.2 Metadata attributes

5.1.2.1 Document ClassCode

*[ISPD-003]*When sharing ePrescription documents, the classCode metadata attribute shall be equal to “PRESCRIPTIONS”.

5.1.2.2 Document typeCode

*[ISPD-004]*When sharing ePrescription document, the typeCode metadata attribute shall be equal to “57833-6”.

5.1.2.3 Document formatCode

*[ISPD-005]*When sharing ePrescription document (CDA), the formatCode metadata attribute shall be equal to “urn:epSOS:ep:pre:2010”.

[ISPD-006] When sharing the PDF version of the ePrescription, the formatCode metadata attribute shall be equal to “urn:ihe:iti:xds-sd:pdf:2008”.

5.1.2.4 Document mimeType

*[ISPD-007]*When sharing ePrescription document, the mimeType metadata attribute shall be equal to “text/xml”.

6 Appendices

6.1 Appendix A: Interoperability sequence diagrams

The following sequence diagram provides an overview of the combined flow of transactions resulting from the above selected profiles and standards.

6.1.1 ePrescription workflow

The first sequence diagram (Figure 6-1 High Level ePrescription Workflow) is a high level representation of the default workflow. It assumes that the ePrescription is built using the data extracted from the HL7v2 messages. The workflow is made of two parts that might not occur in a timely manner. In a first phase, the ePrescription Source Use Case Actor registers the documents it is able to assemble upon receipt of an HL7v2 message. In a second phase, an ePrescription Consumer Use Case Actor requires access to an ePrescription document.

The second sequence diagram (Figure 6-2 ePrescription Source publishing a document) makes use of the IHE transactions to describe all the interactions which occur when the ePrescription Source Use Case Actors registers a document.

The third sequence diagram describes all the IHE transactions in action for the ePrescription Consumer Use Case Actor to retrieve an ePrescription document.

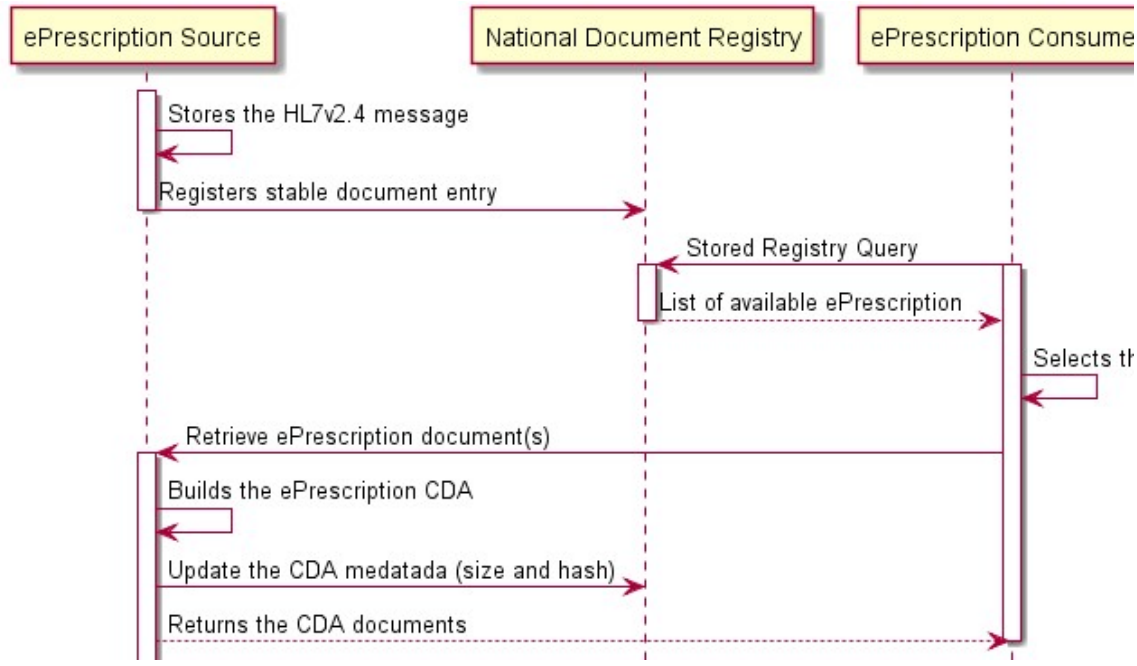

FIGURE 6-1 HIGH LEVEL EPRESCRIPTION WORKFLOW

The sequence diagram below also introduces pre-requites in terms of security and privacy constraints.

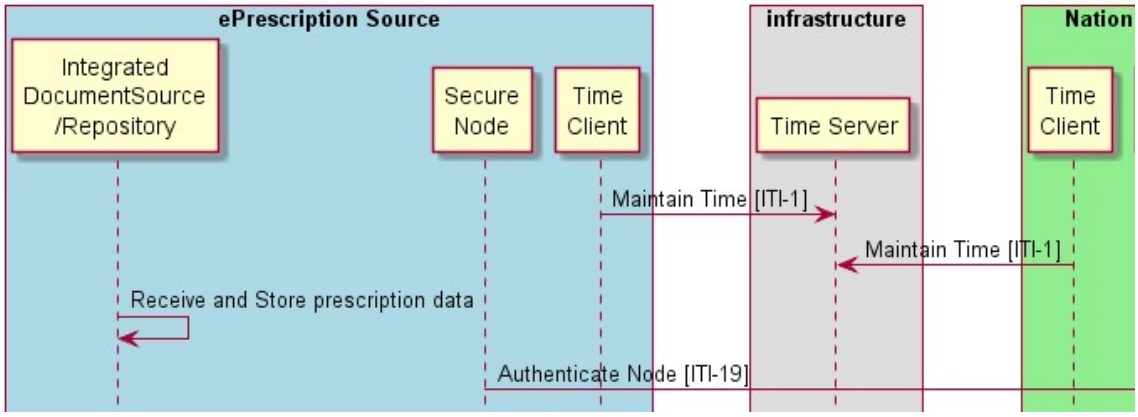

FIGURE 6-2 EPRESCRIPTION SOURCE PUBLISHING A DOCUMENT

To simplify the workflow below, the pre-requisites steps (Maintain Time and Authenticate Node) have been hidden on purpose.

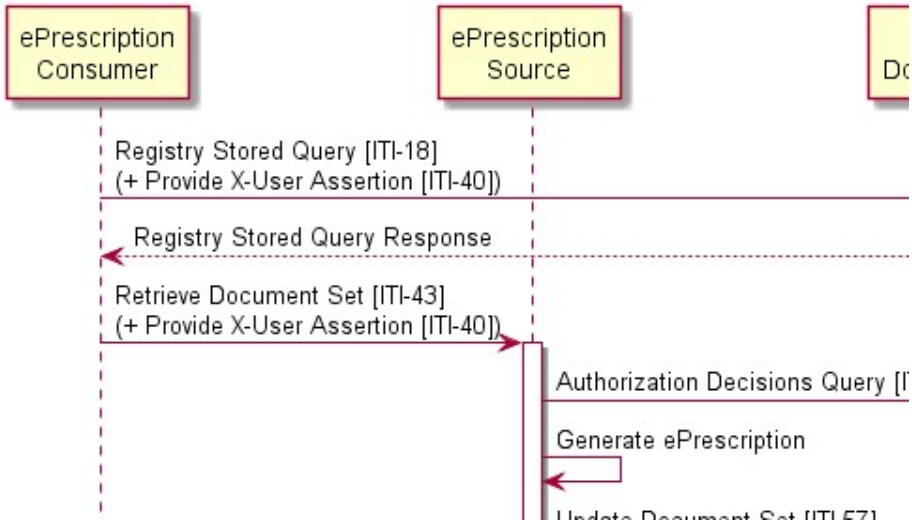

FIGURE 6-3 EPRESCRIPTION CONSUMER QUERIES AND RETRIEVES EPRESCRIPTION