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IHE Pharmacy Technical Framework Supplement

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Common Parts

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Trial Implementation

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Foreword

This document contains sections which will be common sections in the forthcoming Pharmacy Technical Framework.

The following supplements refer to these common parts:

- CMPD - Community Medication Prescription and Dispense
- HMW - Hospital Medication Workflow
- PRE - Content Profile for Prescription
- PADV - Content Profile for Pharmaceutical Advice
- DIS - Content Profile for Dispense

This supplement is published on September 29, 2014 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the forthcoming Pharmacy Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/Pharmacy_Public_Comments.

This supplement describes changes to the existing technical framework documents.

“Boxed” instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

<i>Amend Section X.X by the following:</i>
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Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: <http://www.ihe.net>.

Information about the IHE Pharmacy domain can be found at: http://ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://ihe.net/IHE_Process and <http://ihe.net/Profiles>.

The current version of the IHE Pharmacy Technical Framework can be found at: http://ihe.net/Technical_Frameworks.

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1 Pharmacy Business processes and models

1.1 Pharmacy domain business process

In this section we describe, from a high level perspective, the processes of the Pharmacy domain, focusing on interoperability among systems that belong to one or more institutions.

1.1.1 General medication process

In general, the medication business process consists of four distinct processes, which have to be connected through interactions that transfer information and/or guide the workflow. Figure 1.1.1-1 shows this flow.

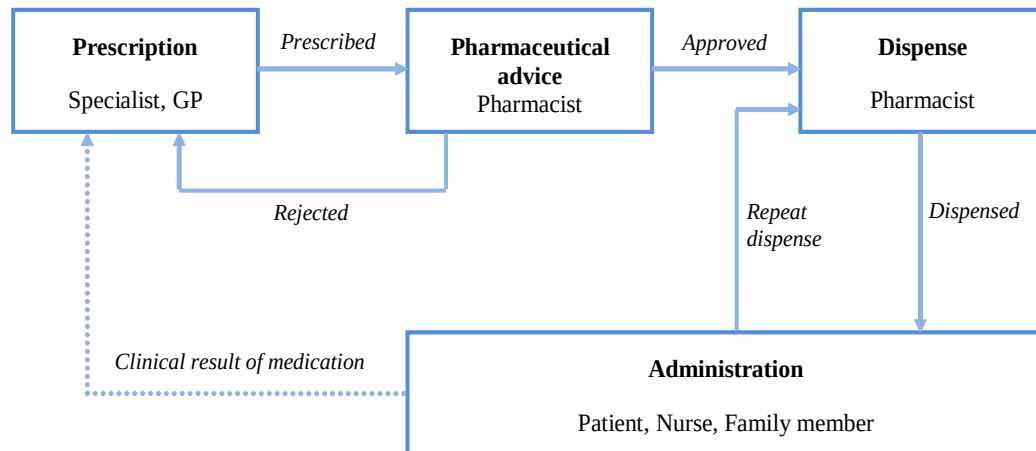


Figure 1.1.1-1: Time flow diagram showing the main elements in the general medication process.

The four main processes are:

1. **Prescription of medication:** the process in which a health care professional (HCP: in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. The HCP produces a prescription, an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient.

- 115 2. **Pharmaceutical Advice**¹: the process in which an HCP (typically a different HCP than the prescriber, in most cases, but not necessarily always, a pharmacist) takes in the prescription and checks it against pharmaceutical knowledge and regulations. On positive outcome of the validation the pharmacist decides to what specific medication the prescription will lead, and makes that medication available to the patient. Record is kept then of the specificities of the dispensed medication (brand, type, form, quantity, etc.).
- 120 3. **Dispense of medication**: the process in which an HCP (typically a different HCP than the prescriber, in most cases, but not necessarily always, a pharmacist) takes in the prescription, and dispenses the physical medication. By dispensing we understand the assigning (giving) of a medication for a particular patient, including the necessary actions that lead to that dispensing (stock management and medication supply included) Record is kept then of the specificities of the dispensed medication (brand, type, form, quantity, etc.). In many cases the dispenser is entitled to make changes to the prescription (e.g., change the brand of the medication), or reject the prescription and inform the prescriber on this rejection. Variations here can exist from health care system to health care system, depending on legislation and/or the role of the pharmacist.
- 125 In many cases one prescription can lead to more than one dispense action, like with repeat prescriptions for chronic diseases. Also here differences may exist between health care systems, in some systems repeat dispenses require repeat prescriptions, yielding a 1:1 relationship between prescriptions and dispenses, in some health care systems multiple dispenses per prescription are allowed.
- 130 4. **Administration of medication**: the process in which the medication is actually administered to the patient. Here, the human actor typically is the patient, a family member or a nurse.
- 135

The loop is finally closed (in the most general case) by the fact that the prescriber takes notice of the result of the medication, and yes or no decides on further action. This clinical process is outside the current scope of this document, as is the clinical process leading to the prescription at the start.

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As stated before, the emphasis of this Technical Framework is on the medication specific interoperability aspects. These occur in this domain because of the fact that GP's and pharmacies are in general different institutions. The other intra-pharmacy processes, like preparation, stock-keeping, drugs purchasing are not included in the scope of this document.

145 A further source of interoperability problems lies in the fact that in the prescription process, as well as in the dispense process, knowledge needs to be available on the total medication regime of the patient, in order to avoid unwanted drug interactions. Since in most health care systems patients can be on medication from different pharmacies, originating from different prescribers,

¹ From the clinical work practice perspective, a prescription is reviewed by a clinical pharmacist. The review may or may not result in recommendation(s) or advice(s) to the prescribing clinician to modify the prescription. Hence semantically more accurate this process could be referenced as Pharmaceutical Review. However, given the pervasive use of this profile, it is agreed through the international review that this term remains unchanged.

150 simultaneously, complete knowledge of all recent dispenses from all possible pharmacies is needed. For similar reasons complete knowledge of recent prescriptions and administrations might be necessary as well in some health care systems.

1.2 Actors

1.2.1 Prescription placer

155 The main role of this actor consists in placing the prescription (initial or modified in case of a substitution of invalidation, for example). It sends the cancellation of the prescription or its discontinuation, as well. In order to fulfill this task, the prescription placer retrieves the current treatment of the patient and medication already dispensed recently.

160 The prescription placer receives the pharmaceutical validation and status tracking information such as substitution, availability, administration plan and reports and cancellation. The corresponding human actor is a prescriber.

1.2.2 Pharmaceutical adviser

165 This actor is responsible for the validation of prescriptions from a pharmacist's perspective. Therefore, it receives the initial prescription, validates it and sends it back (accepted, cancelled, modified, substitution of pharmaceutical product); therefore it provides the pharmaceutical advice. To perform this task it checks the current treatment.

The pharmaceutical advice can be due to clinical, legal, or supply aspects.

This actor may be implemented in the hospital pharmacy module of a hospital information system or the point of sale software of the pharmacy. The corresponding human actor is typically a pharmacist (or pharmacist assistant).

170 1.2.3 Medication dispenser

This actor is responsible for the process of dispensing medication to the patient, fulfilling the prescription. Therefore it produces the information on the medication dispensed to the patient. In order to achieve this, it receives prescriptions already validated. It also confirms drug availability for administration and it receives the administration plan and administration reports.

175 This actor may be implemented as the point of sale software of a community pharmacy or the hospital pharmacy module of a hospital information system. The human actor behind this system actor is usually a pharmacist or a pharmacist assistant.

In addition to the dispense, in this version this actor is considered to take care of all the dependencies to ensure a proper dispensing.

180 1.2.4 Medication administration Informer

The medication administration informer's main responsibility consists in creating and placing the medication administration plan and the corresponding administration reports. In order to achieve

this, it receives the initial prescription, the pharmaceutical validation or a “simple” substitution. It also receives the confirmation of drug availability for administration.

185 Through administration reports, the Medication Administration Manager Actor reports, among others:

- The replacements (e.g., the 1g tablet by two 500 mg single dose packets)
- The follow-up (e.g., injectable follow-up)

1.2.5 Prescription repository

190 This repository contains the medication prescribed to the patient from the prescription placer and may receive updates to the current treatment (cancellations, changes, etc.). It also provides the current treatment to other actors such as the prescription consumer.

1.2.6 Pharmaceutical advice repository

195 This repository contains the pharmaceutical advice issued by the pharmaceutical adviser (typically a pharmacist). It provides this information to the prescription & pharmaceutical advice consumer.

1.2.7 Dispensed medication repository

200 This repository contains the medication actually dispensed to the patient; this information is received from the medication dispenser. The dispensed medication repository provides the medication record of the patient to other actors such as the dispensed medication consumer.

NOTE: The need for an Administered Medication repository is not yet required, as the repositories are used in Community use cases only, and in this case the administered medication is determined to be the same as the dispensed. The need for such a repository may arise on the evolution of the needs, and in this case, the Community Pharmacy model will provide the means to populate and/ or consult the two repositories as adequate.

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1.3 Subdomains

Two subdomains are addressed. The development of the technical framework follows this distinction, due to the different scenarios that occur and due to the document-based architecture in the Community Pharmacy subdomain and the message-based architecture expected for the Hospital subdomain.

The operational conditions are distinct in the subdomains:

1.3.1 Community Pharmacy subdomain

- The patient is not hospitalized.
- The prescriber is in most cases a GP or a medical specialist, the latter in an outpatient clinic or in a private practice environment.
- The dispenser in most cases is a community pharmacist, who also will give any pharmaceutical advice. The inexistence of feedback to the prescription placer is interpreted as positive advice.
- The medication administrator in most cases is the patient or someone from the family.
- Administration of the drug is not traced. The only available information is about the dispensed medication.

1.3.2 Hospital Pharmacy subdomain

- The patient is hospitalized
- The prescriber in most cases is a medical specialist in the clinical environment
- The dispenser in most cases is the hospital pharmacist
- The medication administrator in most cases is a nurse or the patient
- Administration of the drug is usually traced.

It is important to note, that these subdomains cannot be treated totally independently, because there are transitions between the subdomains. As a standard, every patient is in the community pharmacy subdomain, and when the patient needs to be admitted to the hospital he or she changes to the hospital pharmacy subdomain, and vice versa on discharge from the hospital.

Figure 1.3.2 –1 shows this in a scheme.

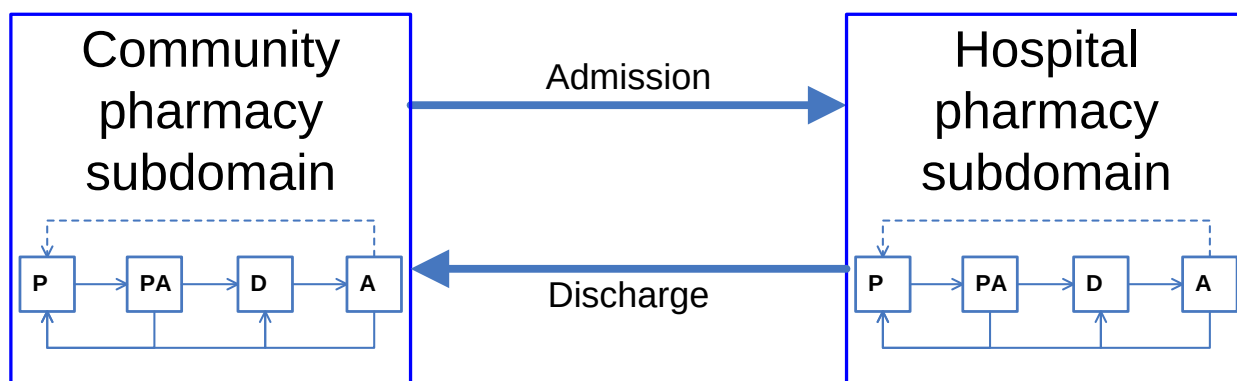


Figure 1.3.2-1: Subdivision of the pharmacy domain into two subdomains, each having the cycles Prescribe - Pharmaceutical Advice - Dispense - Admission and Clinical Discharge.

In addition to these transitions between the two main subdomains, there are cases where the participants are somewhat combined. The occurrence of such cases will determine the need to integrate data across the two domains.

Thus, in order to be complete, the integration profiles should include:

- All relevant medication transactions in the community pharmacy subdomain
- All relevant medication transactions in the hospital pharmacy subdomain
- All relevant transactions needed to support the medication issues of the clinical admission process
- All relevant transactions needed to support the medication issues of the clinical discharge process
- All relevant transactions needed to support the cases where the two subdomains coexist, and integration is needed.

We identified the following cases where the two subdomains coexist. In these situations, special attention should be given, depending on the local situation:

- **In hospitals** the hospital pharmacy organization might also run a community-pharmacy service, mostly in the outpatient environment, as a service to their outpatients. In this case, the actors (Medication Dispenser, possibly also Pharmaceutical Advisor) will implement the needed transactions of the profiles involved.
- **In some special cases** the hospital pharmacy will deliver drugs to ambulatory patients. The most common examples are the administration of drugs which are not available in community pharmacy like expensive coagulation factors or drugs for rare disorders. Typical for these situations is the fact that, although in an outpatient setting, the administration process needs close monitoring and recording. Also in this case, the transition between the two domains requires that transactions from both domains exist.

- **Day-care surgery:** in these situations patients do not always undergo the total clinical admission process. No clinical bed is assigned; there is no nursing ward involved. Nevertheless the medication processes being involved here in most cases should be considered to be of clinical nature, because the anesthesiologist will always want to “take over” the medication regime, or, at least, be informed on all medication. Medication needed specifically to support the day-care surgery will come from the hospital pharmacy.
- **Nursing homes:** here many different mixtures of the subdomain model might occur, varying from country to country. Some nursing homes might closely resemble the hospital situation, in other cases it might resemble the community model, in most cases with administration monitoring added. Also, the role of the prescriber might vary (the visiting GP in some cases, a specialized nursing home doctor in other cases) and the pharmacy might be a regular community pharmacy, a pharmacy belonging to the nursing home (or chain of nursing homes) or the hospital pharmacy of a near-by hospital. Here, always careful consideration is needed in order to choose the right set of domain actors.
- **Hospital-hospital transfers:** these require special precaution in the implementation. In some health care systems the process might be a discharge followed by an admission, but also direct couplings between hospitals might be involved.

1.4 Information elements

In this section we briefly describe the main information elements involved in the various processes. The next chapter describes them in more detail. The four elements are:

- **Prescription:** describes the medication that the prescriber (in most cases a doctor) wants to be taken by the patient. It is input to the pharmaceutical validation and dispense process. Prescriptions are also used as input for the patient or the nurse on how to use the medication. Variations in the content of the prescriptions can occur, varying from country to country, depending upon regulations, responsibilities, and standards.
- **Dispensed medication information:** describes the medication that actually has been dispensed. Recorded within this process for later reference, and in order to follow up on repeat-medication. Again, depending on the local situation in different counties, dispenses might or might not show significant differences from the originating prescriptions². The dispensed medication information needs to be linked to the prescriptions it originates from. There can be, in general, multiple dispenses originating from one prescription.
- **Administration of medication:** describes the administration event (only in hospitals for the time being). These events need to be linked to the prescription.
- **Pharmaceutical advice:** when a prescription is received by a pharmacist three steps may follow:
 - a) The pharmacist dispenses the prescribed medication.

² In such case the dispenser will document these changes prior to dispensing (by acting as a Pharmaceutical Adviser)

- 300 b) The pharmacist decides to dispense medication different from the prescription, though still serving the same clinical goal as the original prescription (e.g., a generic version of a branded medication). The situations where pharmacists are allowed to do so might differ from health care system to health care system.
- 305 c) The pharmacist decides that it is not appropriate to dispense the medication prescribed to the patient. No dispense is done.

The pharmaceutical advice is the information element that contains the observations and actions of the pharmacist in this validation process. In situation a., in most cases no explicit advice is generated, in situations b. and c., an explicit pharmaceutical advice is generated, communicated and saved.

310 It should be noted that there is a distinct need for use of these information elements outside the direct reach of the current medication process that generates them. The most important examples of this are:

- 315 • HCP's prescribing in other processes need all dispensed or administered medication information of recent nature in order to check drug incompatibilities. In some cases they might need previous prescriptions as well; this varies from country to country.
- Pharmacists dispensing medication might also be checking incompatibilities through insight from recently dispensed and administered medication.
- 320 • Any HCP treating or diagnosing a patient might need to check recently prescribed, dispensed or administered medication in order to assist correct interpretations of clinical observations, lab results, etc., or to avoid adverse effects in treatment in general (other than only treatment by medication).

1.5 Pharmacy Domain OID Tree

325 In computing, an **object identifier** or **OID** is an identifier used to name an object (compare [URN](#)). Structurally, an OID consists of a node in a hierarchically-assigned namespace, formally defined using the [ITU-T's ASN.1](#) standard. Successive numbers of the nodes, starting at the root of the tree, identify each node in the tree. Designers set up new nodes by registering them under the node's registration authority.

This chapter describes the OID tree of the Pharmacy domain.

OID	Identifies	Description
1.3.6.1.4.1.19376.1.9	IHE Pharmacy	Root OID for Pharmacy domain
1.3.6.1.4.1.19376.1.9.1	CDA	CDA related OIDs in Pharmacy
1.3.6.1.4.1.19376.1.9.1.1	Template IDs	CDA Template IDs in Pharmacy
1.3.6.1.4.1.19376.1.9.1.1.1	Document Templates	CDA Template IDs identifying document content modules
1.3.6.1.4.1.19376.1.9.1.1.2	Section Templates	CDA Template IDs identifying section content modules
1.3.6.1.4.1.19376.1.9.1.1.3	Entry Templates	CDA Template IDs identifying entry content modules

OID	Identifies	Description
1.3.6.1.4.1.19376.1.9.1.2	Codelists	OIDs identifying Codelists

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1.5.1 Pharmacy Root OID

The IHE Pharmacy domain in turn has been assigned a Root OID for all Pharmacy domain related purposes by IHE. All IHE Pharmacy related object identifiers are organized below this node.

335 The Root OID of the IHE Pharmacy domain is the following: **1.3.6.1.4.1.19376.1.9**.

1.5.1.1 CDA related OIDs

Structured documents following the Clinical Document Architecture (CDA) require OIDs for identifying certain elements.

CDA related object identifiers in Pharmacy are organized under the following OID:

340 1.3.6.1.4.1.19376.1.9.1

1.5.1.1.1 Pharmacy TemplateIds

The <templateId> elements in CDA are used to indicate that other elements follow a specific template.

- 345
- Pharmacy related templates are organized under the following OID:
1.3.6.1.4.1.19376.1.9.1.1
 - Document Templates: 1.3.6.1.4.1.19376.1.9.1.1.1
 - Section Templates: 1.3.6.1.4.1.19376.1.9.1.1.2
 - Entry Templates: 1.3.6.1.4.1.19376.1.9.1.1.3

1.5.1.1.2 Pharmacy Codelists

350 Codelists in CDA are used to indicate that other elements follow a specific template.

- Pharmacy related templates are organized under the following OID:
1.3.6.1.4.1.19376.1.9.1.2

2 Real World Information Model

355 The properties of the information objects listed in this section may be mandatory or optional depending on the contextual workflow. These optional/required characteristics will be refined later on, at profile building time.

2.1 Common elements

This section introduces the common external elements leveraged by medication workflows.

360 2.1.1 Healthcare Professional

The healthcare professional who has prescribed the medication, the pharmacist who issues a pharmaceutical advice, the technician who dispenses the medication, the nurse who administers the medication to the patient

- Identifiers
 - 365 • National/regional/local healthcare professional ID(s)
- Person
 - Full name
 - Address
 - Tel
 - 370 • Profession (e.g., physician, dentist, midwife, pharmacist, assistant, nurse, etc.)
 - Specialty of the healthcare professional (e.g., general practitioner, cardiologist, gynecologist, etc.)
- Represented Organization (hospital, primary care structure, pharmacy, etc.)
 - Organization Id(s)
 - 375 • Organization name, address, tel
 - Organization department, care unit, etc.

2.1.2 Patient

- Identifiers
 - National/regional/local healthcare patient ID(s)
 - 380 • National/regional health insurance patient ID
 - Healthcare facility patient ID
- Person
 - Full name
 - Gender
 - 385 • Date of birth, place of birth
 - Address

- Tel
- Physical metrics: weight, height, etc.
- Patients contacts
- Guardians

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2.1.3 Encounter in the healthcare institution

- Encounter ID
- Healthcare institution information
 - Organization ID(s), name, address, etc.
 - Organization department, care unit in charge with the patient (with care responsibility, medical responsibility, hosting responsibility)
- Date/time of encounter (start, end)
- Location inside the hospital

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2.1.4 Medication

400 Most of the time, prescribers can opt for the prescription of active substances or brand-name products.

A medication has the following properties:

- Brand name or generic name
- Name of the manufacturer
- National/regional drug code(s)
- Active substance(s) denomination(s) (e.g., WHO ATC, International Non-proprietary Name – INN or other standard medicine terminology)
- Codification of active substance(s)
- Pharmaceutical form (tab, syrup, etc.)
- Unit dosage/strength
- Packaging, type of container, number of units
- Economic information: price, reimbursement data, conditions, etc.
- Prescribing rules (e.g., required specialty for the prescriber, limited time length, etc.)
- Dispensing rules (e.g., to be delivered only at hospital, legal status)

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2.1.5 Prescription

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A prescription is issued by one ordering healthcare professional for one patient, in the context of zero or one administrative encounter (between the patient and the ordering physician and/or the healthcare institution).

Medications dispensed or administered (by a nurse or another care provider) outside the context of any prescription are considered as attached to an order session, which can be associated with a

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prescription. In case a prescription is necessary but not available at the time of administration, this order will be used to create a prescription.

A prescription may contain one or more prescription items (lines on a paper prescription). Each line relates to one medication or treatment. Prescription is the outcome of a clinical decision.

425 A prescription may refer to another former prescription that it supersedes or renews³.

An electronic prescription has the following internal properties:

- Prescription ID
- Date/Time of prescription
- Reason for prescribing (e.g., diagnosis, prognosis, protocol, clinical assessment, etc.)
- 430 which may or may not be explicitly stated
- Additional comment (may be used by the prescriber to inform the pharmacist that he is aware of a potential ICA)
- Prescriber's signature
- Status (see the “Relevant Standards” chapter)

435 2.1.5.1 Prescription Status Management

A prescription or a prescription item can take one of these statuses:

Table 2.1.5.1-1: Order Statuses

Status	Description
ORDERED	The prescription has been produced by the ordering provider and published, but is not yet assigned to or retrieved by any pharmacy. This status is mainly used by the Community subdomain in the “publish and pull” mode.
PLACED	The prescription is produced and placed to a pharmacy that has received it or retrieved it from a repository, but has not accepted it yet. Either the pharmaceutical analysis is not yet performed Or it has detected an issue and reported it via pharmaceutical advice, which is awaiting resolution through further interactions/dialog between the pharmacist and the prescriber.
IN PROGRESS	A pharmacy has accepted the item, checked that the prescription is free of potential adverse issues (e.g., interactions, overdose), and will dispense the medications (which may need time for preparation or stock provision). Some of the prescribed medications may have been dispensed. Further dispenses may be expected in the future.
COMPLETED	The prescription is completely dispensed (and completely administered, in a hospital setting). No more action is expected on this prescription.
CANCELLED	The prescription, which was ORDERED has been cancelled by the ordering provider ⁴ .

³ This case is not addressed in the Integration Profiles at this time.

⁴ The case when a patient never shows up to get the medication and subsequently the prescription might be expired at some date is not yet covered by the Integration Profiles.

Status	Description
DISCONTINUED	The prescription is not carried out by the pharmacy for some specific reason. (e.g., after detection of an adverse issue by the pharmacist, and dialog with the prescriber, the final decision is made to abort this prescription, and possibly issue a new different one in replacement)
SUSPENDED	This status is useful in the hospital workflow: The prescription which was IN PROGRESS is held for a period of time, for some clinical (surgical procedure) or physical (patient temporary leave) reason. Dispense and administration of the medication to the patient is suspended, and is expected to be resumed at a later point. This is also the case when the validation fails – in this case, the pharmaceutical advisor has checked the prescription and discovered some problems. The prescription or prescription item is not ready to be dispensed. It also pertains to ambulatory workflow: Prescriptions can be held for a variety of reasons (prescriber advice, pending resolution of errors/changes) where it is anticipated that the prescription may be reactivated.

440 The following diagrams show the major status transitions of a prescription in hospital and community subdomains:

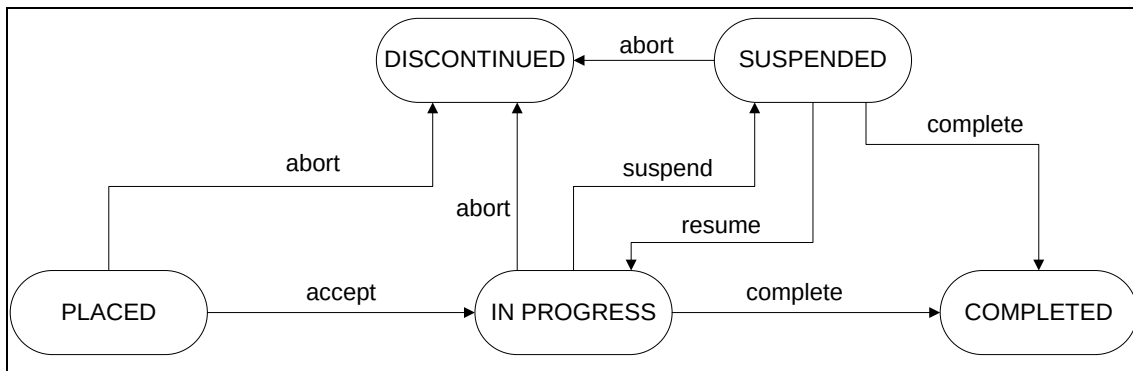


Figure 2.1.5.1-1: State transitions of Medication Prescription (item) in the Hospital Pharmacy subdomain

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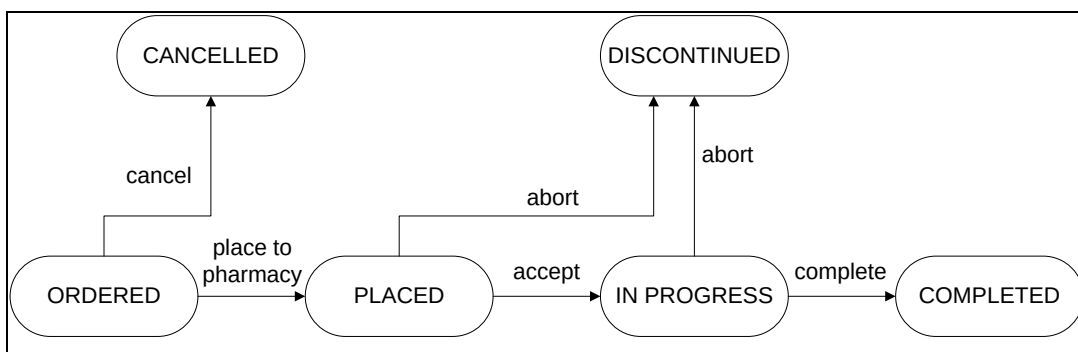


Figure 2.1.5.1-2: State transitions of Medication Prescription (Item) in Community subdomain

450 **2.1.5.2 Prescription Item**

A prescription item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations.

A prescription item has the following properties:

- Prescription Item ID
- 455 • Treatment TimeLine
 - Beginning date of treatment
 - Length of treatment
 - End of treatment date (the date the treatment is due to end)
- Number of refills
- 460 • Reason for prescribing (e.g., diagnosis, prognosis, protocol, clinical assessment, etc.)
- Intake pattern for the medication
 - Frequency and times of intake
 - Dosage
- Route of administration
- 465 • Medical instructions
 - Substitution allowed or not (can the pharmacist do a substitution of medication?)
 - Alert about prescribing restrictions
 - Related to a chronic disease or not (listed or unlisted)
 - Specific follow-up elements
- 470 • Additional comment (may be used by the prescriber to inform the pharmacist that he is aware of a potential ICA)
- Status (see the “Relevant Standards” section)

2.1.6 Pharmaceutical Advice

475 Pharmaceutical advice relates to one or more prescription items of one prescription. It is issued by one pharmacist. It may be associated with one or more observations.

Pharmaceutical advice has the following properties:

- Pharmaceutical advice ID
- Date/Time of advice
- Zero, one or more detected problems
- 480 A problem can be a supply problem (suspended medication, out-of-stock, etc.), a legal issue (medication recalled or not allowed under certain conditions), or a medical issue (redundancy, interaction, contra-indication, overdose, adverse effect, etc.)
 - Summary of physician/pharmacist discussion (by phone, mail, messages, etc.)

- Status: (Open|Closed)
- 485 • Decision (i.e., dispense without change|dispense with changes|refusal to dispense until further discussion with prescriber|definite cancellation of the prescription item)
- Date/Time of decision
- Pharmacist's signature

2.1.6.1 ICA

490 ICAs are Intolerances, Contra-indications and Allergies.

An ICA may be considered as a relationship between a patient and a medicine. A detected problem in a Pharmaceutical Advice may refer to an ICA.

An ICA has the following properties:

- Type of interaction
- 495 • Date
- Reaction
- Severity
- Confidence
- Treatment/Management

500 2.1.7 Medication Dispense

A medication dispense relates to zero or one prescription item of one prescription. There are cases when a medication is dispensed before the prescription is created.

505 Medications dispensed outside the context of any prescription are considered as implicitly prescribed by the professional who dispenses. Thus they are still attached to a pseudo-prescription (i.e., a prescription that may not have a physical/paper version) .

A medication dispense is issued by one pharmacy staff.

A medication dispense has the following properties:

- Dispense ID (e.g., unique number, composite of Prescription ID and refill number, etc.)
- Refill number
- 510 • Date/Time of dispensing
- Location
- Expected quantity (number of packs/number of units)
- Quantity delivered (number of packs/number of units)
- Dispensing period (period for which the medication is dispensed)
- 515 • Dispensing presentation: blister, box, single dose unit
- Delivery mode : bulk, nominative (per patient)
- Batch number

- Expiration date
- Pharmaceutical instructions
- Price paid by the patient
- Pharmacy staff's signature

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2.1.8 Administered Medication

An administered medication relates to zero or one prescription item of one prescription. There are cases when a medication is administered before the prescription is created. Medications administered (by a nurse or another care provider) outside the context of any prescription are considered as implicitly prescribed by the professional who administers. Thus they are still attached to a pseudo-prescription.

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An administered medication is issued by a member(s) of ward staff (e.g., a nurse). It is related to one encounter of care. It may be associated with one or more observations.

530

An administered medication has the following properties:

- Effective date/time of administration (start, end)
- Planned date/time of administration (start, end)
- Location
- Expiration date
- Batch number
- Quantity administered (which may be later updated e.g., following patient vomiting, extravasation, etc.)
- Ward staff's signature (e.g., nurse, physician, internist, midwife, etc.)
- Administration comments
- Reason for non-administration (for instance patient refused medicine, medicine is not available, etc.)

535

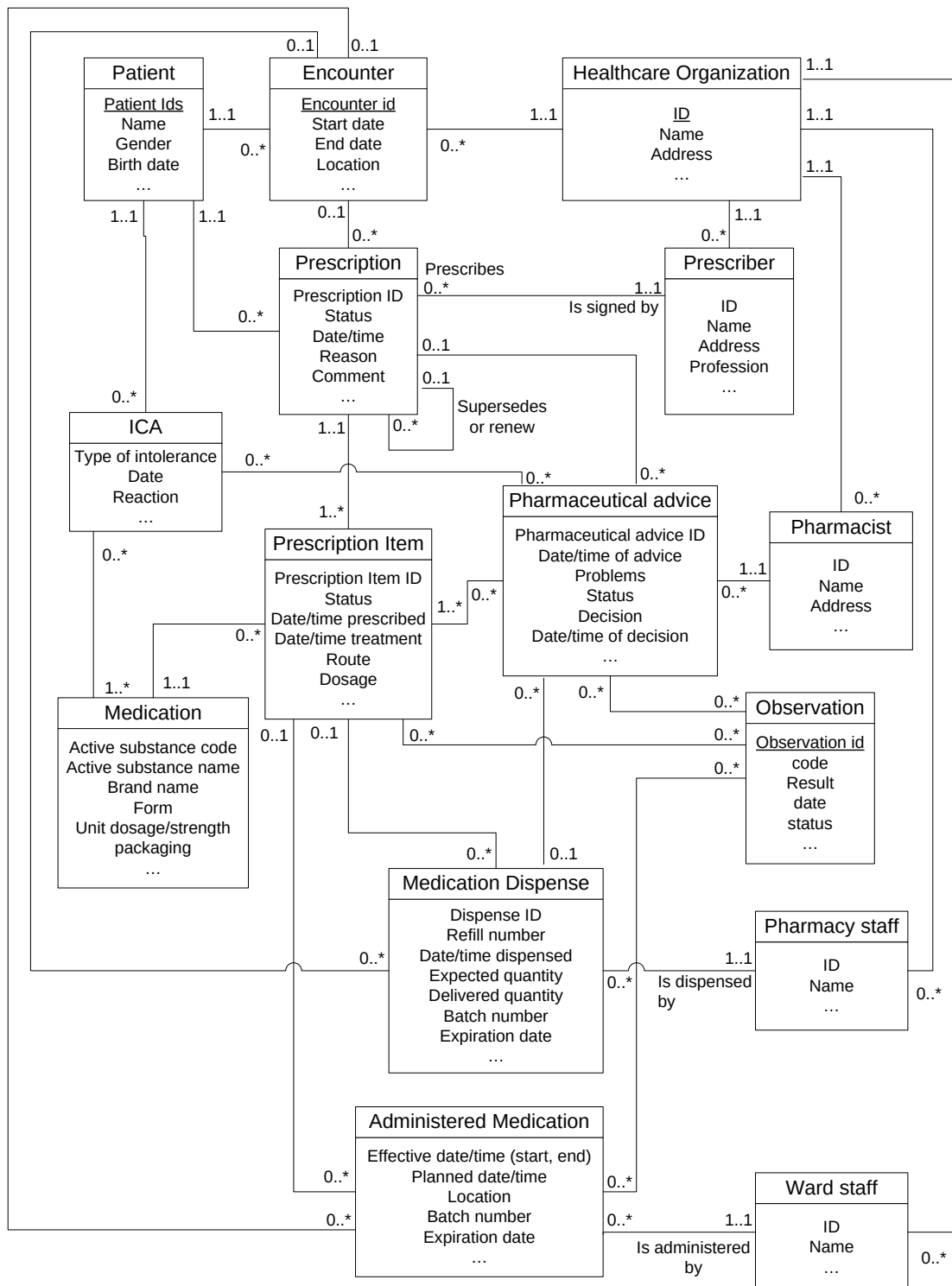
540

2.1.9 Entity-relationship model

The entities described above and their relationships are synthesized in the simplified entity-relation diagram next page. The diagram is simplified because some entities have not been considered at this stage; in particular: prescription protocol, dosage requirement, medication component, consolidated administration report.

545

It is expected to refine this model while building the integration profiles that will come out of this supplement.



550

Figure 2.1.9-1: Entity-relationship model for hospital and community pharmacy.

2.2 Use cases covered

555 Using the actors, the model and ER diagram described above, the following scenarios are expected to be covered, although not described in detail yet. This list is used to assert the validity of the model.

2.2.1 Hospital Pharmacy use cases

The following chapters describe use cases in the hospital environment.

2.2.1.1 Hospital, Basic inpatient scenario

560 **2.2.1.2 Hospital, Inpatient, unexpected administration events:**

2.2.1.2.1 Skipped administration

2.2.1.2.2 Substitution at ward

2.2.1.3 Hospital, Inpatient, simple case of substitution (substitution at pharmacy)

2.2.1.4 Hospital, Inpatient, active substance prescription

565 In this case, the pharmaceutical adviser will “replace”/encode the active substance into a product in use at the clinical setting.

2.2.1.5 Hospital, Inpatient, active substance prescription and use of active substance naming in administration

570 In some cases, the whole clinical process refers to the active substance, not commercial name. In this case, the only part where a commercial name is used is inside the supply chain. Throughout the clinical path, the name used is the same as the active substance.

2.2.1.6 Hospital, Admission-Discharge with Continuity of Treatment

In this case, the patient’s prescription is imported, and the dispensed medication is also imported into the hospital’s system upon admission, and considered as “patient stock”.

575 **2.2.1.7 Hospital, Admission/discharge with hospital taking over medications during stay**

In this case, the patient’s prescription is imported, possibly including the dispensed medication. The amount of medication to dispense upon discharge is determined based on the medication dispensed prior to admission.

580 **2.2.1.8 Hospital, Hospital Dispense for Outpatients**

In this case, the hospital pharmacy can consult the Community Prescription repository, thus implementing the Community Pharmacy transactions associated with the Medication Dispenser.

2.2.1.9 Hospital, Sequence Diagram with Interaction detected and dispense refused

585 2.2.1.10 Hospital, Cascading of Validation

In some cases, the Pharmaceutical Adviser may have a long process (like calling other Pharmaceutical Advisers). This is a case of cascading the same actors, and is controlled by the Pharmaceutical Adviser that receives the prescription.

2.2.1.11 Hospital, Administration without prescription, prescription needed

590 The Administration creates an Order that is to be converted into a prescription and validated by a prescriber. The order is marked as administered, so the dispenser will receive the validated prescription but not dispense this medication (stock refill may be necessary, but not a dispense for the patient)

2.2.1.12 Hospital, Administration without prescription, prescription not needed

595 The Administration creates an Order that is to be converted into a prescription by the Prescription Placer Actor, without an explicit submission of the prescription. The order is marked as administered, so the dispenser will receive the validated prescription but not dispense this medication (stock refill may be necessary, but not a dispense for the patient)

600 In future extensions, the consideration of aspects related to supply chain will allow for additional possibilities; this should not require changing the current model.

2.2.2 Community Pharmacy use cases

The following chapters describe use cases in the community environment.

2.2.2.1 Community pharmacy-active substance, publish & pull

605 The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders an active-substance (generic) medicine in the “publish & pull” model.