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## **Integrating the Healthcare Enterprise**



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## **Hospital Pharmacy and Community Pharmacy Use Cases and Standards White Paper**

**Version 1.0**

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## Contents

|      |   |    |
|------|---|----|
| 1    | Introduction.....   | 5  |
| 2    | Glossary .....  | 6  |
| 303  | Scope.....  | 7  |
| 4    | Pharmacy domain business process.....   | 8  |
| 4.1  | General medication process.....   | 8  |
| 4.2  | Subdomains.....   | 9  |
| 4.3  | Information elements.....   | 12 |
| 355  | Real World Information Model .....  | 14 |
| 5.1  | Common elements .....   | 14 |
| 5.2  | Prescription.....   | 15 |
| 5.3  | Prescription Item.....  | 15 |
| 5.4  | Pharmaceutical Advice.....  | 16 |
| 40   | 5.5 Medication Dispense .....   | 16 |
| 5.6  | Administered Medication (generally in hospital workflow) .....                  | 17 |
| 5.7  | Entity-relationship model .....   | 17 |
| 6    | Interoperability Use cases.....   | 19 |
| 7    | Use Case Actors.....  | 23 |
| 45   | 7.1 Introduction.....   | 23 |
| 7.2  | Link between system actors and human actors.....                                | 24 |
| 7.3  | Prescription placer .....   | 24 |
| 7.4  | Medication administration Informer.....   | 25 |
| 7.5  | Prescription repository.....  | 25 |
| 50   | 7.6 Dispensed medication repository.....  | 25 |
| 7.7  | Pharmaceutical advice repository.....   | 25 |
| 7.8  | Prescription & pharmaceutical advice consumer .....                             | 25 |
| 7.9  | Dispensed medication consumer .....   | 25 |
| 7.10 | Pharmaceutical adviser .....  | 25 |
| 55   | 7.11 Medication dispenser .....   | 26 |
| 8    | Use cases for Community Pharmacy.....   | 27 |
| 8.1  | Models .....  | 27 |
| 8.2  | Use Case community pharmacy-active substance, publish & pull.....               | 27 |
| 8.3  | Use Case community pharmacy-repeat medication.....                              | 28 |
| 60   | 8.4 Use Case Community pharmacy-cancellation proposed .....                     | 29 |
| 8.5  | Use Case community pharmacy-substitution of medicine .....                      | 31 |
| 8.6  | Use Case Community pharmacy-superseding a prescription .....                    | 32 |
| 8.7  | Use Case community pharmacy-active substance, direct push .....                 | 33 |
| 8.8  | Use Case community pharmacy-cancellation proposal, direct push .....            | 35 |
| 659  | Use Cases for Hospital Pharmacy.....  | 36 |
| 9.1  | Flow Chart .....  | 36 |
| 9.2  | Use Case hospital pharmacy - inpatient, basic scenario.....                     | 37 |
| 9.3  | Use Case hospital pharmacy – inpatient, unexpected administration events .....  | 39 |
| 9.4  | Use Case hospital pharmacy - inpatient, simple case of substitution .....       | 40 |
| 70   | 9.5 Use Case hospital pharmacy - inpatient, active substance prescription ..... | 42 |
| 10   | Pan Hospital/Community Pharmacy Use Cases.....                                  | 44 |
| 10.1 | Admission-Discharge with Continuity of Treatment.....                           | 44 |

|         |  |    |
|---------|--|----|
| 10.2    | Admission/discharge with hospital taking over medications during stay..... | 46 |
| 10.3    | Hospital Dispense for Outpatients .....                                    | 48 |
| 7511    | Relevant standards for the pharmacy domain.....                            | 51 |
| 11.1    | HL7 V2 .....   | 51 |
| 11.2    | HL7 v3 messages .....  | 52 |
| 11.3    | HL7 v3 documents .....   | 52 |
| 11.4    | The XDS family of IHE profiles to support documents .....                  | 57 |
| 80 11.5 | Relevant semantic standards .....  | 58 |
| 11.6    | NCPDP.....   | 60 |
| 11.7    | PN13 – SIPh2_v2.....   | 60 |
| 11.8    | Recommendations .....  | 60 |
| 12      | Examples of deployment architecture in Pharmacy domain .....               | 61 |
| 85 12.1 | Community Pharmacy.....  | 61 |
| 12.2    | Hospital .....   | 64 |
| 13      | References.....  | 69 |

## 1 Introduction

90The Pharmacy domain is increasingly adopting Information & Communication Technologies to support their main activities like prescription and medication dispense. In order to guarantee interoperability among the different ICT systems in the Pharmacy domain, it is important that all stakeholders (users, vendors, payers) agree on a set of common communication standards.

95The purpose of this White Paper is to identify the critical interoperability needs in the Pharmacy domain, describe the corresponding interoperability Use Cases and propose a set of communication standards to implement these Use Cases.

The White Paper can serve as basis for the development of one or more IHE Pharmacy  
100Integration Profiles.

The document starts with an overview of the main business processes in the pharmacy domain, describing the workflow and the information flows. These business processes are the basis for describing the various Interoperability Use Cases. The most critical Use Cases are then described  
105in more detail, identifying the actors and interactions. Starting from these Use Cases, high level reference architecture is proposed. Finally, some possible implementations of the reference architecture are described.

## 2 Glossary

- 110• **Treatment or medication regime:** a treatment or medication regime is a series of medications intended to heal the patient or to improve the health status or to diagnose a disease.
- **Prescription:** a prescription is an order given by a clinician (usually physicians and in some particular cases pharmacists, nurses), for a medication to be dispensed to the patient
- 115 according to an established pattern. The prescription includes the dosage, instructions to the patient for the intake, etc.
- **Dispensed medication:** to dispense is the act of giving out a medication to the patient as indicated in the corresponding prescription. Since prescriptions can span long periods of time, a single prescription may result medicines dispensed several times.
- 120• **Medication record:** medication already dispensed to the patient. This can also include the medication still not given out to the patient, prescriptions not fulfilled yet.
- **Pharmaceutical analysis:** the action performed by a pharmacist to approve/modify or reject a prescription before it is given out to the patient.
  - **Pharmaceutical advice :** the outcome of the pharmaceutical analysis;
- 125• **Healthcare Professional (HCP) :** individual that provides healthcare services like a GP, specialist, nurse and pharmacist.
- **System actor:** information system that supports a particular function in the pharmacy domain.
  - **Human actor:** individual (physician, pharmacist, etc.) that usually makes use of a system
- 130 actor to perform an activity in the e-pharmacy domain

### 3 Scope

The White Paper focuses on the interoperability needs of information sharing systems and workflow systems existing in the pharmacy domain, respecting the patient's privacy.

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More specific, the scope of the document is:

- Managing the medication dispenses of a patient in a community and hospital
- Transfer of the electronic prescriptions in a hospital and community
- Managing the interactions between community pharmacist and hospital pharmacist (e.g. admission – discharge prescription/dispense)
- The interoperability between pharmacy systems and other ICT systems on hospital and community level (e.g. EPR, EHR)
- ICA : Drug interaction checking, contra-indications, allergies

140

145The following items are out of scope:

- OTC (Over the Counter) medication dispense and medication samples
- Creation of the electronic Prescription
- Access to patient's medical record by prescriber, validator, ...
- Order and delivery of chemicals, reagents, sterilized medical supplies
- Approval of prescriptions for administrative purposes
- Individual Case Safety Report for secondary use applications like bio-surveillance, clinical trials
- Supply chain of ordering and delivering medication, stock management
- Administrative validation for expensive drugs (e.g. indications )

155

- Billing

## 4 Pharmacy domain business process

160 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.

### 4.1 General medication process

In general, the medication business process consists of three distinct processes, which have to be connected through interactions that transfer information and/or guide the workflow. Figure 4.1 165 shows this flow.

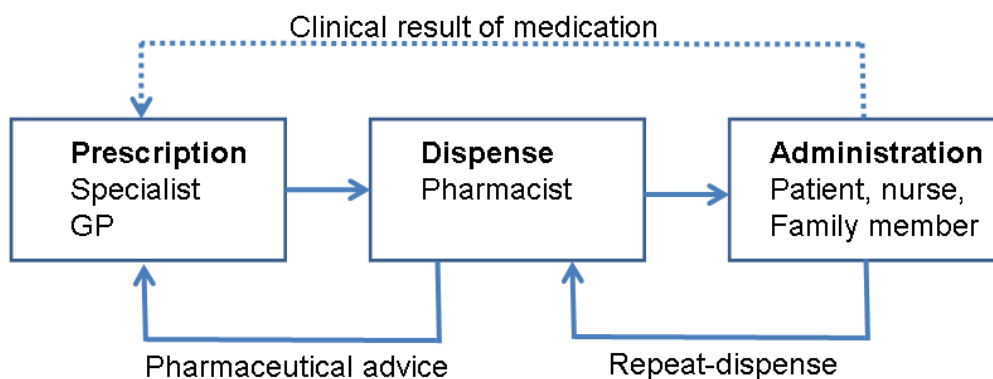


Figure 4.1: Time flow diagram showing the main elements in the general medication process

The three main processes are:

1701. **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.
2. **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 validates the prescription 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). 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. The information from the dispenser to the prescriber about the validation is called the pharmaceutical advice. Variations here can exist from health care system to health care system, depending on legislation and/or the role of the pharmacist.
- 185 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.

190

3. **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.

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 scope of this white paper, as is the clinical process leading to the prescription at the start.

As stated before, the emphasis of this white paper 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, buying of medication are not included in the scope of this white paper.

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

## 2104.2 Subdomains

For this white paper, and for subsequent development of integration profiles, it is necessary to distinguish two subdomains. The distinction is made because there are clear differences for the mediation process between these subdomains. The subdomains are named by the pharmacy that is involved

### 4.2.1 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.
- 220• The dispenser in most cases is a community pharmacist.
- The medication administrator in most cases is the patient or someone from the family.

### 4.2.2 Hospital Pharmacy subdomain

- The patient is hospitalized
- 225• 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

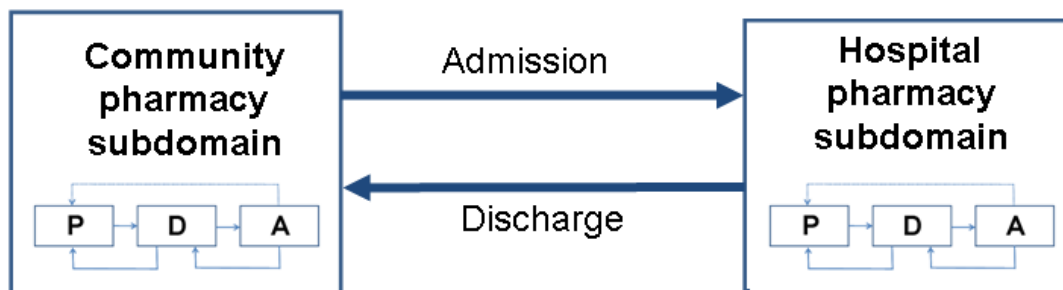
### 4.2.3 Rationale

The reason for this distinction lies in the following:

- 230• Medication regime:
  - In the community pharmacy subdomain the relation between patients and prescribers and patients and dispensers is not unique. That means, a patient can be under a medication regime with different prescribers simultaneously, e.g. a GP and a psychiatrist. Moreover, in many countries the patient is free to choose a different pharmacist for every other prescription.
  - 235• In the hospital pharmacy subdomain, however, a patient is brought under one medication regime (for safety and clinical control reasons mainly). In most countries all dispenses are executed over by the hospital pharmacy.
  
- 240• Coupling to other processes:
  - In the community environment the medication process is in most cases only loosely coupled to other processes.
  - In the hospital environment the medication process is very closely linked to other processes of diagnostic and/or therapeutic nature. Most hospitals see prescription as a clinical order comparable with the ordering of laboratory investigations and/or radiological investigations. This close linkage is necessary for the close monitoring of clinical conditions, in which medication is an important factor.
  
- Administration of medication:
  - 250• In the community environment the administration process is generally not recorded in any computer system at all.
  - In the hospital environment in many cases the administration of medication is supervised by a nurse, who, in many cases, also records the administration event in a computer system. In some cases, typically with the use of “lighter” medication, the administration is not recorded explicitly.
  - 255• As a consequence of the fact that the human actors for administration are different in both subdomains (patient in community, nurse in hospital) there is a difference in the dispense process: in the community pharmacy subdomain the dispense is from pharmacist to patient (or family member), in the hospital pharmacy subdomains the dispense process is from pharmacy to the nursing ward, typically.
  - 260

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 4.2 shows this in a scheme.



270 Figure 4.2: Subdivision of the pharmacy domain into two subdomains, each having the cycles prescribe-dispense-administer implemented. The transitions lie in the clinical admission and clinical discharge.

275 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;
- 280 • All relevant transactions needed to support the medication issues of the clinical discharge process;

There are several situations where this distinction between two subdomains might be disputed. In these situations, special attention should be given, depending on the local situation. We identified 285 the following cases:

- In hospitals the hospital pharmacy organization might also run a community-pharmacy service, mostly in the outpatient environment, as a service to their outpatients. We consider, for this white paper, then, two pharmacies to be present, a hospital pharmacy and a community pharmacy. Thus, actors of both subdomains will need to be implemented.
- 290 • In some special cases the hospital pharmacy will deliver drugs to ambulatory patients. The most common examples are the administration of (expensive) cancer drugs and narcotics. Typical for these situations is the fact that, although in an outpatient setting, the administration process needs close monitoring and recording. Per situation it needs to be decided whether these situations will have to be treated as being in the community pharmacy 295 subdomain or in the hospital pharmacy subdomain.
- 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 300 during or around 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.
- 310• Hospital-hospital transfers 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 conceived.

### 4.3 Information elements

315

In this section we briefly describe the main information elements involved in the various processes. The next chapter describes them in more detail. These 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 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 habits, 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 with the prescriptions they originate from. The dispensed medication information needs to be linked to the prescriptions it originates from. There can be, in general, more dispenses originating from one prescription.
- 330• 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 might follow:
  - The pharmacist dispenses the prescribed medication.
  - 335 • The pharmacist decides to dispense medication different from the prescription, though still serving the same clinical goal as the original prescription. The situations where pharmacists are allowed to do so might differ from health care system to health care system.
  - The pharmacist decides that it is not valid to dispense the medication prescribed to the patient. No dispense is done.
- 340

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.

345

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:

- 350 • HCP's prescribing in other processes need all dispensed medication information of recent nature in order to check on 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 on incompatibilities through insight in recently dispensed medication.
- 355 • Any HCP treating or diagnosing a patient might be needing to see recently dispensed medication in order to make correct interpretations of clinical observations, lab results, etc, or to avoid adverse effects in treatment in general (other than only treatment by medication). Here it might be considered to be important to see the recent prescriptions as well.

## 5 Real World Information Model

360 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.

### 5.1 Common elements

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

#### 365.1.1 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

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

#### 5.1.2 Patient

- Identification(s)
  - national/regional/local healthcare patient ID(s)
  - national/regional health insurance patient ID
- 385 - healthcare facility patient ID
- Person
  - Full name
  - Gender
  - Date of birth, place of birth
- 390 - Address
- Tel
- Physical metrics: weight, height...

#### 5.1.3 Encounter in the healthcare institution

- Encounter ID
- 395- Hospital information
  - Organization ID(s), name, address...
  - Organization department, care unit in charge with the patient (with care responsibility,

medical responsibility, hosting responsibility)

- Date/time of encounter (start, end)
- 400- Geographic location inside the hospital

#### 5.1.4 Medication

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

A medication has the following properties:

- 405- Brand name or generic name
  - Name of the producing laboratory
  - National/regional drug code(s)
  - Active substance(s) denomination(s) (International Non-proprietary Name - INN)
  - Codification of active substance(s)
- 410- Pharmaceutical form (tab, syrup...)
  - Unit dosage/Strength
  - Packaging, type of container, number of units
  - Agreed price of the medicine

#### 4155.2 Prescription

A prescription is issued by one ordering healthcare professional for one patient, in the context of zero or one 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 self-prescribed by the professional who dispenses or administers. Thus they are still attached to a pseudo-prescription, with the same properties.

A prescription may contain one or more prescription items (lines on a paper prescription). Each line relates to one medication.

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

425An electronic prescription has the following internal properties:

- Prescription ID
- Date/Time of prescription
- Reason for prescribing (e.g. diagnostic, prognostic, protocol, clinical assessment ...)
- Additional comment
- 430- Prescriber's signature
  - Status (see the "Relevant Standards" chapter)

#### 5.3 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

- Beginning date of treatment / length of treatment / End of treatment date ( the date the treatment is due to end) and/or number of renewals
- 440- Frequency
  - Substitution allowed or not (can the pharmacist do a substitution of medication?)
  - Route of administration
  - Dosage
  - Intake pattern for the medication
- 445- Medical instructions
  - Diagnosis or reason for prescribing
  - Alert about prescribing restrictions
  - Related to a chronic disease or not (listed or unlisted)
  - Prescribing restrictions (e.g. required specialty for the prescriber, limited time length ...)
- 450- Dispensing restrictions (e.g. to be delivered only at hospital)
  - Specific follow-up elements
  - Economic information: price, reimbursement data, conditions ...
  - Additional comment
  - Prescriber's signature
- 455- Status (see the “Relevant Standards” chapter)

#### 5.4 Pharmaceutical Advice

A 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.

460A pharmaceutical advice has the following properties:

- Pharmaceutical advice ID
- Date/Time of advice
- Zero, one or more detected problems
  - A problem can be a supply problem (suspended medication, out-of-stock...) or a medical
- 465 issue (redundancy, interaction, contra-indication, overdose, adverse effect...)
  - Summary of physician/pharmacist discussion (by phone, mail, messages...)
  - Status: (Open | Closed)
  - Decision (i.e. dispense without change | dispense with changes | refusal to dispense until further discussion with prescriber | definite cancellation of the prescription item)
- 470- Date/Time of decision
  - Pharmacist's signature

#### 5.5 Medication Dispense

A medication dispense relates to one prescription item of one prescription.

475Medications dispensed outside the context of any prescription are considered as self-prescribed by the professional who dispenses. Thus they are still attached to a pseudo-prescription.

A medication dispense is issued by one pharmacy staff. It is related to zero (community use case) or one (hospital use case) encounter of care.

A medication dispense has the following properties:



- 480- Dispense ID
  - Refill number
  - Date/Time of dispensing
  - Location (in the hospital)
  - Expected quantity (number of packs/number of units)
- 485- Quantity delivered (number of packs/number of units)
  - Batch number
  - Expiration date
  - Pharmaceutical instructions
  - Price paid by the patient
- 490- Pharmacy staff's signature

### **5.6 Administered Medication (generally in hospital workflow)**

An administered medication relates to one prescription item of one prescription. Medications administered (by a nurse or another care provider) outside the context of any prescription are 495 considered as self-prescribed by the professional who administers. Thus they are still attached to a pseudo-prescription.

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

An administered medication has the following properties:

- 500- Effective date/time of administration (start, end)
  - Planned date/time of administration (start, end)
  - Location
  - Expiration date
  - Batch number
- 505- Quantity administered
  - Ward staff's signature (e.g. nurse, physician, internist, midwife ....)
  - Administration comments

### **5.7 Entity-relationship model**

The entities described above and their relationships are synthesized in the simplified entity- 510 relation diagram next page. The diagram is simplified because some entities have not been considered at this stage ; in particular: prescription protocol, posology item, medication component, consolidated administration report.

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

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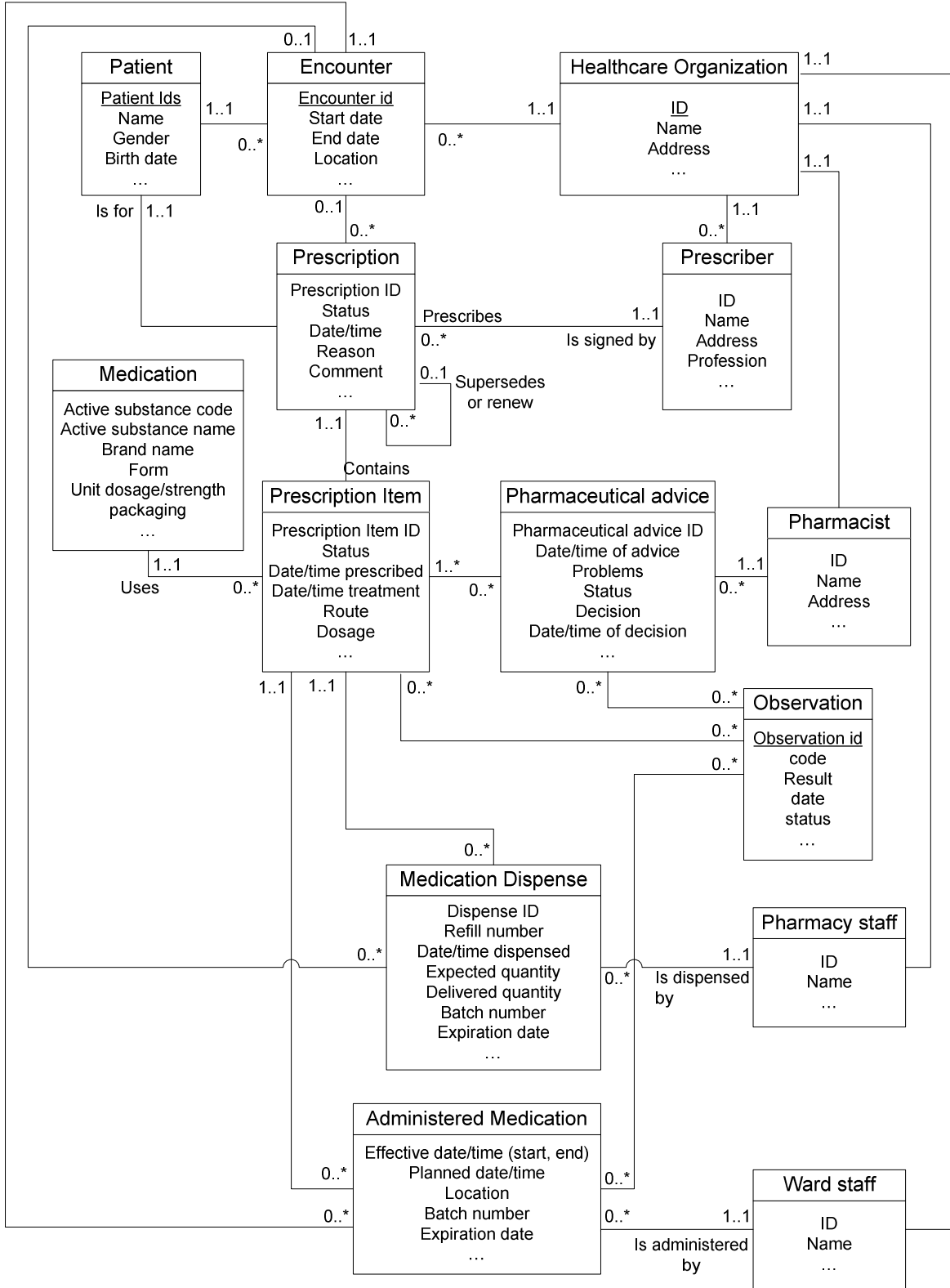
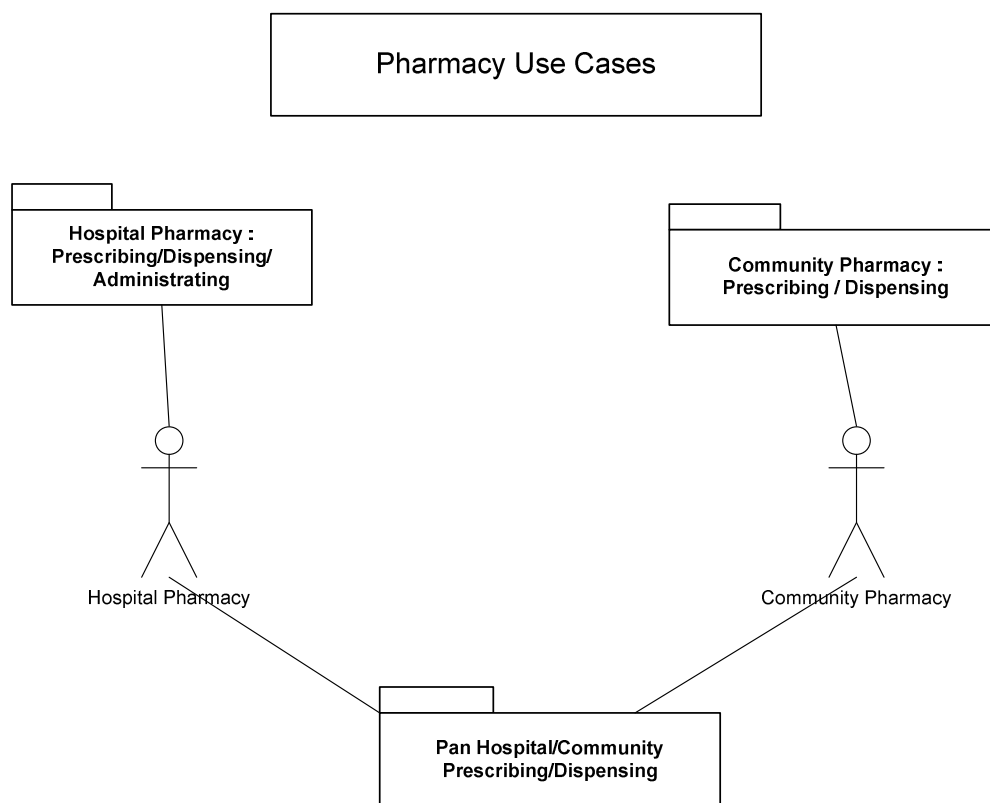


Figure 5.1: Entity-relationship model for hospital and community pharmacy

## 6 Interoperability Use cases

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This section describes the Interoperability Use Cases in the Pharmacy Domain. They are derived from the Businesses Processes (section 4 Pharmacy domain business process) by identifying the interactions between the Business Processes and the external world.



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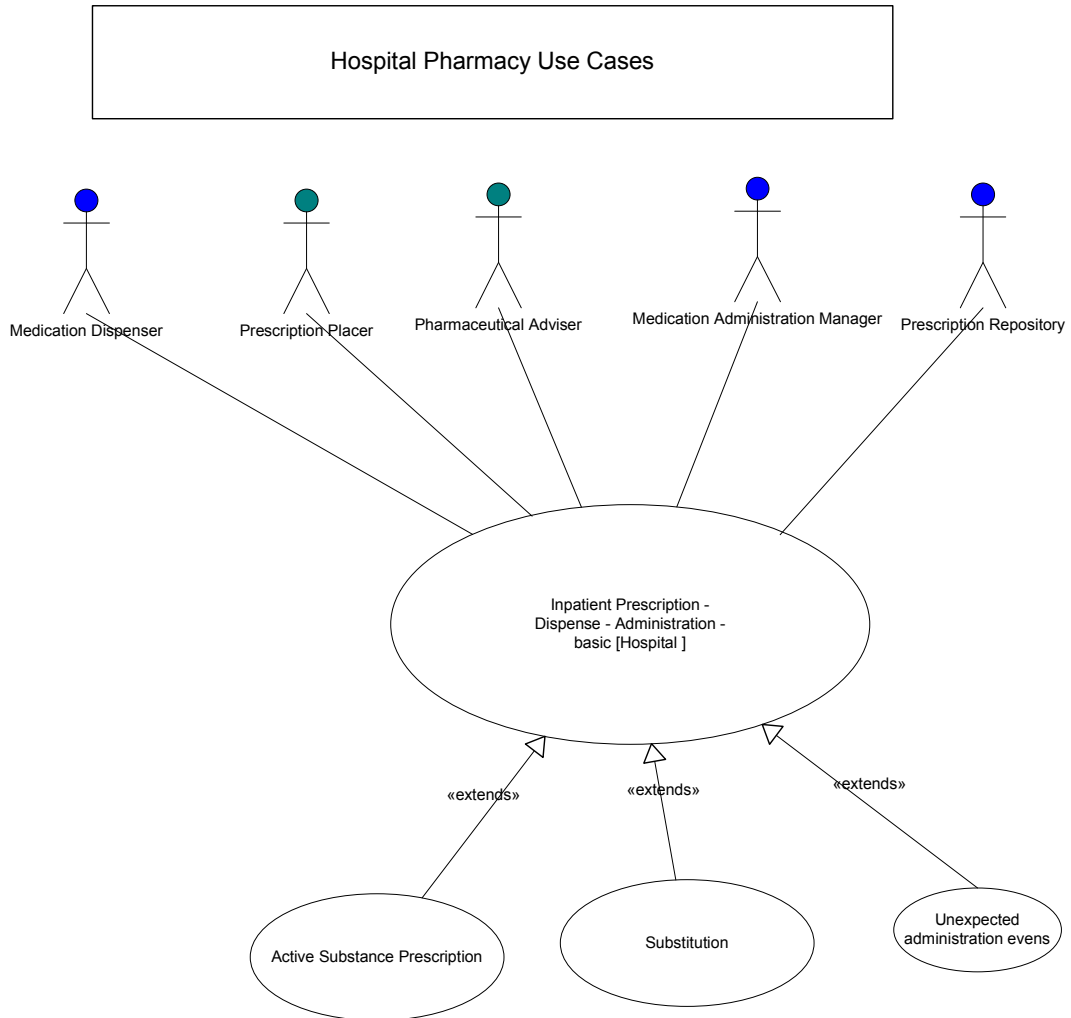
**Figure 6.1 : Pharmacy Use Cases**

The Interoperability Use Cases can be grouped in the following categories :

- Hospital Pharmacy Use Cases : focus on Prescriptions, Dispense and Administration activities in a hospital
- Community Pharmacy Use Cases : focus on Prescriptions and Dispense activities in a community (between GPs and Pharmacist)
- Pan Hospital/Community Pharmacy Use Cases : focus on Prescriptions and Medication activities that result from Admission/Discharge of a patient from a community to a hospital (and vice versa)

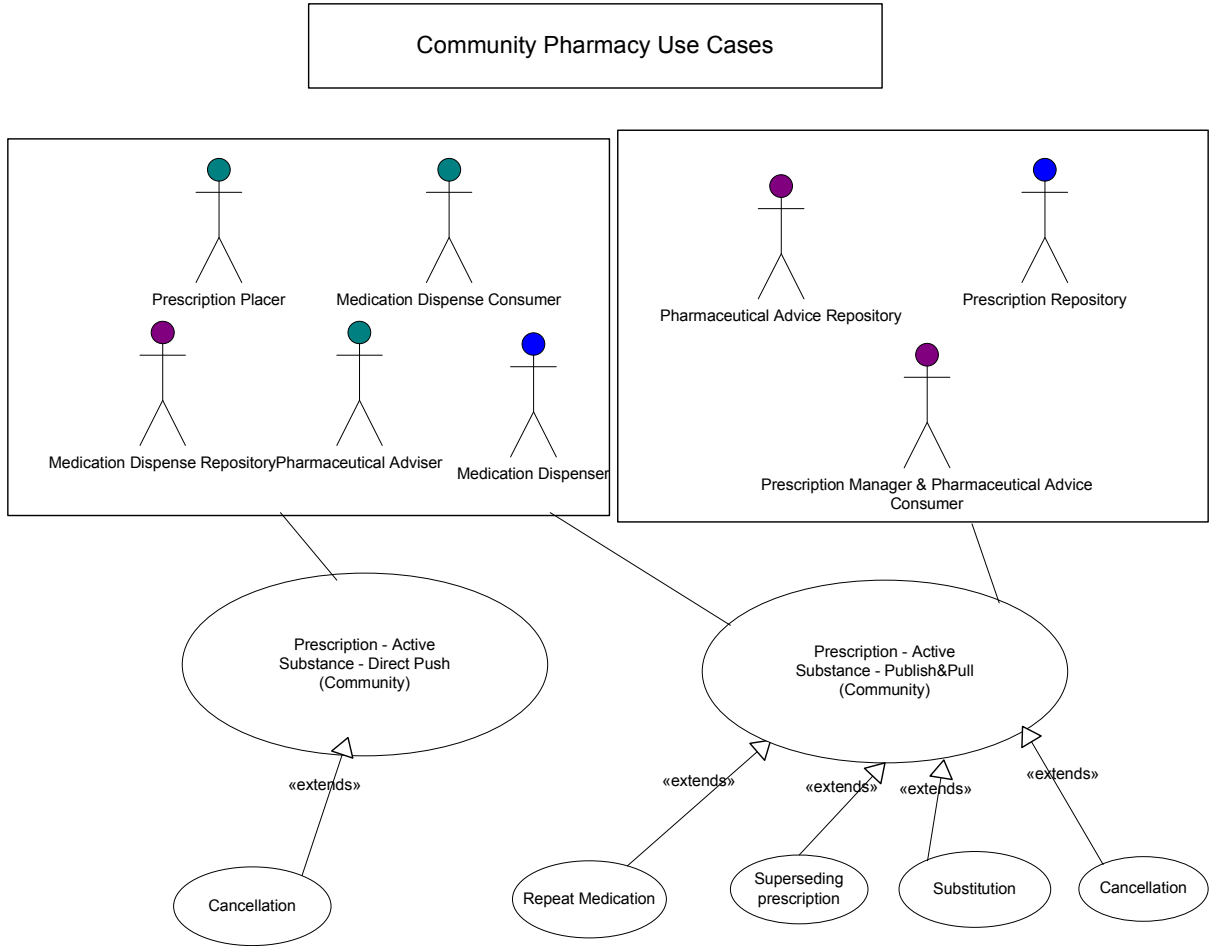
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The following figures give an overview of the different Use Cases. Section 7 describe the different Actors; Section 11 and 12 describe the different Use Cases in more detail.



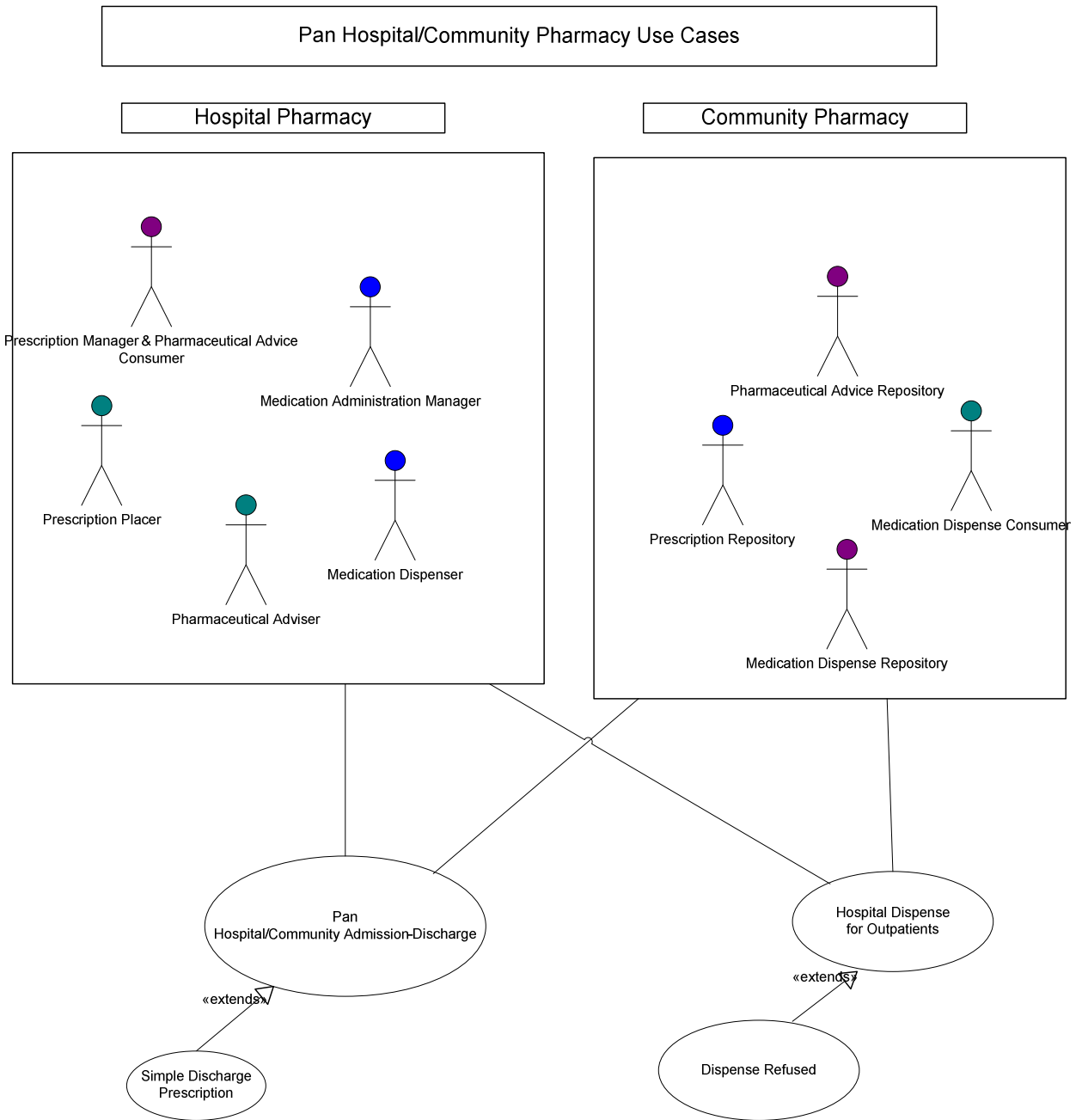
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**Figure 6.2: Hospital Pharmacy Use Cases**



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**Figure 6.3: Community Pharmacy Use Cases**



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**Figure 6.4: Pan Hospital/Community Pharmacy Use Cases**

## 7 Use Case Actors

### 7.1 Introduction

In this section we will define the actors involved in the prescription-dispense process by specifying their main responsibility. These are the so-called system actors, i.e., they represent computer software running in facilities such as physicians' offices, hospitals, health systems' datacenters and community pharmacies.

The actors listed below represent the computer software usually found in settings taking part in the prescription-dispensation process. This comprise a variety of information systems such as hospitals information systems (HIS), electronic health records, electronic medical records, CPOE software, pharmacy's point of sale software, or health system's (central) databases.

Actual implementations of the model defined in this white paper may consist in pieces of software implementing more than one actor. As an example of this, the prescription producer may also provide the medication consumption feature in the hospital environment.

In order to standardize the naming of actors, the following conventions have been adopted:

- The actors producing a key piece of information (a prescription, a dispense, an administration report) and consuming some other piece of information are named after the main action taken by the care professional using this actor.
- Repository: under this name we will find those actors whose main responsibility consists in providing data either by hosting it (such as a central database) or by providing the means to reach it (such as a dispatcher or registry linked to multiple databases). Prescription and dispensed medication repositories are examples of this kind of actor. Both can be implemented as a standalone database or by means of a dispatcher linked to multiple databases actually running in hospitals, physicians and pharmacies' settings.
- Consumer: under this naming we will find actors whose main responsibility consists in querying and retrieving information from repositories. The prescription and dispensed medication consumers are examples of this kind of actor.

The following table lists the actors in the prescription-dispense process, grouped by type and use in the hospital and community environments:

| Data                      | Type       | Community | Hospital |
|---------------------------|------------|-----------|----------|
| Prescription              | Placer     | x         | x        |
| Medication Administration | Informer   |           | x        |
| Pharmaceutical            | Adviser    | x         | x        |
| Medication                | Dispenser  | x         | x        |
| Prescription              | Repository | x         | x        |

| Data                                 | Type       | Community | Hospital |
|--------------------------------------|------------|-----------|----------|
| Medication Dispense                  | Repository | x         | x        |
| Pharmaceutical advice                | Repository | x         | x        |
| Prescription & Pharmaceutical Advice | Consumer   | x         | x        |
| Medication Dispense                  | Consumer   | x         | x        |

## 7.2 Link between system actors and human actors

In order to emphasize the relationship between human actors and system actors, the following table depicts the link between both types of actors:

| System actor                                  | Human actor  |
|---|--|
| Prescription Placer                           | Prescriber such as physician (GP or specialist), nurse, pharmacist, etc. |
| Medication Administration Informer            | Nurse  |
| Pharmaceutical Adviser                        | Pharmacist   |
| Medication Dispenser                          | Pharmacist   |
| Prescription Repository                       | n.a.   |
| Medication Dispense Repository                | n.a.   |
| Pharmaceutical Advice Repository              | n.a.   |
| Prescription & Pharmaceutical Advice Consumer | Pharmacist, physician, etc.  |
| Medication Dispense Consumer                  | Pharmacist, physician, etc.  |

## 7.3 Prescription placer

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.

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.



#### 7.4 Medication administration Informer

The medication administration producer'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.

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).

#### 7.5 Prescription repository

This repository contains the medication prescribed to the patient from the prescription producer 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.

#### 7.6 Dispensed medication repository

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.

#### 7.7 Pharmaceutical advice repository

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

#### 7.8 Prescription & pharmaceutical advice consumer

This actor allows for the retrieval of current prescriptions and pharmaceutical advice from the prescription repository. This information may be required to dispense medication or to check the current treatment when prescribing further medication.

#### 7.9 Dispensed medication consumer

This actor obtains information on medication already dispensed to the patient, aggregates it and provides it to the human actor (e.g. direct check of the medication record of the patient) or to other (information system) actors such as the prescription producer. This information is received from the dispensed medication repository. The human actor behind this system actor may be a pharmacist, a prescriber or other healthcare professional authorized to access the medication record.

#### 7.10 Pharmaceutical adviser

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.

635

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).

### **7.11 Medication dispenser**

640 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.

This actor may be implemented as the point of sale software of a community pharmacy or the 645 hospital pharmacy module of a hospital information system. The human actor behind this system actor is usually a pharmacist or a pharmacist assistant.

## 8 Use cases for Community Pharmacy

### 6508.1 Models

Current implementations of the community pharmacy process (prescribe & dispense medication) may be categorized in two different alternatives.

The first alternative is the so-called publish & pull which corresponds to a rather centralized approach. In this model, generally speaking, information is generated by a placer type actor (prescriber or dispenser) and stored by means of a central repository type actor. Other actors retrieve data by pulling it from repositories. This approach may apply to health systems where information is accessed on a centralized basis and, therefore, is made available to a collective of potential users (such as prescriptions available for dispense in any community pharmacy).

660

The alternative approach is the direct push model where information is sent directly to the actor intended to use it (e.g. prescriptions sent directly to the pharmacy named by the patient) and therefore no information is stored on a centralized basis. This model focuses on direct communication instead of availability to (more) potential users.

665

Generally speaking, the use cases defined in this document do not cover the process of prescribing a medicine since it is considered out of the scope of the white paper. Therefore, use cases focus on the transfer of prescriptions to pharmacies.

### 8.2 Use Case community pharmacy-active substance, publish & pull

#### 6708.2.1 Purpose

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.

#### 8.2.2 Story Board

675 John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance “Fenoterol” in his “prescription placer” software. The prescription is electronically sent to the “prescription repository”. Since prescriptions are available to a wide range of pharmacies, John picks the pharmacy closest to his office. The pharmacist asks for John’s health card in order to  
680 retrieve the patient’s active prescriptions (from the “prescription repository”) and recent dispensed medication (from the “dispensed medication repository”). Since John also suffers from arthritis he was prescribed ibuprofen. The pharmacist checks for interactions and finds nothing outstanding. He consults his inventory and picks Berotec which is in the range of prices approved by the health system. He gives out this medicine to the patient and records the  
685 transaction in the “medication dispenser”. The information on the medication dispensed is electronically sent to the “dispensed medication repository”.

### 8.2.3 Sequence Diagram

The following diagram represents the sequence of data exchanged between “system actors” involved in this use case.

690

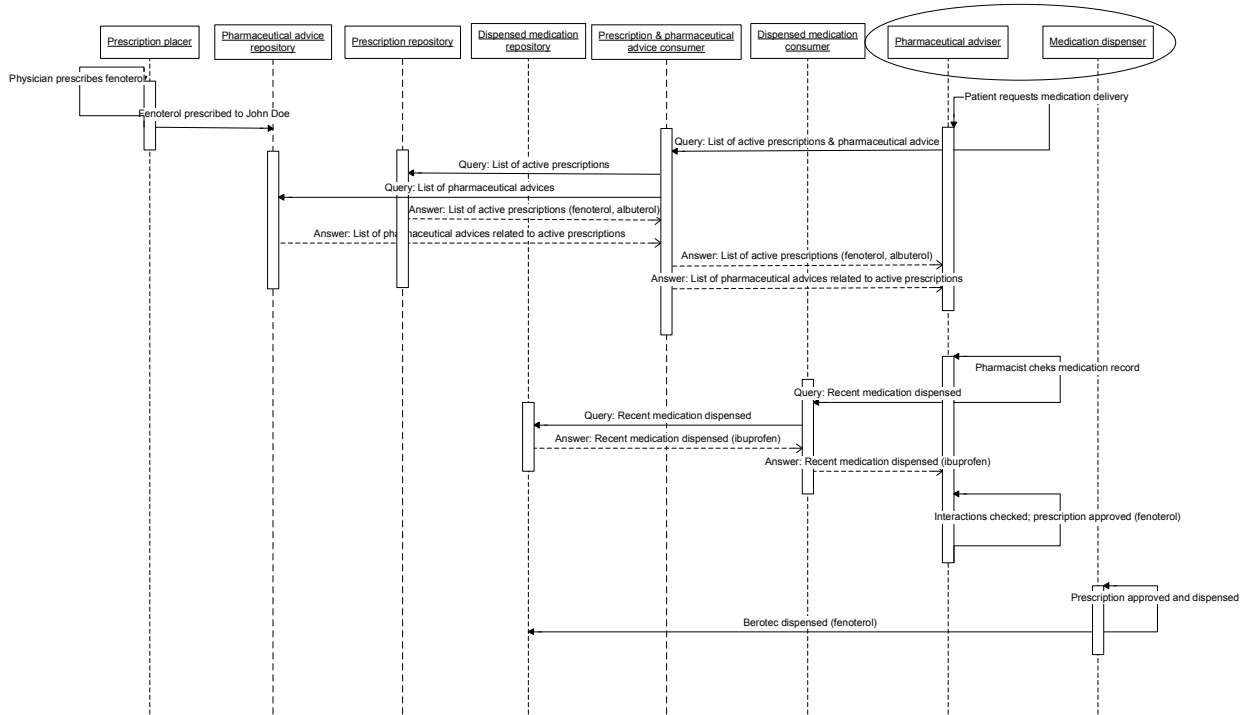


Figure 8.1: Use Case community pharmacy-active substance, publish & pull

695

This diagram illustrates the sharing of pharmaceutical advice among pharmacists which is done by querying the pharmaceutical advice repository when requesting the list of current prescriptions. For simplicity, this checking of pharmaceutical advice is not repeated in further diagrams.

### 7008.3 Use Case community pharmacy-repeat medication

#### 8.3.1 Purpose

The purpose of this use case is to illustrate a base version of the prescription-dispense process in case of a repeat medication.

#### 8.3.2 Story Board

705 Since John Doe has a mild breathing condition, his GP prescribed him Fenoterol for five months. The most common presentation of this medicine lasts one month; therefore John goes to the pharmacy every month for refills.



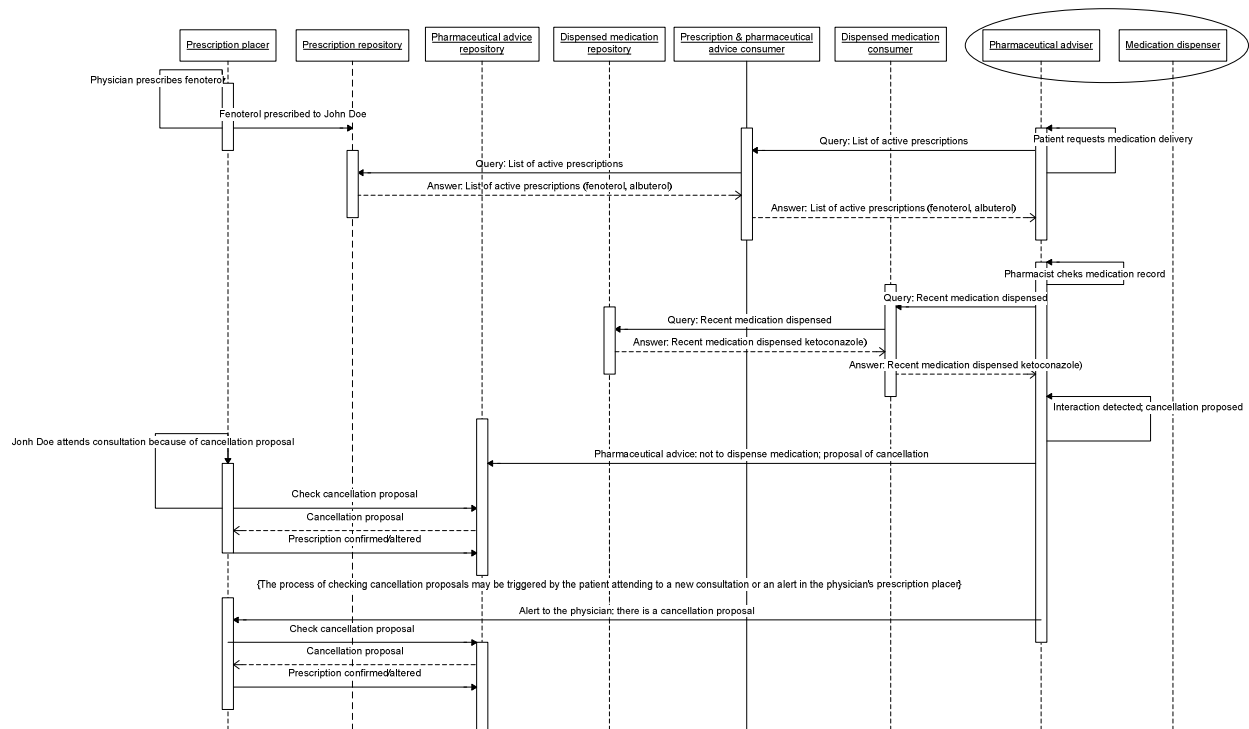
and the pharmacist proposes a cancellation; this cancellation can be considered as pharmaceutical advice.

### 7358.4.2 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist's proposal is recorded in the "pharmaceutical adviser".

This cancellation proposal is sent electronically to the "pharmaceutical advice repository" and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the "pharmaceutical advice repository" and reads the cancellation proposal sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

### 8.4.3 Sequence Diagram



750 Figure 8.3 : Use Case Community pharmacy-cancellation proposed

This diagram portrays the process from the prescription act to the confirmation/amendment of the prescription. From this point on, the process is similar to the one illustrated in the first community pharmacy use case.

755

The physician checking the cancellation proposal may be triggered by the patient attending consultation or by an alert sent by the pharmaceutical adviser actor of the pharmacist’s system to the prescription placer actor of the physician’s system.

760 Finally, this use case also represents the scenario where the substitution of a commercial brand medicine has to be approved by the prescriber.

## 8.5 Use Case community pharmacy-substitution of medicine

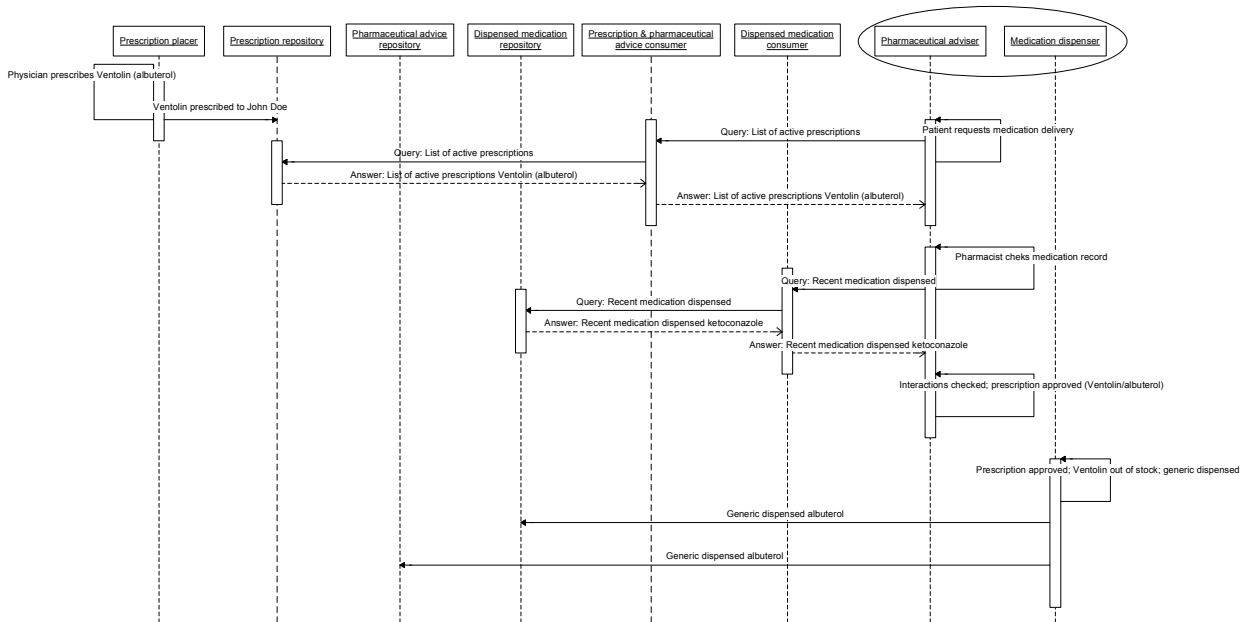
### 8.5.1 Purpose

765 The purpose of this use case is to illustrate the substitution of a medicine when a particular brand is not available at the pharmacy.

### 8.5.2 Story Board

At the pharmacy the particular commercial brand (Ventolin) prescribed by the GP has run out of stock. The pharmacist proposes a substitution (generic medicine with active substance Albuterol) to John Doe who agrees since both medicines have the same active substance (Albuterol). The new dispensed medication is recorded in the “medication dispenser” and the related information is sent to the “dispensed medication repository”.

### 8.5.3 Sequence Diagram



775

Figure 8.4: Use Case community pharmacy-substitution of medicine

## 8.6 Use Case Community pharmacy-superseding a prescription

### 8.6.1 Purpose

The purpose of this use case is to illustrate the process of a specialist (hospital) superseding a  
780repeat prescription made by a general practitioner (community).

### 8.6.2 Story Board

John Doe attends a consultation to his general practitioner because he is experiencing some  
breathing difficulty. The practitioner examines John and prescribes the active substance  
“Fenoterol” as a repeat medication.

785

Additionally, the GP refers John Doe to a specialist (pneumologist) for a thorough diagnostic.  
Since the appointment with the specialist will take place in one week’s time, John Doe requests  
the delivery of the medication (Fenoterol) at a pharmacy nearby. As usual, the medication record  
is checked for interactions and the medicine (Berotec) is given out to John.

790

One week later, John Doe attends the consultation to the pneumologist who checks for John’s  
medication record (medicines already dispensed such as Fenoterol) and active prescriptions. The  
exploration conducted by the specialists leads to a precise diagnosis: chronic bronchitis.

Therefore, the specialist cancels the prescription done by the GP and prescribes a new active  
795substance: Ipratropium (whose corresponding commercial brand may be Atrovent inhaler). In  
terms of information systems this cancellation is sent to the prescription repository.

John Doe requests the new medication at a different pharmacy where interactions are checked  
and the new medicine is dispensed (Atrovent). Since the previous prescription (Fenoterol) was  
800superseded, it cannot be dispensed any more.



### 8.6.3 Sequence Diagram

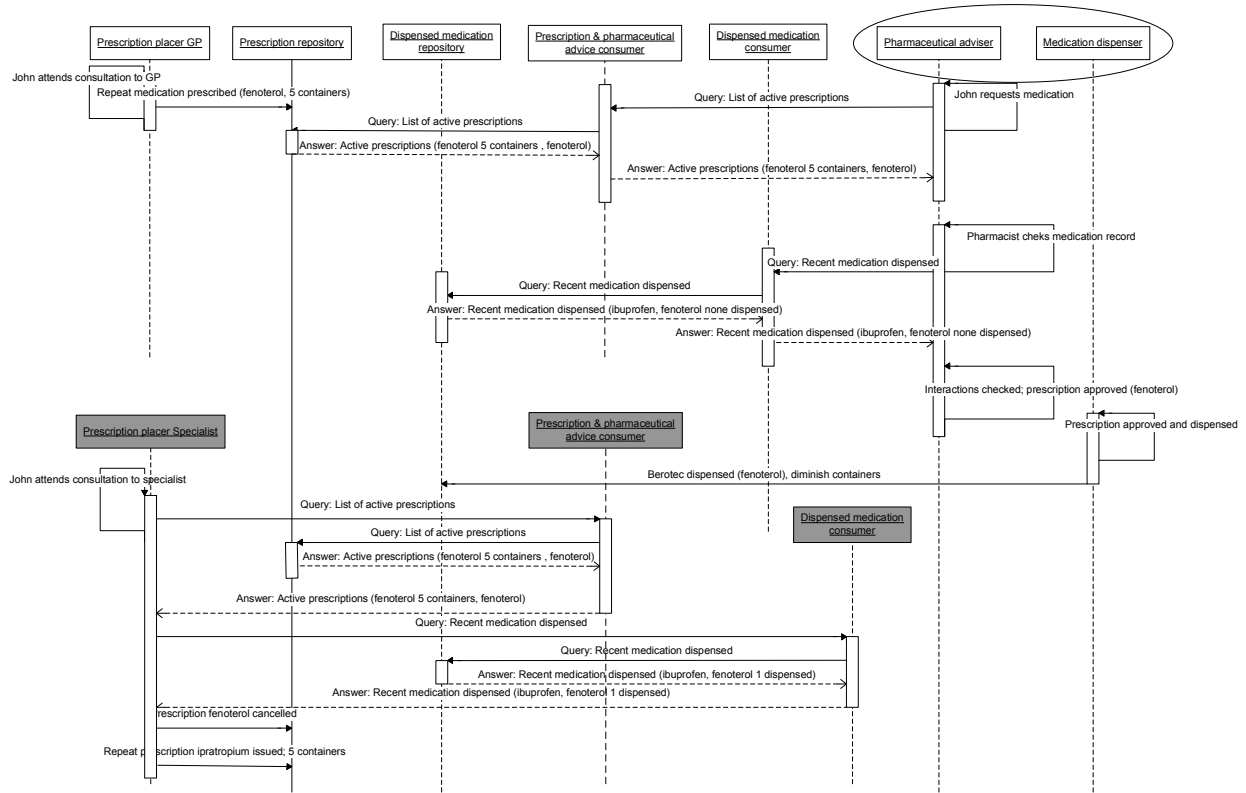


Figure 8.5: Use Case Community pharmacy-superseding a prescription

805 This diagram illustrates the process from the initial prescription, medication dispensed and new prescription issued superseding the initial one. Since two prescribers intervene in this process, a GP and a specialist, two instances of the prescription placer are depicted. The same applies to the prescription & pharmaceutical advice consumer and dispensed medication consumer. This example also illustrates how the prescriber learns the number of refills left, by comparing the 810 initial prescription with the medication already dispensed of that particular prescription; in order to achieve this, it queries the prescription repository and the dispensed medication repository.

From this point on, the process follows the common path already described in previous use cases.

## 8158.7 Use Case community pharmacy-active substance, direct push

### 8.7.1 Purpose

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 direct push model.

### 8208.7.2 Story Board

John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance “Fenoterol” in his “prescription placer” software. The GP asks John for his preferred pharmacy which is the one closest to his house, Farmaxia. John indicates this to the GP who electronically sends the prescription to the pharmacy.

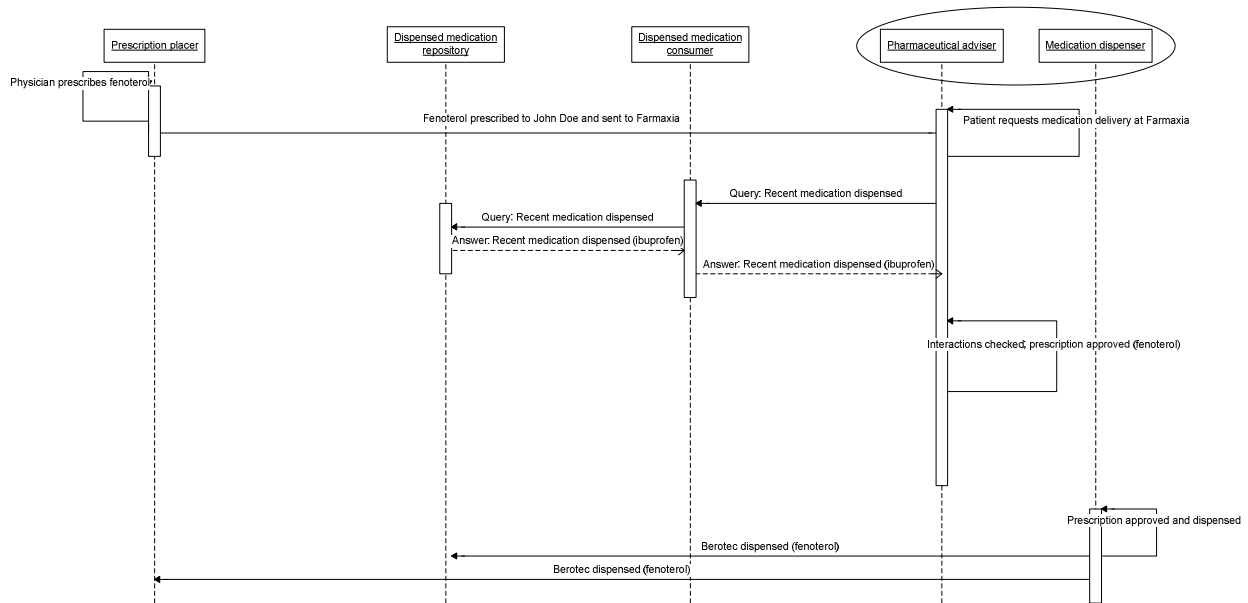
At the pharmacy, John authenticates himself by means of this health or ID card; the pharmacist gets the prescription from the “medication dispenser” embedded in his pharmacy’s software and gives out Berotec (which besides having the active substance also fits in the price range agreed with the health system) to John. The transaction is recorded in the “medication dispenser” and electronically sent to the “dispensed medication repository” and “prescription placer” for the GP to be updated on the medication actually dispensed to John Doe.

A possible implementation of this use case may use the health card as the means to convey the prescription to the pharmacy.

835

The following diagram portrays the exchange of data between in this case.

### 8.7.3 Sequence Diagram



840

Figure 8.6: Use Case community pharmacy-active substance, direct push

845

## 8.8 Use Case community pharmacy-cancellation proposal, direct push

### 8.8.1 Purpose

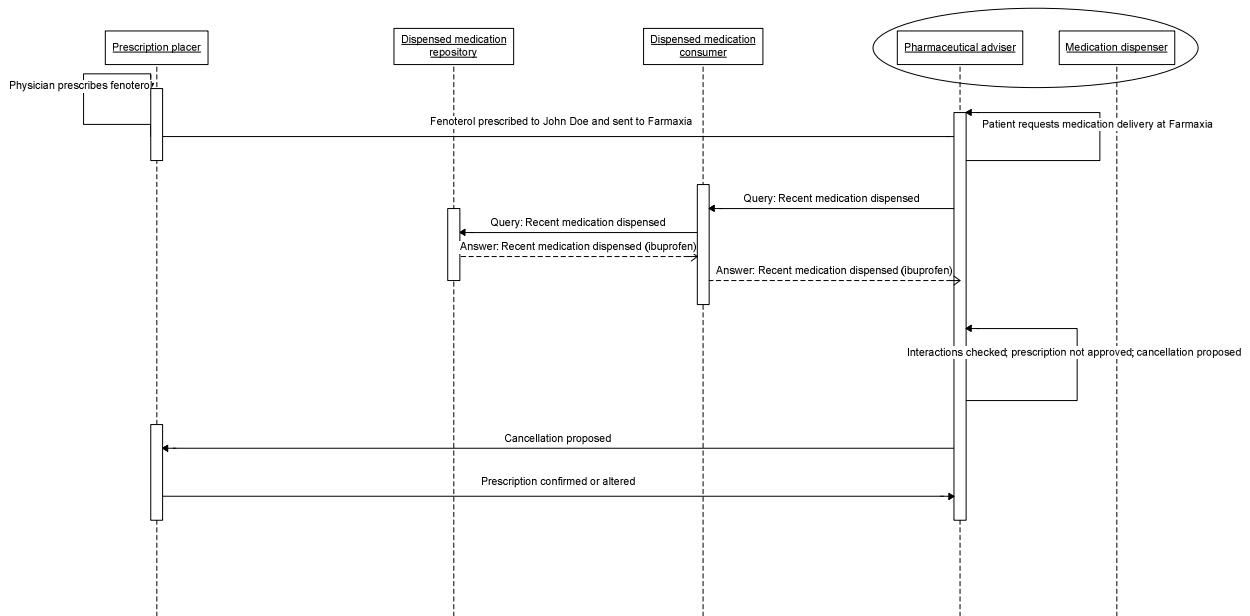
The purpose of this use case is to illustrate the prescription-dispense process in the direct push model when the prescriber orders a medicine which interacts with a recently dispensed medicine 850 and the pharmacist proposes a cancellation.

### 8.8.2 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the 855 prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist’s proposal is recorded in the “pharmaceutical adviser”.

This cancellation proposal is sent electronically to the “prescription placer” and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the “prescription placer” and reads the cancellation proposal 860 sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

#### Sequence Diagram

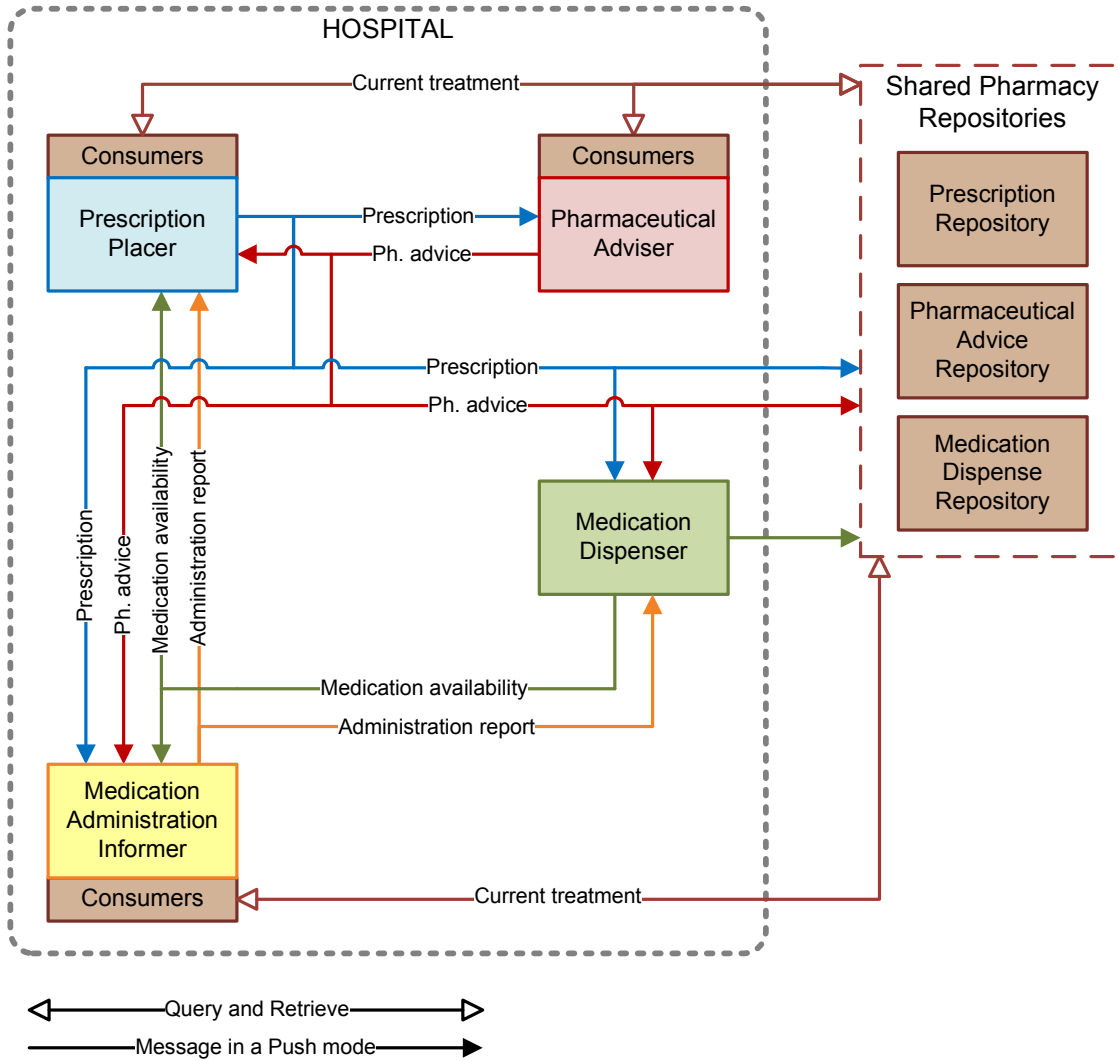


865 Figure 8.7: Use Case community pharmacy-cancellation proposal, direct push

The previous diagram depicts the process until the prescription is confirmed or amended by the prescriber. From this point on, the process is similar to the regular dispensing one detailed in the precedent use case.

## 8709 Use Cases for Hospital Pharmacy

### 9.1 Flow Chart



875

Figure 9.1: Flow Chart Hospital Pharmacy

“Consumers” = Prescription & Pharmaceutical Advice Consumer + Medication Dispense Consumer, both integrated with a Hospital Pharmacy Actor.

Some flows are optional, depending on the use cases. In many circumstances, the Prescription Repository does not have to be updated by the Hospital Pharmacy.

## 9.2 Use Case hospital pharmacy - inpatient, basic scenario

### 8859.2.1 Storyboard

Adam Everyman was admitted to Good Health Hospital. Dr. Hippocrates, after having reviewed current treatment, prescribes Doliprane 1000 mg tablets, 1 orally three times a day for the duration of the inpatient admission. Susie Supply, a hospital pharmacist, reviews the medication order, the current treatment, and local pharmacotherapy guidelines as well as the appropriateness 890of the medicine, form, strength, route and dose. She authorizes the dispensing of this medication. The order is then scheduled for administration. Florence Nightingale, a nurse, does the drug administration round next morning and checks the physician's order, electronic signature and the patient's identity. She opens the appropriate container, visually checks the medication, scans its barcode and administers it to Adam Everyman. Shared information about Adam Everyman's 895current treatment does not have to be updated.

There are use cases which are more or less similar, but with different medications, where shared information about patient's current treatment would have to be updated. Example: chemotherapy.  
900

### 9.2.2 Sequence Diagram

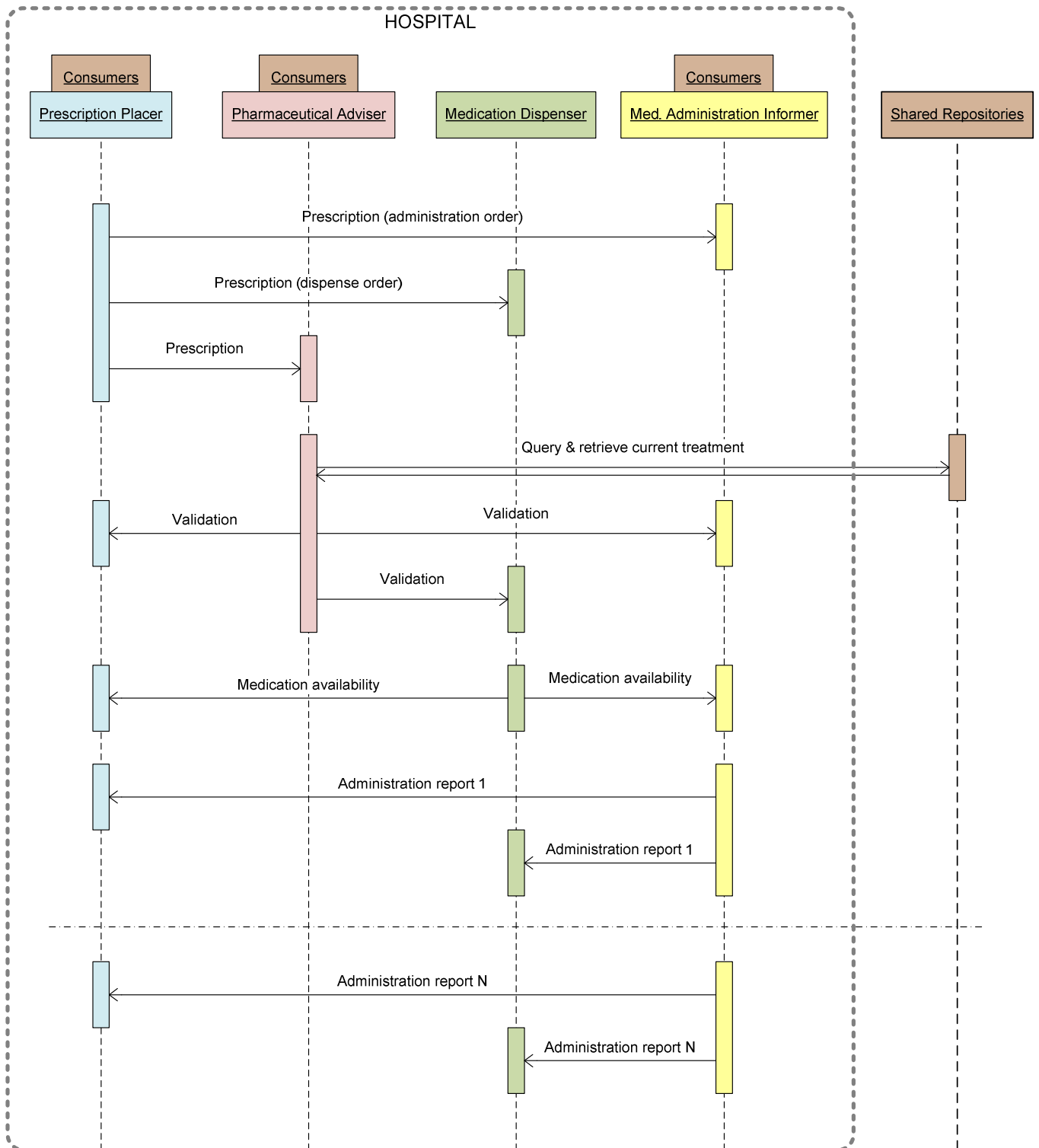


Figure 9.2: Use Case hospital pharmacy - inpatient, basic scenario

905 The sequence diagram begins when the prescription is ready to send. The Query and Retrieve which was necessary for the prescriber to review the current treatment, is not represented.

The drug prescription has two purposes at the same time, namely:

- It is the order to administer for the care unit and/or;
- 910 • An order to the pharmacy to make a supply.

Both messages could be the same. But in some cases, each could contain complementary information, specifically intended for the care unit and/or for the pharmacy.

In real life, many circumstances may lead to situations where the set of administration reports  
915 will not conform exactly to the scheduled administration plan.

### **9.3 Use Case hospital pharmacy – inpatient, unexpected administration events**

#### **9.3.1 Storyboard**

This use case is the same as use case #1, except that:

- 920 • The second day, Adam Everyman, the patient, has to be fasting for a hepatic (ultrasound) scan. Florence Nightingale, the nurse, does not administer the medication to the patient.
- The third day, there are no more 1g tablets left on the ward for administration.
  - Florence Nightingale, the nurse, therefore substitutes the 1g tablet for two 500 mg single dose packets in lieu of the resupply of 1g tablets being available.

925

The sequence diagram is the same as for use case #1.

Among 9 administration reports, two of them will therefore contain more specific information:

- 930 • The second day, one of the reports points out the medicine has not been administered and explains why.
- The third day, one of the reports indicates that the 1g tablet has been replaced by two 500 mg single dose packets.

### 9.4 Use Case hospital pharmacy - inpatient, simple case of substitution

#### 9359.4.1 Storyboard

This use case is the same as use case #1, except that:

- Susie Supply, the hospital pharmacist, decides that Doliprane 1000 mg, effervescent tablet, will be substituted by Efferalgan 1 g, effervescent tablet.

#### 9.4.2 Sequence Diagram

940

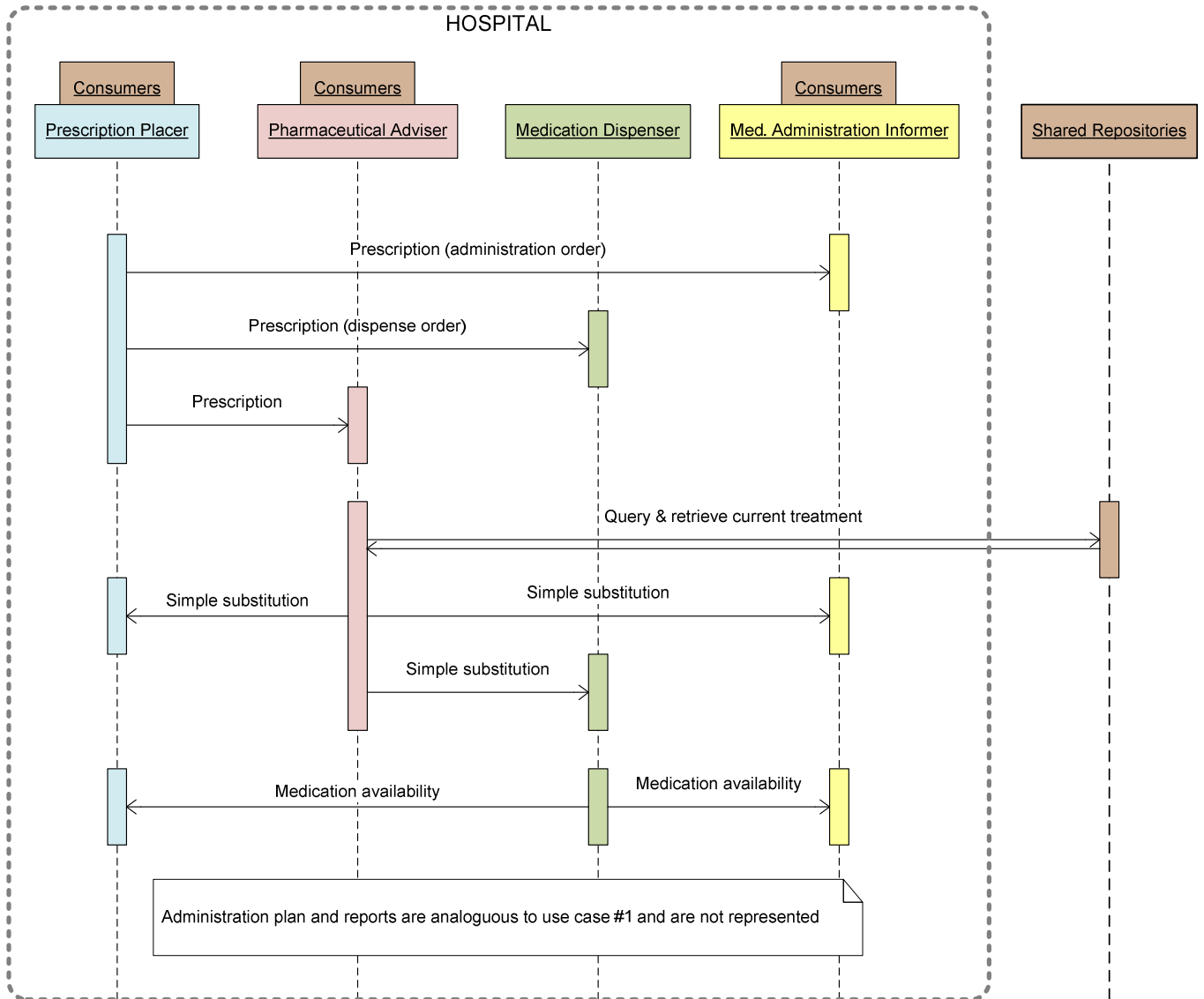


Figure 9.3: Use Case hospital pharmacy – inpatient, unexpected administration events

945



A simple substitution rule repository is defined at the hospital level to support situations as described above i.e. where appropriate alternatives may be administered to patients without the intervention of a prescriber or pharmacist being required per dose. This repository is  
950 implemented by the Pharmaceutical Adviser actor (software or human user). This process allows for the identification of any situation which results in a "simple substitution" interaction with the concerned actors. No explicit back-validation is required from the Prescription Placer, the physician agreeing in principle to the rule applied by the pharmacist.

955 A simple substitution remains a type of validation. The hospital pharmacist is supposed to check the current treatment.

Note #1: Any complex substitution proposed by a pharmacist proposal will need validation by the Prescription Placer actor. Complex substitution will be addressed in a specific use case,  
960 which is not in the scope of this proposal.

Note #2: This simple substitution should not be confused with an INN (International Nonproprietary Names) or an active substance prescription. Active substance prescription is addressed in the next use case.

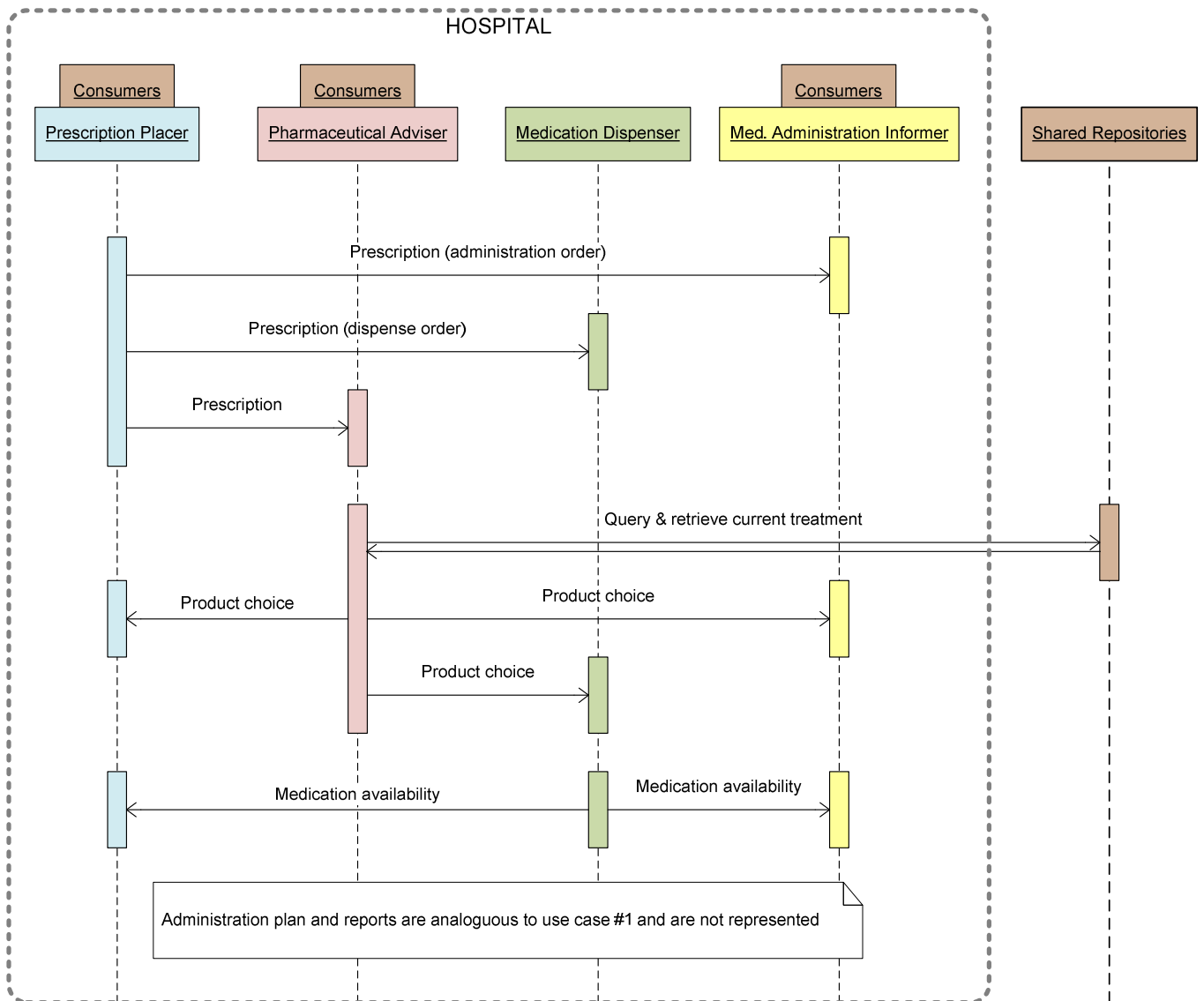
9659.5 Use Case hospital pharmacy - inpatient, active substance prescription

9.5.1 Storyboard

This use case is the same as use case #1, except that:

- Dr. Hippocrates prescribed Paracetamol, which is the active substance of either Doliprane or Efferalgan, without specifying the form.
- 970• Susie Supply, the hospital pharmacist, chooses Doliprane 1000 mg, effervescent tablet, to fulfill the active substance prescription.

9.5.2 Sequence Diagram



975 Figure 9.4: Use Case hospital pharmacy - inpatient, active substance prescription

The relationship between medicinal, branded products to active substances is defined at a national level. A simple repository is available or accessible at the hospital level. This repository is implemented by the Pharmaceutical Adviser actor (software or human user). No explicit back-validation is awaited from the Prescription Placer, the physician agreeing in principle to the relationships defined/applied by the pharmacist.

The choice of a product for fulfilling an active substance prescription remains a kind of validation. The hospital pharmacist is supposed to check the current treatment.

## 10 Pan Hospital/Community Pharmacy Use Cases

990 These Use Cases focus on the interactions between hospital and community in order to create a Continuity of Treatment context.

### 10.1 Admission-Discharge with Continuity of Treatment

#### 10.1.1 Purpose

This use case illustrates an organization that ensures continuity of current medications between 995 the community space and the hospital space, as is often the case with hospitals in United Kingdom.

#### 10.1.2 Storyboard

A patient is to be admitted at hospital, coming from home. His initial inpatient prescription remains identical to the medicines that he has been taking at home.

1000

His prescription is written up (1) and the medicines that he has brought in with him assessed by a pharmacy technician to confirm that they are appropriate to be used during his stay (2). A pharmacist verifies that the medicines are appropriate for the patient and annotates the prescription to identify that the check has occurred.

1005

Of the four medicines that he has been taking three have sufficient supply and can be used. He does not have sufficient of his fourth medicine which the pharmacy technician re-dispenses from pharmacy. The pharmacy supplies a one month pack of medicines labeled ready for him to take home (3). All of his medicines are stored in a locked box at the side of his bed and used during

1010 his stay.

Two days later a new medicine is prescribed late at night (4). The ward staff uses a ward stock box of the medicine to administer the first three doses (5) until an original pack of medicines labeled for the patient (including discharge instructions) is supplied by pharmacy (6).

1015

The following day the patient is discharged – his discharge prescription is the same as his inpatient one. It is recorded in the hospital information system as well as in the community prescription repository (7). His ‘take-home’ medicines are supplied from the locked box at the side of his bed (8). The delivery is published into the shared medication dispense repository (8).

1020

### 10.1.3 Sequence Diagram

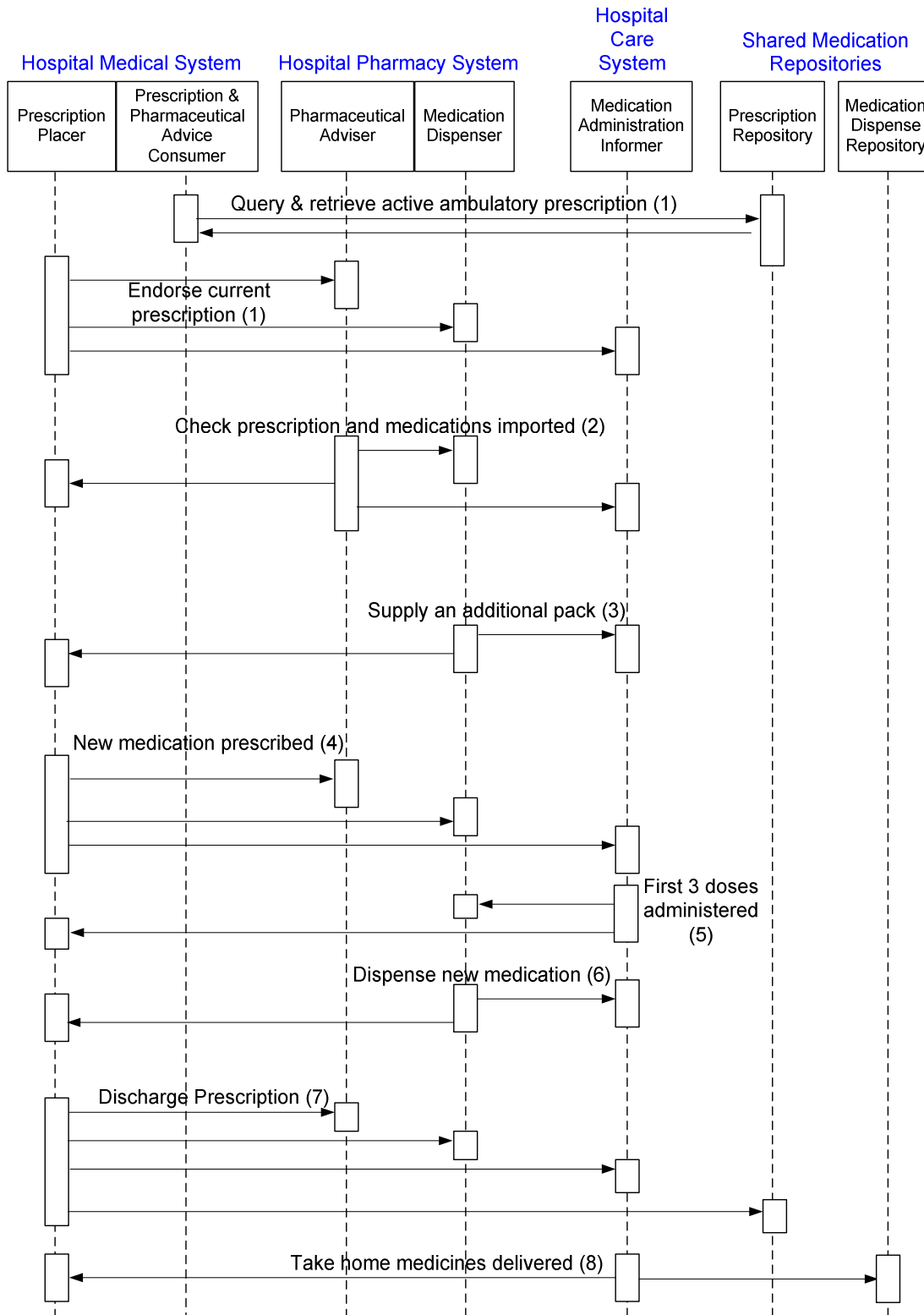


Figure 10.1: Use Case Admission-Discharge with Continuity of Treatment

## 102510.2 Admission/discharge with hospital taking over medications during stay

### 10.2.1 Purpose

This use case illustrates the admission process with the hospital taking over the control on all medications to be administered to the patient during their stay. The medications that the patient may have brought with them are discarded and replaced by medications exclusively delivered by 1030the hospital pharmacy. Conversely, at discharge time the hospital prescribes medications to the patient but does not dispense them. This is a common organization in most European countries.

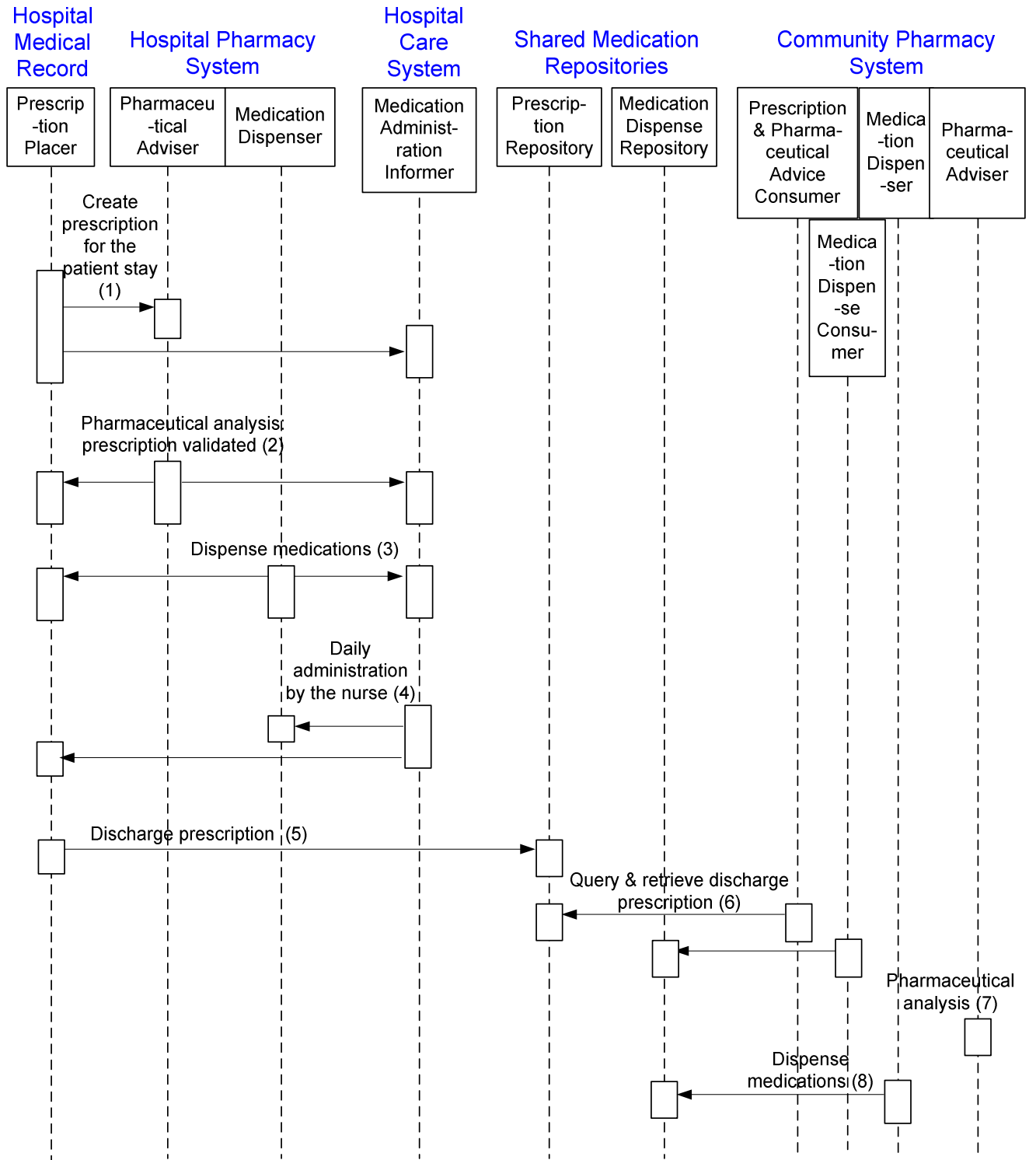
### 10.2.2 Storyboard

A patient is admitted at hospital. The admitting physician checks any medications that the patient used to intake while at home, and recognizes that one – Digoxin - has to be pursued during the 1035patient stay. None of the medications that the patient brought with them is kept. The physician writes a new prescription, which includes the Digoxin (1). After pharmaceutical analysis by the pharmacist (2), the pharmacy dispenses the prescribed medications (3), which are daily administered by the nurse (4).

Finally, the patient is discharged. The physician discharging the patient prescribes medications 1040that the patient will have to get delivered from a community pharmacy. The patient is given a paper prescription describing the medicine prescribed containing all the intake instructions (posology, starting date, end date...). At the same time, the electronic prescription is published by the hospital medical system into the regional prescription repository (5).

Later on, the patient goes to a community pharmacy to obtain the medications. The pharmacy 1045system queries the regional prescription repository together with the dispense repository to look up for the prescription and check that no other dispenses have already been performed (6). The pharmacist analyses the prescription (7), and then dispenses the medicines to the patient. The dispense is registered into the shared repository (8).

### 10.2.3 Sequence Diagram



1050

Figure 10.2: Use Case Admission-Discharge with hospital taking over medications during stay

1055

### 10.3 Hospital Dispense for Outpatients

#### 10.3.1 Purpose

This use case shows the hospital dispensing specific medications to outpatient, in fulfillment of a prescription that has been produced in the community space. This category of hospital dispense for outpatients is called “retrocession” in France. The official list of medications that can only be dispensed by hospitals is regularly updated by the ministry of health.

#### 10.3.2 Storyboard

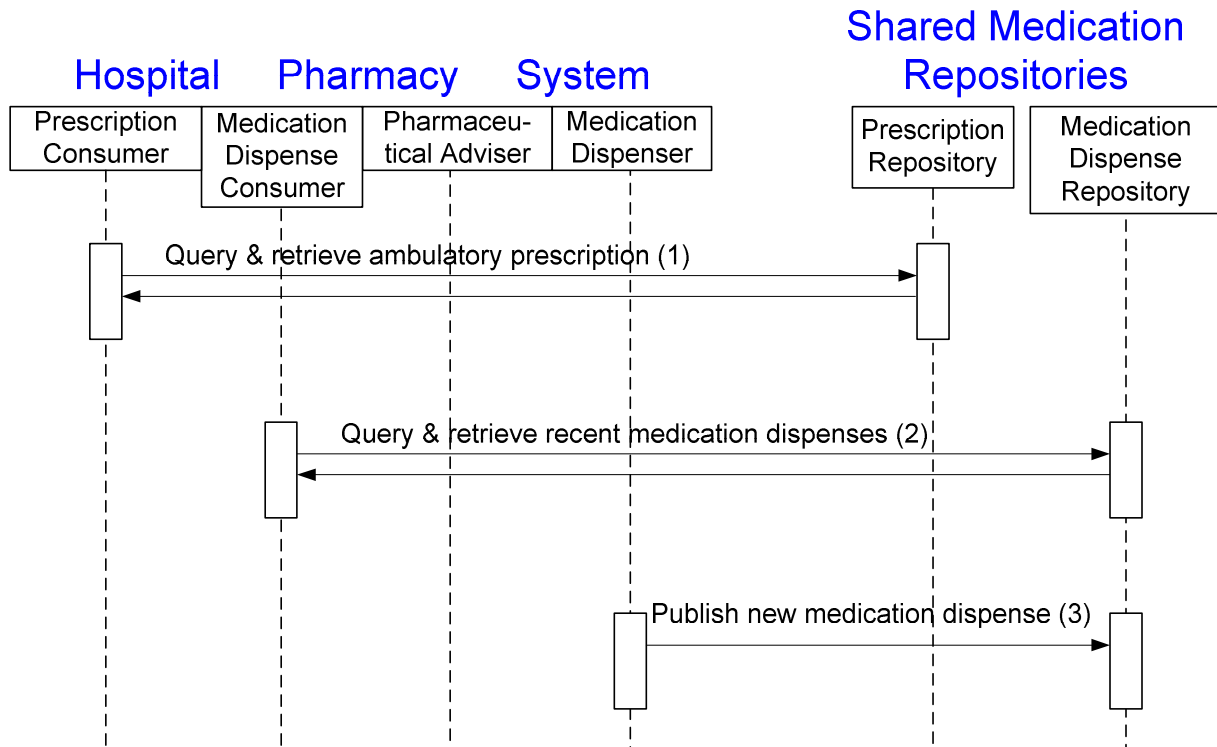
1065A patient was hospitalized for a resistant schizophrenia, and then discharged by the neurologist with a renewable prescription of cocaine. Since then, the patient is regularly checked by his psychiatrist in town. The psychiatrist renews the initial Clozapine prescription as needed.

This particular medication is to be obtained at a hospital pharmacy. The prescription is published into the national prescription repository.

- 1070 (1) The patient goes to a hospital pharmacy in order to retrieve his medication. The patient brings the initial prescription by the neurologist as well as the renewal ordered by the psychiatrist. The hospital pharmacist queries the national prescription repository and retrieves the prescription.
- 1075 (2) The hospital pharmacist queries the national dispense repository for current dispenses. The pharmacist checks that no dispense have already been performed for the current prescription and that it does not interact with any other current medications dispensed to the patient.
- (3) No interaction being detected, the pharmacist accepts the prescription, dispenses the medication and records it into the national dispense repository.
- 1080 (3 bis) Variation of (3): An interaction is detected. The pharmacist refuses the prescription. His pharmaceutical advice is recorded into the pharmaceutical advice repository. The prescriber is notified.



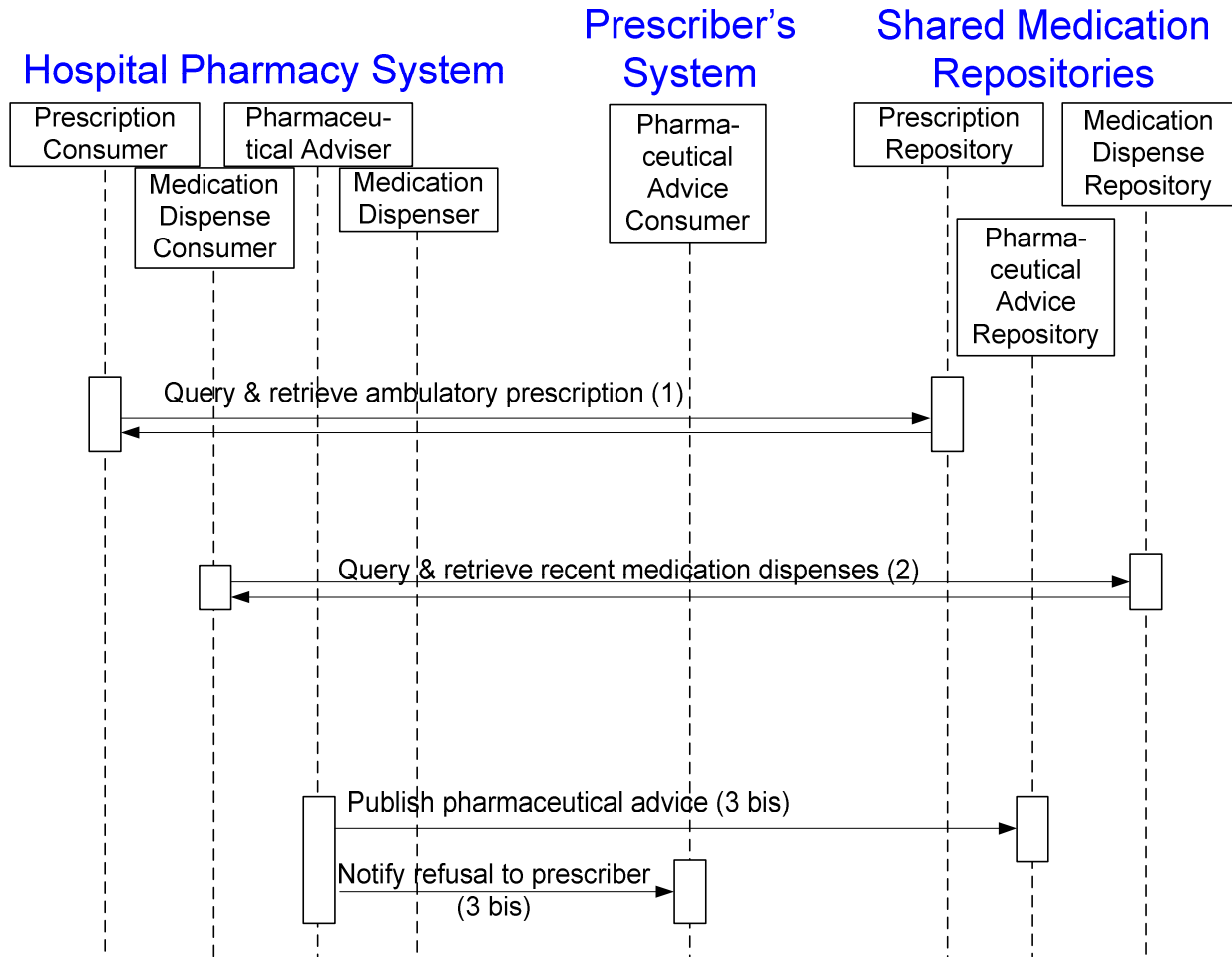
### 10.3.3 Sequence Diagram: Normal dispense



1085

Figure 10.3: Use Case Hospital Dispense for Outpatients – normal

10.3.4 Sequence Diagram with Interaction detected and dispense refused



1090

**Figure 10.4:** Use Case Hospital Dispense for Outpatients – with Interaction detected and dispense refused

## 11 Relevant standards for the pharmacy domain

### 109511.1 HL7 V2

HL7 v2 messages supporting the pharmacy workflow have been in play for a long time.

These messages support the intra hospital workflow as well as the community workflow, and some real implementations exist in both subdomains.

These messages and their content (data segments and fields) are described in chapter 4 “Order Entry” of HL7 2.5.1 or 2.6. The messages relevant to the pharmacy hospital sub domain use cases described earlier in this document are listed below:

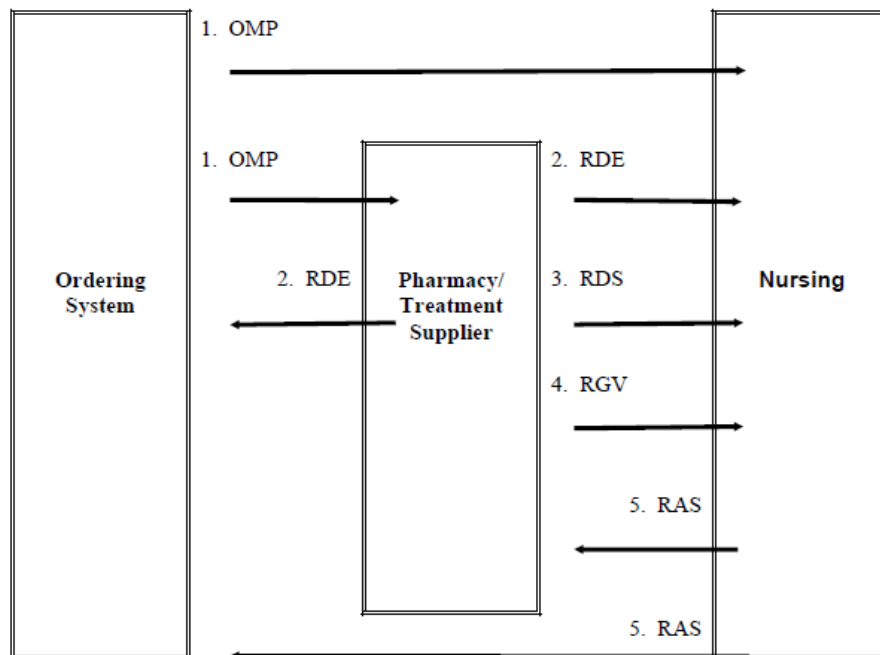
| Main process              | Message | Actions  | Sender                             | Receiver   |
|---------------------------|---------|--|------------------------------------|--|
| Prescription              | OMP^O09 | prescription created, cancelled or updated             | Prescription Placer                | Pharmaceutical Adviser<br>Medication Dispenser<br>Medication Administration Informer |
|                           | ORP^O10 | Ack  |                                    |  |
| Pharmaceutical analysis   | RDE^O11 | prescription accepted and encoded, changed, or refused | Pharmaceutical Adviser             | Prescription Placer<br>Medication Dispenser<br>Medication Administration Informer    |
|                           | RRE^O12 | Ack  |                                    |  |
| Dispense                  | RDS^O13 | Dispensed medication                                   | Medication Dispenser               | Prescription Placer<br>Medication Administration Informer                            |
|                           | RRD^O14 | Ack  |                                    |  |
| Medication Administration | RAS^O17 | Medication administered                                | Medication Administration Informer | Prescription Placer<br>Medication Dispenser  |
|                           | RRA^O18 | Ack  |                                    |  |

For all messages listed in the table above, the real action requested is coded in field ORC-1 “Order Control”, which is the 1<sup>st</sup> field of each “Common Order” segment in the message. For instance, when placing a new order the Prescription Placer will populate this field with the value “NW” ( “new order placed”). When accepting a new order and deciding a substitution, the Pharmaceutical Adviser will populate this field with the value “RU” (“replaced unsolicited”). These messages use a set of common segments (e.g. PID for patient, OBX to provide clinical observations) and some other segments dedicated to the pharmacy domain: RXO (order), RXR (route), RXE (encoding), RXD (dispense), RXA (administration).

Chapter 4 of HL7 v2.5 standard diagrams an example of intra hospital workflow based on these messages:

### PHARMACY/TREATMENT TRANSACTION FLOW DIAGRAM

The following are possible routes at a generic site.



1115

## 11.2 HL7 v3 messages

HL7 v3 is providing messages, which are built per domain. The v3 messages for the Pharmacy domain are still in the building process. After normalizing the medication model, HL7 has moved forward again with messages, starting with the community space. The Medication Order message is about to become normative, after May 2009 ballot. The Medication Dispense message will enter ballot process in May 2009 and should become normative early 2010. Messages for hospital pharmacy are a distinct project, yet to be started. They're unlikely to be ready in the same time frame.

1125

## 11.3 HL7 v3 documents

On the other hand HL7 v3 offers a standard for clinical documents: CDAR2, which is normative, stable, and widely adopted for the sharing of clinical documents such as referrals, medical summaries, consultation reports...

This section tries to assess the appropriateness of CDAR2 for pharmacy objects appearing in the pharmacy use cases

### 11.3.1 Act Moods

The objects described in this white paper (prescription, pharmaceutical advice, dispense ...) represent acts, and are represented in HL7 v3 as specialization of the Act class.

1135V3 models acts in various “moods”:

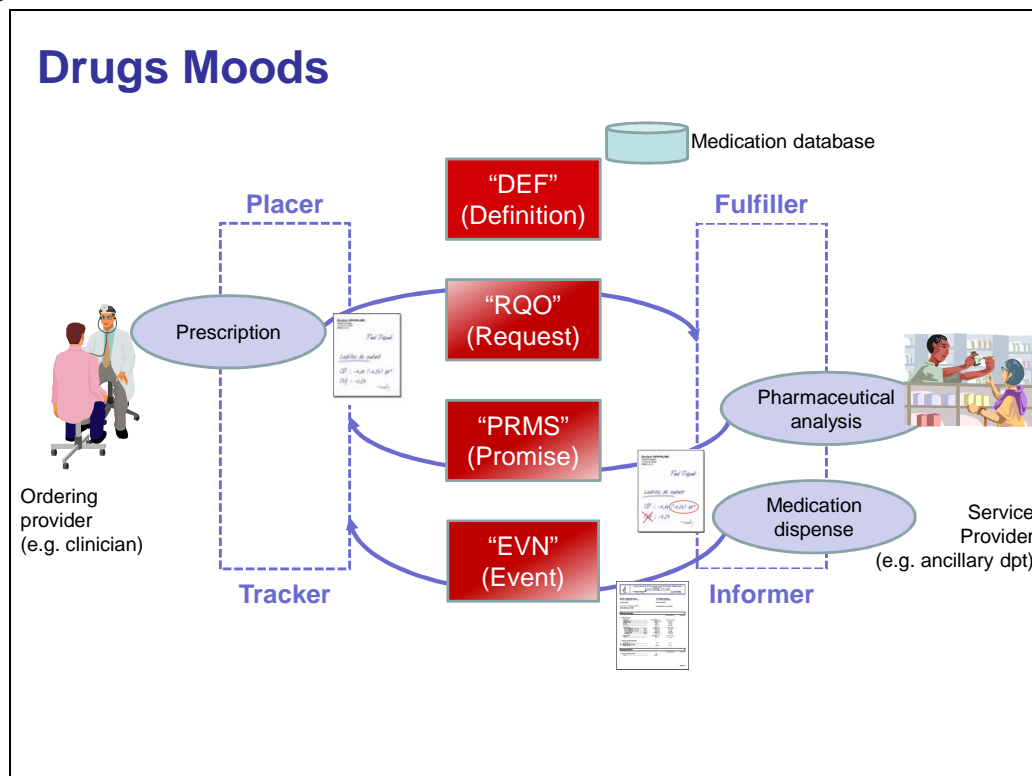
- “Definition” (when the act is represented in a catalogue)
- “Request” when the act is prescribed
- “Promise” when the performer (the fulfiller) has accepted to perform this act.
- “Event” when the act has actually been performed (or cancelled, or aborted).

1140The prescription is a “request” from the ordering provider to the pharmacist for dispense, and intra-hospital, to the nurse for administration of the drug.

The pharmaceutical advice can be considered as a “promise” from the pharmacist.

The dispense is an event: The requested service has been performed (unless it was cancelled). So is the medication administration by the nurse.

1145



Each object has its own life cycle, keeping its own mood:

The prescription may evolve over time, with new drugs added or replacing others. But this object only belongs to the ordering physician. The pharmacist cannot update it.

1150

The pharmacist may require replacements of a drug by a new one. This takes place in the “promise” object, coming from the pharmaceutical analysis process. This object belongs to the pharmacy and cannot be updated by anyone outside the pharmacy.

1155Similarly, the dispense event is produced by the pharmacist or his assistant. This dispense belongs to the pharmacy.

### 11.3.2 What kind of documents CDA was designed for

## What content CDA is meant for?

```

<ClinicalDocument>
...
<recordTarget>
  <!-- ... the patient -->
</recordTarget>
...
<inFulfillmentOf>
  <!-- ... references of the order fulfilled -->
</inFulfillmentOf>
...
<documentationOf>
  <serviceEvent moodCode= "EVN" >
    <!-- ... the documented service event -->
  </serviceEvent>
</documentationOf>
...
<component>
  <structuredBody>
    <!-- ... body of the document
    carrying the output of the
    service event -->

```

The diagram illustrates the clinical workflow. It starts with an 'Ordering provider (e.g. clinician)' who creates a 'Prescription'. This leads to a 'Tracker' which contains four stages: 'DEF' (Definition), 'RQO' (Request), 'PRMS' (Promise), and 'EVN' (Event). The 'EVN' stage is highlighted with a red circle. The 'Fulfiller' (e.g. ancillary dpt) performs 'Pharmaceutical analysis' and 'Medication dispense'. A 'Medication database' is also shown at the top.

CDA represents clinical documents describing a service event performed for a patient, possibly in fulfillment of an order.

CDA is convenient for dispenses. CDA does not seem appropriate for a prescription or a pharmaceutical validation

1160

The CDA schema is suitable for representing the dispense as a document. A CDA dispense shall reference the prescription it fulfils in the <inFulfillmentOf> element of the CDA header.

Conversely, the CDA standard was not really designed to represent orders (prescriptions) or promises (pharmaceutical advice). However it still can represent these objects if one considers the act of prescribing as an event in itself, that needs to be recorded and kept over time as it was at prescription time.

1165

The other decision factors that have to be considered regarding CDA are the key factors that favor the choice of a document standard versus a message standard:

### 117011.3.3 Persistency

How long do the objects represented in the workflows of this white paper have to persist, and be available for use by the various human actors and their system actors?

1175

- The use cases of the community sub domain (including the exchanges between hospital and community) clearly need prescriptions, pharmaceutical advices and dispenses to persist as they were produced by their authors (physician, pharmacist), and be accessible over time by the actors, for checking against new prescriptions, and also for liability purpose.

1180

- Conversely, the intra hospital use cases need not that prescriptions, validations, dispenses and administration reports persist as shared objects. The intra hospital use cases need real time exchange between all system actors, with fine grained status change notifications, ensuring that all systems involved keep at all time the same knowledge of the ongoing process and the last status of its structured data. Liability in this sub domain is ensured

by a tighter coupling of the systems within one unique organization, with precise policies regulating the workflow, and common tools supporting these policies.

**118511.3.4 Stewardship**

A CDA document is authored and issued by a healthcare professional or organization who wants to share its content with other actors. The professional or organization source of the document is liable for its content and is entitled to administrate this document, that is:

- Deprecate it when comes a time it’s no longer relevant.
- 1190 • Replace it in case an error in this content has been detected and needs to be corrected.
- Complement it with addenda (documents appended to it) when needed.

The key point here is that stewardship is a role assumed by the source of the document, and no-one else. For instance a prescription issued by a GP will never be updated by a pharmacist (wanting to substitute a medication) or another physician (wanting to add a medication) or a

1195nurse (wanting to change the dose packaging).

**11.3.5 Degree of interactivity of the workflow**

The more real-time oriented and interactive the workflow is the less suitable documents are.

For instance, the hospital workflow surely cannot be handled with documents, which does not preclude this workflow to produce some persistent documents to be shared within the institution

1200and/or with the community.

**11.3.6 Workflow requirements that cannot be handled only with documents**

The requirements presented in this section come from the use cases presented earlier in this document. These requirements need other artifacts than documents (e.g. messages or services)

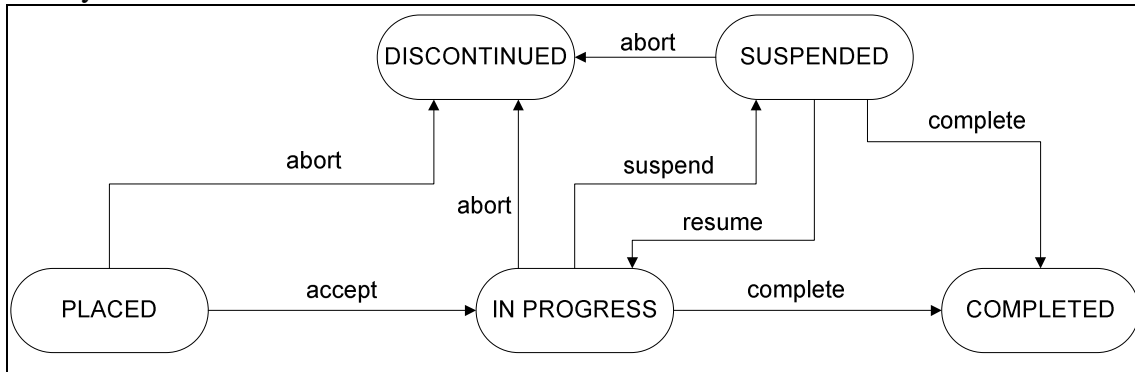
- **Prescription Status Management**

1205A prescription or a prescription item can take one of these statuses

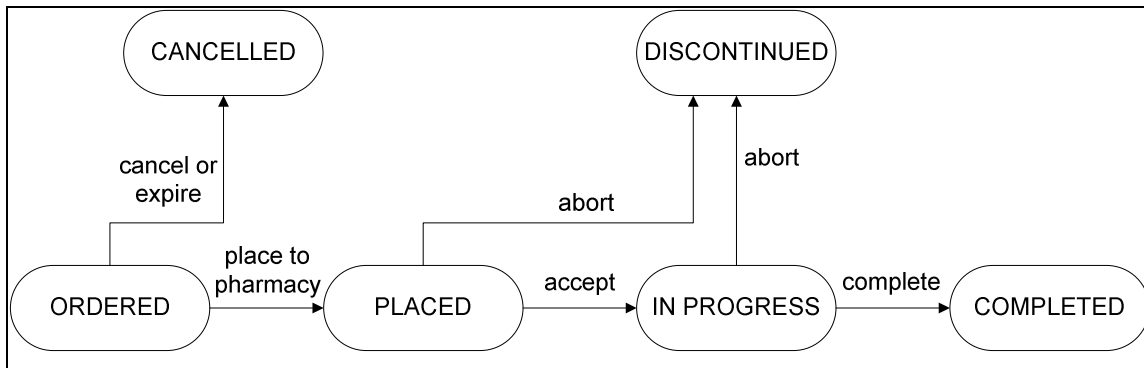
|             |  |
|-------------|--|
| ORDERED     | The prescription has been produced by the ordering provider and published, but is not yet assigned to or retrieved by any pharmacy. This status is mainly used by the Community subdomain in the “publish and pull” mode.  |
| PLACED      | The prescription 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 performed yet Or it has detected an issue and reported it in a pharmaceutical advice, which is awaiting resolution through further interactions/dialog between the pharmacist and the prescriber. |
| IN PROGRESS | A pharmacy has checked that the prescription is free of potential adverse issues (e.g. interactions, overdose) and has accepted to dispense the medications (which may need time for preparation or stock provision). Some of the prescribed medications may have been dispensed. Further dispenses are expected in the future.  |
| COMPLETED   | The prescription is completely dispensed. No more action is expected on this prescription.   |
| CANCELLED   | The prescription, which was ORDERED has been cancelled by the ordering provider, or has expired because the patient never showed up to any pharmacy.   |

|              |  |
|--------------|--|
| 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 may be 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 are suspended, and are expected to be resumed at a later point. |

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



1210 Figure 11-1: State transitions of Medication Prescription (Item) in the Hospital subdomain



1215 Figure 11-2: State transitions of Medication Prescription (Item) in Community subdomain

The management of these status transitions and the presentation of the prescription current status to the healthcare professional cannot be handled with documents. This management needs a service layer around the prescription document. Conversely, if the prescription is a message, the message carries this status.

- **Linking the pharmaceutical advice and the dispenses to their prescription**

When a prescription is retrieved from a repository by a system used by a healthcare professional, the retrieval must always bring back the prescription along with the existing pharmaceutical



1225advices and/or dispenses related to that prescription, in order to present a coherent view of the prescription to the professional, detailing what was prescribed, what was accepted, what was substituted, what was refused, what was dispensed.

This management needs two or three additional features:

- 1230 - A new type of external link between documents: This link should be carried in the “parentDocumentId” metadata associated to a document, with a new type of association “SUCC” for successor. (e.g. a dispense document is a successor to the prescription document if the dispense was performed in fulfillment of this prescription)
- 1235 - A new type of internal link between CDA documents: The “relatedDocument” element of the CDA schema should provide a new possible value for its “typeCode” attribute, which would be something like “SUCC” (successor, e.g. a pharmaceutical advice is a successor to the prescription it advises on)
- A service layer over the document infrastructure holding the prescription, pharmaceutical advice and dispense as documents, that will encapsulate the query and retrieval of documents by the Consumer actors, and will process these links.

1240

- **Notification of acceptance/refusal by the pharmacist to the ordering provider**

If the prescription and pharmaceutical advice are documents in repositories, the pharmacist needs an additional notification service over the document infrastructure to notify their decision on the prescription directly to the system of the ordering provider.

1245

- **A prescription supersedes a former prescription issued by another physician**

As shown in the Community Use Case chapter, it may happen that a specialist prescribes new medications superseding an in progress renewable prescription formerly ordered by the GP for the treatment of a chronic disease. This brings a particular relationship between prescriptions considered as documents: Prescription 2 issued by physician B puts prescription 1 formerly issued by physician A in DISCONTINUED status.

This case also needs a service layer over the document sharing infrastructure.

## **11.4 The XDS family of IHE profiles to support documents**

1255The IT Infrastructure domain of IHE has produced a number of profiles that can prove useful for the sharing or the exchange of pharmacy objects as documents.

Some countries may choose to build on these infrastructure profiles. Other countries may choose to rely on a different non-IHE infrastructure, using for instance the Medical Records message set of HL7 v3.

### **126011.4.1 XDS-b – Cross Enterprise Document Sharing**

This profile provides an infrastructure for the storage/query/retrieval of prescriptions, pharmaceutical advices and dispenses as clinical documents. If a country or a region decides to rely on this profile, the repositories actors defined in this white paper will be represented in XDS by:

- 1265• One single Registry Actor: that will handle the metadata associated with all types of documents (prescriptions, pharmaceutical advices, dispenses)
- A set of Repository Actors that can be distributed or centralized, specialized per type of document or not.

The consumer actors presented in this white paper will be represented in XDS by as many  
1270 Document Consumer Actors.

The “Prescription Placer”, “Medication Dispenser”, “Pharmaceutical Adviser” actors presented  
in this white paper will be combined with “Document Source” Actors.

#### **11.4.2 XDM – Cross Enterprise Document Media Interchange**

This profile may be useful for direct exchanges of documents in the community space. The  
1275 profile supports both the exchange on a medium such as a CD or a USB key (carried by the  
patient to the care provider), or attached to an email (sent by one care provider to another).

#### **11.4.3 NAV – Notification of Document Availability**

This profile enables a system having published a document in a repository, to notify an intended  
recipient of the document availability. This could be used for instance by the pharmacist to notify  
1280 the ordering physician with the pharmaceutical advice.

#### **11.4.4 ebRIM and ebRS from ebXML OASIS standard**

The XDS family profile leverages and constrains ebRIM and ebRS. These standards offer also  
capabilities to encode workflow behavior (e.g. status management), which might support some  
of the workflow requirements listed above.

1285

### **11.5 Relevant semantic standards**

- ICSR Framework Reference Model (prEN ISO 27953-1)
- ICSR Human pharmaceuticals (prEN ISO 27953-2)

1290 The standard specifies the data elements for transmission of Individual Case Safety  
Reports of adverse events/reactions that may occur upon the administration of one or  
more medicinal products to a patient, regardless of source and destination

- prEN ISO 11615: Data Elements and Structures for the Exchange of Regulated Medicinal  
Product Information for Drug Dictionaries (MPID)

1295 This standard provides a single structure for the data elements required for the exchange  
of information that uniquely and certainly identifies a medicinal product, wherever  
authorized for marketing. The project will further provide references to other standards  
and external terminological resources required to populate the data elements defined in  
this standard.

1300

- prEN ISO 11616: Structures and Controlled Vocabularies for Pharmaceutical Product  
Identifiers (PhPIDs)

- prEN ISO 11238: Structures and Controlled Vocabularies for Ingredients (substances)

1305 This standard will adapt and adopt, or if necessary, develop structures and content of  
controlled vocabularies for ingredients that are used worldwide in medicinal products.  
Each ingredient will be defined at the molecular level and then assigned a randomly  
generated unique identifier. When an ingredient cannot be defined at the molecular level  
because of insufficient molecular information (e.g., polymers and botanicals), then it will  
1310 be defined at the non-molecular level by a set of criteria that is deemed by experts to be

sufficient. Ingredients include, but are not necessarily limited to, chemicals, biologics (including vaccines, allergenic extracts, and botanicals), and select foods that are known to interact with drugs. Ingredients will include both the active ingredients and the inactive ingredients (excipients).

1315

- prEN ISO 11239: Structures and Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration

This standard defines a controlled vocabulary of dosage forms, units of presentation and routes of administration in the specified domains. The controlled vocabulary is made available in a specified form.

1320

- prEN ISO 11240: Structures and Controlled Vocabularies for Units of Measurement

This international standard specifies information structures and a set of terms and term identifiers that can be used to communicate the units of strength for identification of medicinal products as well as structures and units as parts of medication dosing information, also called posology. This information is necessary to convey the amount of a medicinal product that has been taken or prescribed to be taken in a certain time interval. This Standard thus includes measurements of dose units and relevant dosing time information including intervals. This Standard is applicable for the pharmacovigilance reporting of Individual Case Safety Reports, but may also be applicable to other use cases within the regulatory and clinical areas. The scope includes both the vocabulary structure(s) and the content i.e. controlled terms themselves.

1325

1330

- prEN ISO 11595: Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results

1335

This controlled vocabulary will operate at the level of internationally recognized controlled vocabularies for laboratory test information for the reporting of laboratory results.

- 1340• ISO - Common glossary

[http://www2.dev.cred.ca/skmt\\_isowg8\\_dev/index.asp](http://www2.dev.cred.ca/skmt_isowg8_dev/index.asp)

- SNOMED CT published by IHTSDO
- LOINC, Regenstrief Institute

- 1345• NWIP Metadata Model and XML-interface specification for OID registries in healthcare

- NWIP Guidance for maintenance of object identifiers
- EMEA – EUTCT/Eudrapharm
- WHO-Terminologies (ATC, ICD-10, INN)
- HL7 vocabulary domains and value sets

- 1350• Most countries impose national standards or code sets for dispensable medications. The profiles built in the IHE Pharmacy domain will have to support these national code sets. Example : German Drug Codes, e.g. ASK, PZN

Note: The prefix prEN points ISO pre-standards for the EU, that do not have yet the normative 1355status.

## 11.6 NCPDP

<http://www.ncdp.org/>

Local standard designed for the community pharmacy workflow in the USA.

### 136011.7 PN13 – SIPh2\_v2

Local standard designed for hospital pharmacy workflow in France. This standard specifies a set of 6 xml encoded messages:

- Prescription
- Pharmaceutical analysis report
- 1365 • 3 flavors of Dispense (dispense for one patient, grouped dispense, non-patient related distribution)
- Medication administration report

The documentation in French is made available to the editors members of the SIPh community.

### 137011.8 Recommendations

Given the use cases presented in this white paper, the following statements can be made:

- The hospital pharmacy workflow needs messages or services. In 2009, and probably in 2010, the only international standard available for this workflow is HL7 v2.x.  
1375
- In case messages are chosen to handle the community workflow, the two candidates are HL7 v2 and HL7 v3 messages. The V2.x message pharmacy treatment message set is available and stable. The V3 Pharmacy message set is expected to reach normative status by January 2010. It is explicitly developed for the community space in the rigorous frame of the HL7 Development Framework, and has captured international use cases refined by early adopters such as Canada, NL and UK. It is therefore likely to offer the best coverage for the requirements of the community use cases.  
1380
- A number of countries have expressed a requirement for persistency of pharmacy treatment content, legally authenticated in community shared repositories. One way to fulfill such requirements is to publish these contents as electronic documents, based on the HL7 CDA standard. The document sharing infrastructure can leverage IHE XDS or other standards such as the Medical Records HL7 v3 message set, depending upon national infrastructure choices.  
1390
- If a document infrastructure is in place, the community pharmacy workflow could also leverage it. For that purpose, a number of additional features (e.g. status management, document linking) need messages or services around the document repositories. ebXML is one of the standards to investigate for these additional features.  
1395

## 1400 **12 Examples of deployment architecture in Pharmacy domain**

### **12.1 Community Pharmacy**

#### **12.1.1 Publish & pull model**

In the publish & pull architecture prescriptions and dispensed medication are managed by central repositories. These repositories cover the whole jurisdiction of the health system, either  
1405 nationally or regionally. This means that the health system itself is the main responsible for providing access to prescriptions and dispensed medication.

Thanks to this feature, any practitioner and pharmacist working for the health system and serving the patient can connect to these repositories to retrieve and update data according to their user  
1410 profiles. Therefore, patients may choose any community pharmacy for their medication to be dispensed.

The information on the dispensed medication is managed centrally so that pharmacists can always retrieve the comprehensive medication record of the patient which contains medicines  
1415 (recently) dispensed to the patient and check for interactions with active prescriptions.

### **Approaches**

Providing that the point of sale software of the pharmacy (medication dispenser and pharmaceutical adviser) is not directly connected with the aforementioned repositories (prescription repository, pharmaceutical advice repository and dispensed medication repository),  
1420 the regional health system provides the means for pharmacists and physicians to get prescriptions and dispensed medication and pharmaceutical advice by means of the “prescription & pharmaceutical advice consumer” and “dispensed medication consumer”.

The following scheme represents an implementation based on this alternative where repositories  
1425 and consumers are provided by the health system and, therefore, are centralized applications and databases:

- Prescription repository
- Dispensed medication repository
- 1430 • Pharmaceutical advice repository
- Prescription & pharmaceutical advice consumer
- Dispensed medication consumer

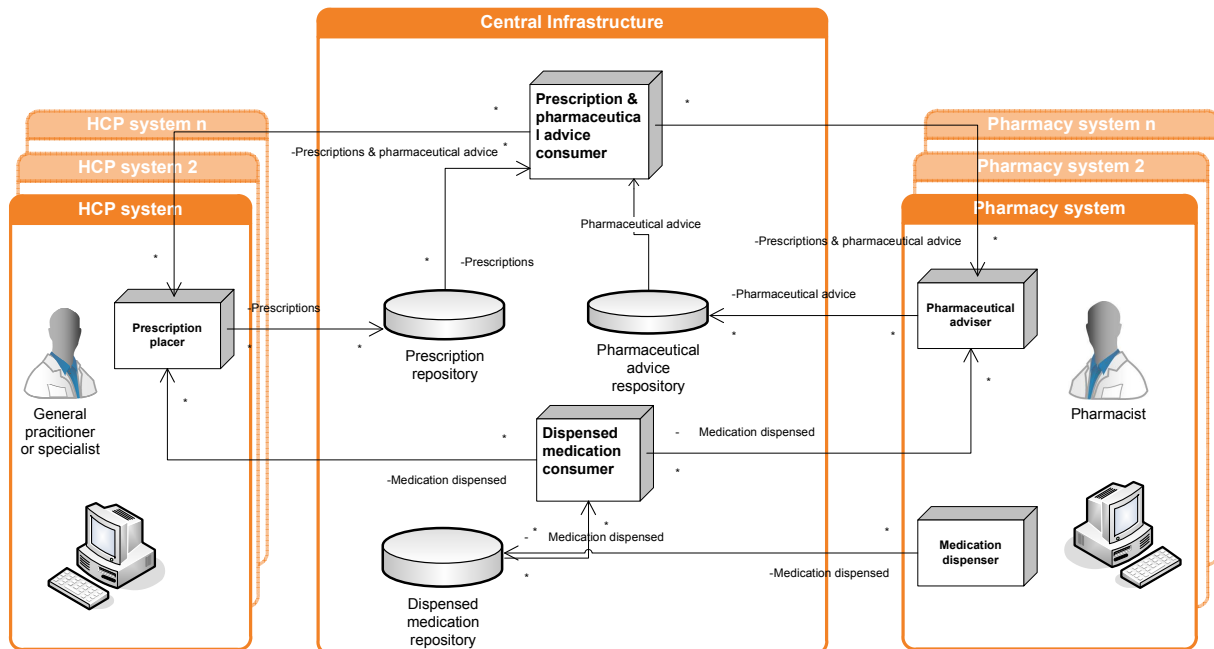


Figure 12.1: Community Pharmacy – Publish & pull model – centralized model

1435

The prescription placer may be implemented in a regional/national electronic health record, a hospital information system (for outpatient practitioners) or the clinicians' electronic medical record of a health centre/clinic. Usually, the medication dispenser is implemented in the point of sale software of a pharmacy which may provide also the features for pharmaceutical advice.

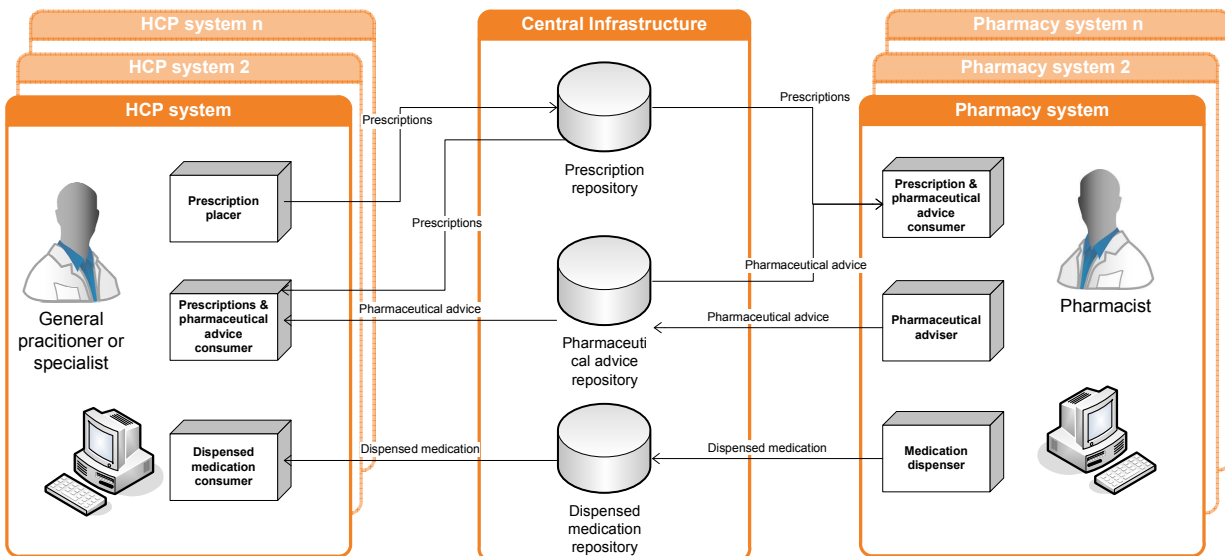
The prescription repository, pharmaceutical advice repository and dispensed medication repository are centralized and are managed by the health system itself and are accessible from any pharmacy, health centre and hospital of the health system. Prescriptions and medication already dispensed are, therefore, centrally accessed.

In this model it is assumed that pharmacies use a middleware to convey dispensed medication information and pharmaceutical advice to repositories. Since this middleware only reroutes and does not transform data, is not considered an actor in the e-pharmacy domain.

1450

An alternative to the previous model is an architecture where the physician's software and pharmacist's software is directly linked to repositories so that the so-called consumer actors are integrated in other information systems.

The following diagram depicts this alternative implementation where consumers are embedded into the practitioner's and pharmacist's software.



**Figure 12.2:** Community Pharmacy – Publish & pull model – federated model

### 146012.1.2 Decentralized architecture

In a decentralized architecture prescriptions and dispense data are stored in the database of the system that generates and/or registers them. These databases cover the business process of the department, organization, or group of organizations that use the system. Each (healthcare) organization is responsible for the management of its own prescriptions and dispense data.

This means that practitioners and pharmacists will need to have a way to access the data in other systems, and that they need to make their data available to those other systems. To this end, there needs to be an infrastructure that connects the systems, either on a regional, national, or international scale. This infrastructure may contain a central component (hub, broker) that acts as an index and/or intermediary. This component does not store (copies of) data, but might store references to data, being informed by the decentral systems on the existence of data as they are produced.

The mechanism for retrieving medication history is based on queries to the source systems.

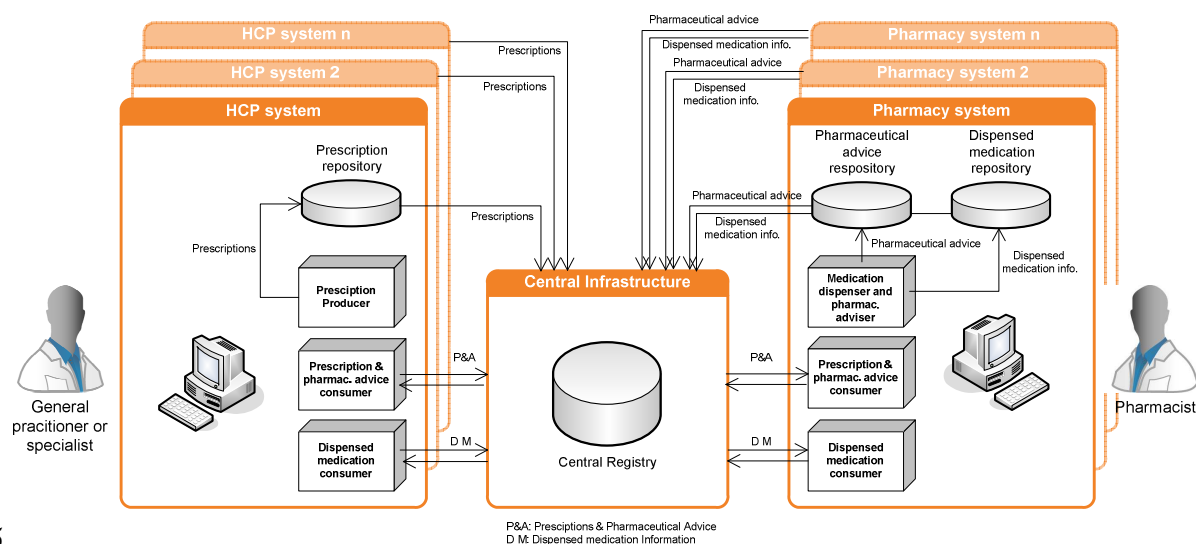
These queries might be routed or combined by an intermediary component, but the result set is always drawn (in real time) from the source database(s) and presented to the querying user.

The scheme functionally is equivalent to the schemes in the previous paragraph, with the only exception that the central repositories (prescription, dispense and pharmaceutical advice) are now

central registries (or elements in a central registry) that act as brokers to give access to the decentralized repositories, which are within the systems of the connected HCP's (pharmacy, GP, specialist).

1485 As a matter of fact, the repositories in the previous paragraph contain a registry function and a repository function combined, and the only difference in the decentralized approach as compared to the centralized approach lies in the fact that registry and repository functions are split, allowing more repositories under one registry.

1490 Figure 12.3 below shows an example of such a decentralized architecture. In this example the repositories are decentral, one central registry exists for all information elements (prescription, pharmaceutical advice and dispensed medication information) and the clients (consumers) are decentral as well.



1495

Figure 12.3: Community Pharmacy – Publish & pull model – de-centralised model

## 12.2 Hospital

1500 The intra-hospital medication workflow involves the information systems used by:

- The clinicians in the wards who prescribe medications and record the effects of treatments: The system implements the hospital's Electronic Medical Record (EMR)
- The nurses in the wards who plan and perform the administration of medications to their patients. The system implements the hospital's Electronic Care Record (ECR).
- 1505 • The pharmacists who analyze new prescriptions, notify their pharmaceutical advices to the prescribers, manage medication dispenses and track medication administration. Their system is the pharmacy information system.

These 3 systems: EMR, ECR, pharmacy information system, may be independent or combined in 1510 any of the following combinations:

- 3 independent systems EMR, ECR, Pharmacy system, exchanging data with one another.



- One Patient Record combining EMR+ECR, exchanging data with the pharmacy system.
- One holistic hospital care system combining EMR+ECR+Pharmacy system.

1515 In any of the above combinations, the hospital professionals (physicians, nurses, clinicians, pharmacists, technicians) are assumed to have a common access through their system, to the hospital master data (e.g. Patient identification, patient encounters and movements, personnel directory, organization directory (building, ward, care unit), medications catalog, clinical terminologies, diseases classifications...)

1520

Moreover, in any of the above combinations, the hospital prescribers and pharmacists are assumed to have access to the community shared medication repositories (prescriptions, pharmaceutical advices, medication dispenses), to be able to fulfill community prescriptions and register the corresponding dispenses, as well as to publish discharge prescriptions to be fulfilled

1525 by the community.

Another variation is induced by the increasing cooperation between the hospitals of a territory around a reference facility, and the sharing of some of its resources. For instance in a territory, the pharmacy of a reference hospital might serve the physicians, clinicians and nurses of a set of 1530 related satellite hospitals.

The architectures supporting the above combinations are depicted in the figures below, which all assume a common repository for community, containing prescriptions, advices and dispenses.

### 12.2.1 Standalone hospital with 3 independent systems

1535

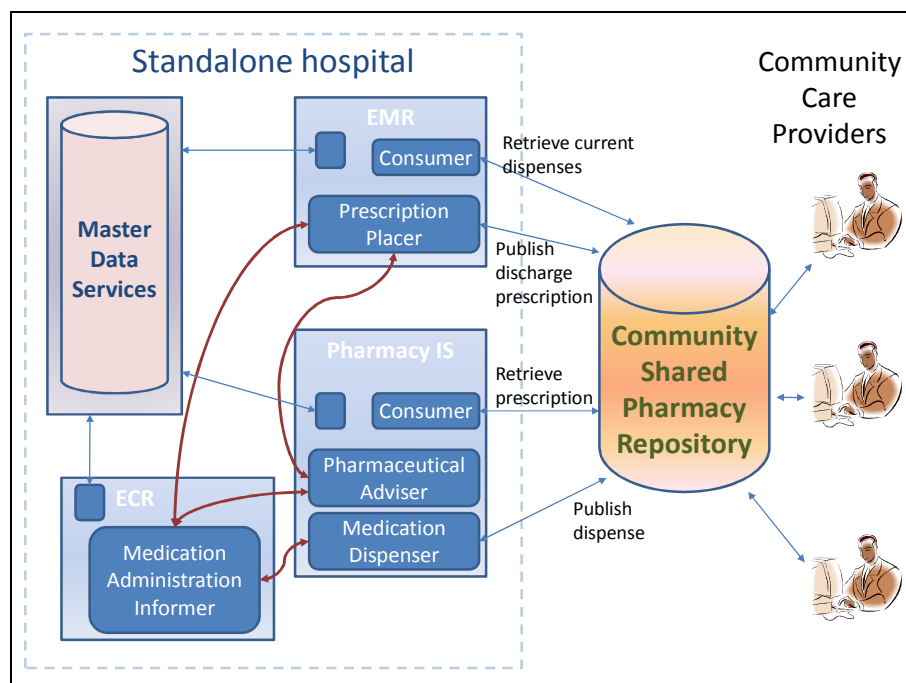


Figure 12.4: Standalone hospital with 3 independent systems

1540Comments:

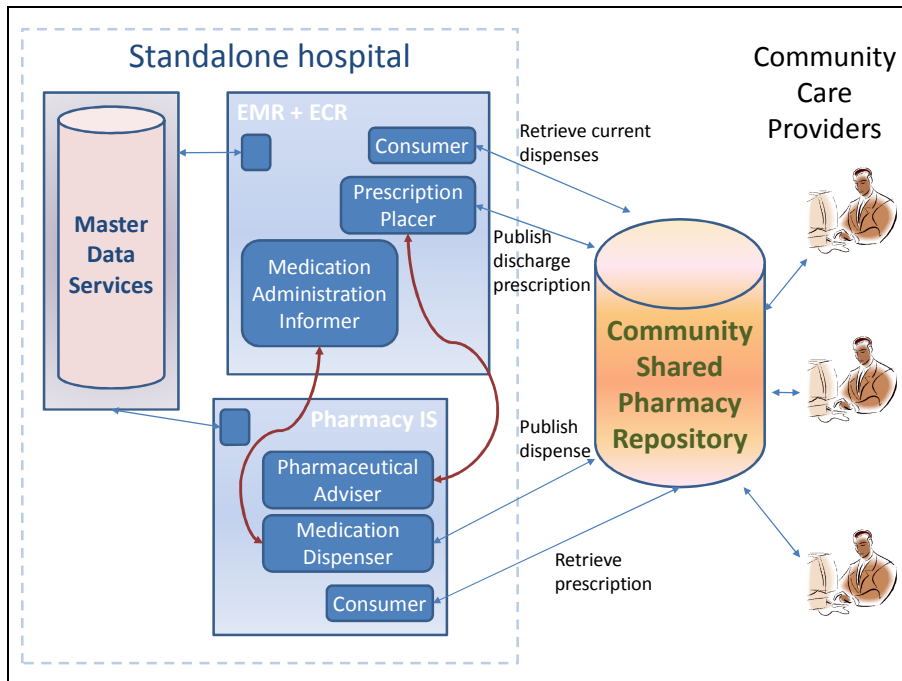
The dark red bidirectional arrows represent the message flows between the hospital systems, supporting prescription, pharmaceutical analysis, dispense and administration.

1545One drawback of this architecture is that the pharmacy system performing the pharmaceutical analysis does not have direct access to the patient EMR, and therefore can miss some piece of information critical to that process. To eliminate this drawback the prescription message must provide rich clinical information extracted from the EMR (e.g. allergies, lab results, history, family history ...)

1550

Another drawback is the heaviness of the message flows: Each system has to synchronize its steps in the workflow through message exchanges with the two others.

### 12.2.2 Standalone hospital with combined EMR+ECR



1555

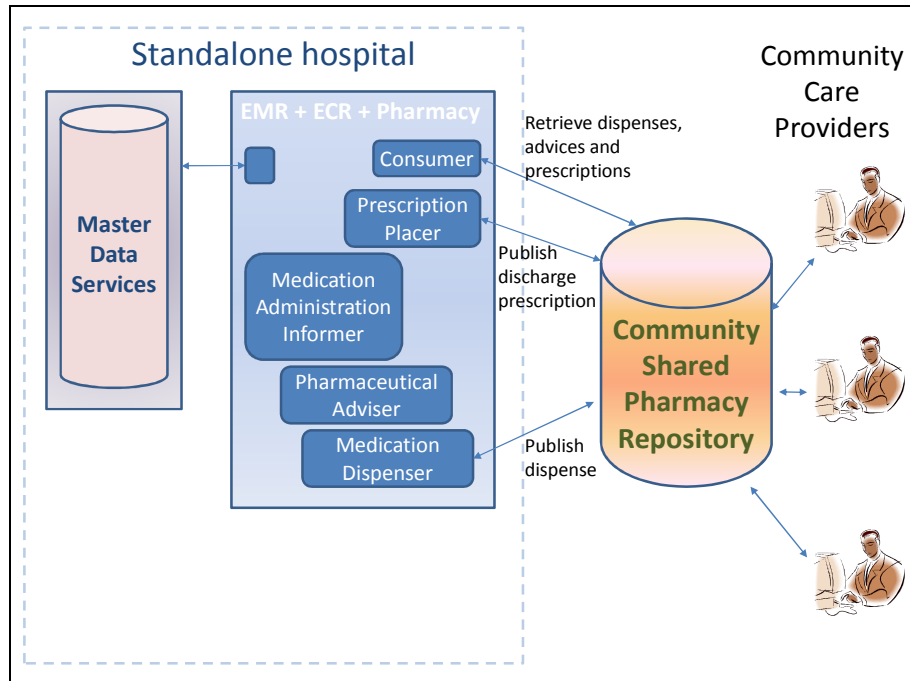
Figure 12.5: Standalone hospital with combined EMR+ECR

Comments:

1560The dark red bidirectional arrows represent the message flows between the hospital systems, supporting prescription, pharmaceutical analysis, dispense and administration.

In this architecture also, the pharmacy system performing the pharmaceutical analysis does not have direct access to the patient EMR, and therefore can miss some piece of information critical to that process. To eliminate this drawback the prescription message must provide rich clinical information extracted from the EMR (e.g. allergies, lab results, history, family history ...)

### 12.2.3 Standalone hospital with holistic information system



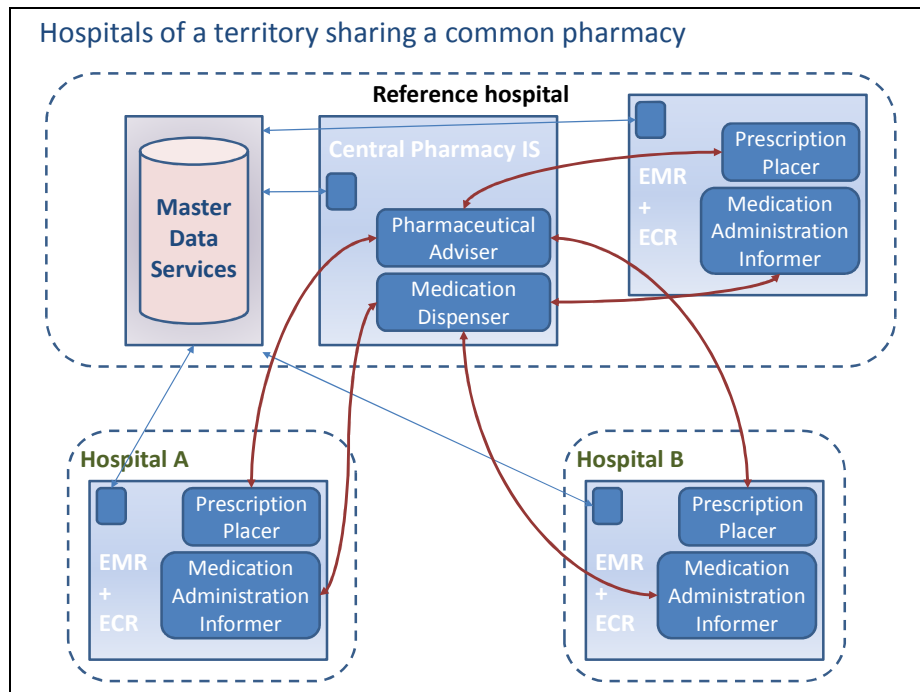
1570

Figure 12.6: Standalone hospital with holistic information system

Comments:

1575 In this architecture one single system holds all hospital actors, therefore no messages are needed to support the internal hospital pharmacy workflow. The flows that persist are the exchanges with the community repositories.

### 12.2.4 Central pharmacy shared by a set of hospitals



1580

Figure 12.7: Central pharmacy shared by a set of hospitals

Comments:

1585 The reference hospital holding the common pharmacy is also assumed to hold the common master data shared by the hospital of the territory.

The exchanges with the community outside the territory are not shown.

## 1590**13** References

- IHE ITI Technical Framework vol1:  
[http://www.ihe.net/Technical\\_Framework/upload/IHE\\_ITI\\_TF\\_4\\_0\\_Vol1\\_FT\\_2007\\_08\\_22.pdf](http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_4_0_Vol1_FT_2007_08_22.pdf)
- 1595• Laboratory Technical Framework:  
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1600