Integrating the Healthcare Enterprise

IHE Pharmacy
Technical Framework Supplement

Community Prescription
(PRE)

Rev. 1.10 – Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the future IHE Pharmacy Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on February 17, 2022 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the future Pharmacy Technical Framework. Comments are invited and may be submitted at Pharmacy Public Comments.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at IHE.

Information about the IHE Pharmacy domain can be found at IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process

The current versions of the Pharmacy Technical Framework supplements can be found at Pharmacy Technical Framework.

CONTENTS

Introduction to this Supplement

The Community Prescription Document Profile (PRE) describes the content and format of a Community Prescription document generated during the process in which a health care professional (in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. A prescription is an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient.

Documents created according to this profile are intended to be used in the context of the "Community Medication Prescription and Dispense" Integration Profile (CMPD). This supplement also references other documents[1]. The reader should have already read and understood these documents:

1. PHARM Common parts document
2. PHARM Community Medication Prescription and Dispense Integration Profile (CMPD)
3. PCC Technical Framework Volume 1
4. PCC Technical Framework Volume 2
5. IT Infrastructure Technical Framework Volume 1
6. IT Infrastructure Technical Framework Volume 2
7. IT Infrastructure Technical Framework Volume 3
8. HL7 and other standards documents referenced in this document

Open Issues and Questions

- Prescription of non-medication products": shall they be covered by this profile?

Closed Issues

- Substitution Handling: Evaluation if incorporating parts of the HL7 COCT_RM360000UV structure to provide a semantically better solution than now. -> The structure has been corrected in accordance with HL7 (see CP-PHARM-005_v2)
- Prescription Section Content Module: It is still in discussion, if it's allowed to state the CCD template as "parent", or if we have to weaken it to "derived from".
  - The Section Content Module has been decoupled from the CCD parent.

[1] The first four documents are located on the IHE Website at http://ihe.net/Resources/Technical_Frameworks/. The ITI Technical Framework can be found at https://profiles.ihe.net/ITI/TF/index.html. The remaining documents can be obtained from their respective publishers.

IHE Technical Frameworks General Introduction

The IHE Technical Frameworks General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

10 Trademark

IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems Society in the United States and trademarks of IHE Europe in the European Community. Please refer to the IHE Technical Frameworks General Introduction, Section 10 - Trademark for information on their use.

IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

*Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located here.*

Appendix A – Actors

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Description
No new actors	

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
No new transactions	

Appendix D – Glossary

*Add the following **new or modified** glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

New (or modified) Glossary Term	Definition	Synonyms	Acronym/ Abbreviation
No new terms			

Please note that the following glossary terms are a subset of the IHE Glossary and are listed here for reference.

Dispense/Dispensation

Dispensation is the act of assigning a medication to a patient, normally as indicated in the corresponding prescription. Since prescriptions can span long periods of time, a single prescription may result in medicines dispensed several times.

Dispense Item

A Dispense Item belongs to one Dispensation and represents one dispensed medication. It contains the dispensed medicinal product including information such as product code, brand name and packaging information.

Dosage Instructions

Dosage Instructions are a set of data elements which together represent the dosage instructions to a medication such as duration of treatment, medication frequency, dose quantity and route of administration.

Community Medication list

A Community Medication list is a collection of Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Items (and their related Pharmaceutical Advice Items) representing the Medication information of the patient at a certain point of time and according to business rules specified.

ICA

ICAs are Intolerances, Contra-indications and Allergies. An ICA may be considered as a relationship between a Patient and a Medicine. A detected problem in a Pharmaceutical Advice may refer to an ICA.

Medication Dispenser

In the domain of community pharmacy a Medication Dispenser is an abstract actor which dispenses prescribed medication to a patient (generally a healthcare professional, usually a pharmacist when the patient enters the pharmacy to get the prescribed medication).

Medication

A medication is part of a Prescription Item and defines the actual prescribed drug. It contains the brand or generic name of the drug, national and/or regional drug codes, unit strength, active ingredients and packaging information.

Medication Brand Name

The brand name is the name given to a medicine by the pharmaceutical company that makes it. This is also called the "proprietary name".

Medication Generic/Scientific Name

The generic or scientific name is the term given to the active ingredient in the medicine that is decided by an expert committee and is understood internationally. This is also called the "non-proprietary name".

Medication Treatment Plan

The Medication Treatment Plan of a patient is the collection of all medications the patient was planned to take in the past, presently or in the future. The Medication Treatment Plan is the complete set of all Medication Treatment Plan Items of the patient, i.e., not partitioned or grouped by pathology, planner, organization, etc.

Medication Treatment Plan Item

A Medication Treatment Plan Item is a single medication the patient was planned to take in the past or is planned to take presently or in the future, including its name, dosage, frequency of intake, etc. as well as other information such as patient- and fulfillment instructions and substitution handling. A Medication Treatment Plan Item triggers prescriptions, dispenses or medication administrations in order to fulfill the medication treatment planned by the item.

Pharmaceutical Adviser

A Pharmaceutical Adviser is an abstract actor which validates Prescription Items issued on a prescription (generally a healthcare professional, usually a pharmacist when the patient enters the pharmacy to get the prescribed medication).

Pharmaceutical Advice

A Pharmaceutical Advice document is the outcome of the validation or review of one Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Item. It contains the overall result of the validation or review which affects the further processing as well as additional information such as Intolerances, Contra-indications and Allergies (ICAs) and all other information which was discovered during validation or review.

A Pharmaceutical Advice document is also used to manage Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Items (e.g., change, cancel, etc.) as well as to document Medication Interaction Checking Issues and their resolutions.

Pharmaceutical Advice Item

A Pharmaceutical Advice Item belongs to one Pharmaceutical Advice and represents the validation outcome, management command or comment regarding the referenced Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Item (e.g., change, cancel, etc.). It may also carry Medication Interaction Checking Issue information regarding the referenced item.

Pharmaceutical Advice Concern Item

A Pharmaceutical Advice Concern Item belongs to one Pharmaceutical Advice Item and represents the information to concerns (e.g., problems, allergies, etc.) which the Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Item referenced by the underlying Pharmaceutical Advice Item causes.

Prescriber

A prescriber is an abstract actor who issues a prescription to a patient (generally a healthcare professional, usually a physician during treatment of a patient).

Prescription

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

Some special cases of prescriptions may exist, namely:

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

Prescription Item

A Prescription Item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations. Prescription Item is the atomic entity for logistics, distribution and billing. It contains the prescribed medicine and dosage information as well as other information to the prescribed item such as patient- and fulfillment instructions and substitution handling.

Volume 1 – Profiles

Add the following to Section 1.10

1.10 History of Annual Changes

- In the 2016-2017 cycle of the IHE Pharmacy initiative, the following major changes were introduced to this supplement (please see the list of this year's change proposals for the complete set of changes at https://drive.google.com/drive/u/0/folders/13jNXdHJZig9w2mCbot87xHjU-wf2IFb0):
  - Profile has been renamed from "Pharmacy Prescription" to "Community Prescription"
  - Glossary extended
  - New Header Content Module "Validity of document" introduced (validity of prescription)
  - Parent template CCD on section level removed
  - Constraint that section id has to be equal to document id has been removed
  - Title and text elements have been added on section level
  - Medicine Entry Content Module
  - Reporting of authors into the entry-level refined
  - References to items of previous process stages (Medication Treatment Plan Items, …) refined and reorganized at "Reference to …" Content Modules
  - Substitution permission structure refined and reorganized at "Substitution Permission Content Module"
  - Renewal Period added
  - Pharm-Namespace "ihe:pharm:medication" changed to "ihe:pharm" (see Medicine Entry Content Module)
- In the 2018-2019 cycle of IHE Pharmacy initiative, the notion of "provisional prescription" has been added.

  Important Note: Due to the nature of some of the changes, this profile version is no longer downward compatible to the former versions.
- In the 2022 cycle, the supplement was updated based on CP-PHARM-143, CP-PHARM-144, and CP-PHARM-1473.

Add the following to Section 2.5

2.5 Dependencies of the Pharmacy Integration Profiles

Community Prescription (PRE)	PCC	Content definition	This profile includes Section and Entry Content Modules of the Patient Care Coordination (PCC) domain.

Add Section 3

3 Community Prescription Content Profile

The Community Prescription Document Profile (PRE) describes the content and format of a Community Prescription document generated during the process in which a health care professional (in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. A prescription is an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient.

Documents created according to this profile are intended to be used in the context of the "Community Medication Prescription and Dispense" Integration Profile (CMPD).

3.1 Purpose and Scope

The Community Medication Prescription and Dispense workflow starts with the creation of a prescription in case the health care professional decides that the patient needs medication.

A Community Prescription document is issued by one ordering healthcare professional for one patient, in the context of zero or one administrative encounter (between the patient and the ordering physician and/or the healthcare institution). A prescription may contain one or more Prescription Items (lines on a paper prescription). Each line relates to one medication. A prescription is the outcome of a clinical decision.

This profile defines the content and format of such a Community Prescription document.

For a detailed overview on the whole Pharmacy domain business processes, please refer to the "Common parts" document, which is accompanying this profile.

3.2 Process Flow

3.2.1 Use Case 1: Placing a prescription

During treatment of a patient, physicians or other allowed persons may have to prescribe drugs for the patient. The prescription shall contain one or more positions (Prescription Items) which contain the drug identified by a medication identifier, the dosing as well as other information necessary for correct dispensing and administering by the patient.

Usually the physician uses the prescribing module in the physician information system for preparing the prescription. After the prescription is completely assembled it shall be submitted to the Community Medication Prescription and Dispense system to be validated and dispensed.

Refer to the Community Medication Prescription and Dispense Integration Profile (CMPD) for detailed use case information.

3.2.2 Use Case 2: Placing a provisional prescription

It regularly occurs that patients are going to a pharmacy for getting drugs without holding a valid prescription. This occurs e.g., when the previous prescription is over or if the patient was instructed by his physician to start a treatment before the visit which occur. It may also occur in the situation where expected prescriptions of long-care or elderly patients are prepared by the caring facility to the prescriber.

In order to enable a coherent documentation of the dispense being performed, the dispenser creates a prescription containing provisional prescription items which will require future validation. Dispense occurs on provisional prescription items under responsibility of the dispenser. Provisional prescription items are later validated by a prescriber.

Refer to the Community Medication Prescription and Dispense Integration Profile (CMPD) for detailed use case information.

Note that the use of provisional prescription (an order that will still be validated, but for an action that has already occurred) introduces additional concerns. For example, when no prescriber responds to the provisional prescription, or when the prescriber approves a provisional prescription but with updates that deviate from the dispense.

These concerns are not covered in this profile, and may or may not be considered later. Implementors are advised to take appropriate measures to detect or mitigate any unwanted complications of implementing this profile in such circumstances.

In addition, it is expected that such scenarios are covered by guidance or legal boundaries at each jurisdiction – in other words, the healthcare system is expected to define the rules for provisional prescriptions.

3.3 Actors/Transactions

There are two actors in this profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE

profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR in PCC TF-2: 4.1.

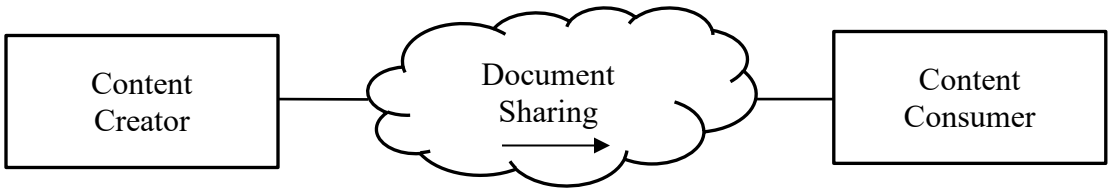


Figure 3.3-1: Actor Diagram

3.4 Options

Options that may be selected for this content profile are listed in Table 3.4-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 3.4-1: Community Prescription Actors and Options

Actor	Option	Section
Content Consumer	View Option (See Note 1)	PCC TF-2: 3.1.1
	Document Import Option (See Note 1)	PCC TF-2: 3.1.2
	Section Import Option (See Note 1)	PCC TF-2: 3.1.3
	Discrete Data Import Option (See Note 1)	PCC TF-2: 3.1.4
Content Creator	No options defined	

Note 1: The actor shall support at least one of these options.

3.5 Groupings

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE profiles.

3.5.1 Community Medication Prescription and Dispense

Actors from the Pharmacy CMPD Profile embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer may be grouped with appropriate actors from the XDS, XDM or XDR Profiles to exchange the content described therein. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the content profile.

The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this profile with actors from the Pharmacy CMPD Integration Profiles.

3.6 Security Considerations

The PRE Integration Profile assumes that a minimum security and privacy environment has been established across all participants. There must exist security policies regarding the use of training, agreements, risk management, business continuity and network security that need to be already in place prior to the implementation of PRE.

The IHE ITI ATNA Integration Profile is required of the actors involved in the IHE transactions specified in this profile to protect node-to-node communication and to produce an audit trail of the PHI related actions when they exchange messages.

In addition, the IHE ITI DSG Integration Profiles can be applied to the actors involved in the transactions specified in this profile to securely identify individuals involved in transactions and verify document integrity and authorizations (DSG).

Interested parties should also read the detailed Security Considerations sections provided for each of the aforementioned profiles in the IHE ITI Technical Framework and its supplements.

The PRE Profile does have a few security considerations of its own.

Pharmacy systems should be thoughtfully designed so that providers are able to review and verify information before it is imported into their Pharmacy system, and that positive user acknowledgements are made before import, and audit trails are recorded when imports occur.

Imported information should be traceable both to the source Pharmacy system, and the receiver that accepted it into the Pharmacy system. XDS Affinity domain policies should support policies and procedures for tracing information flows between Pharmacy systems.

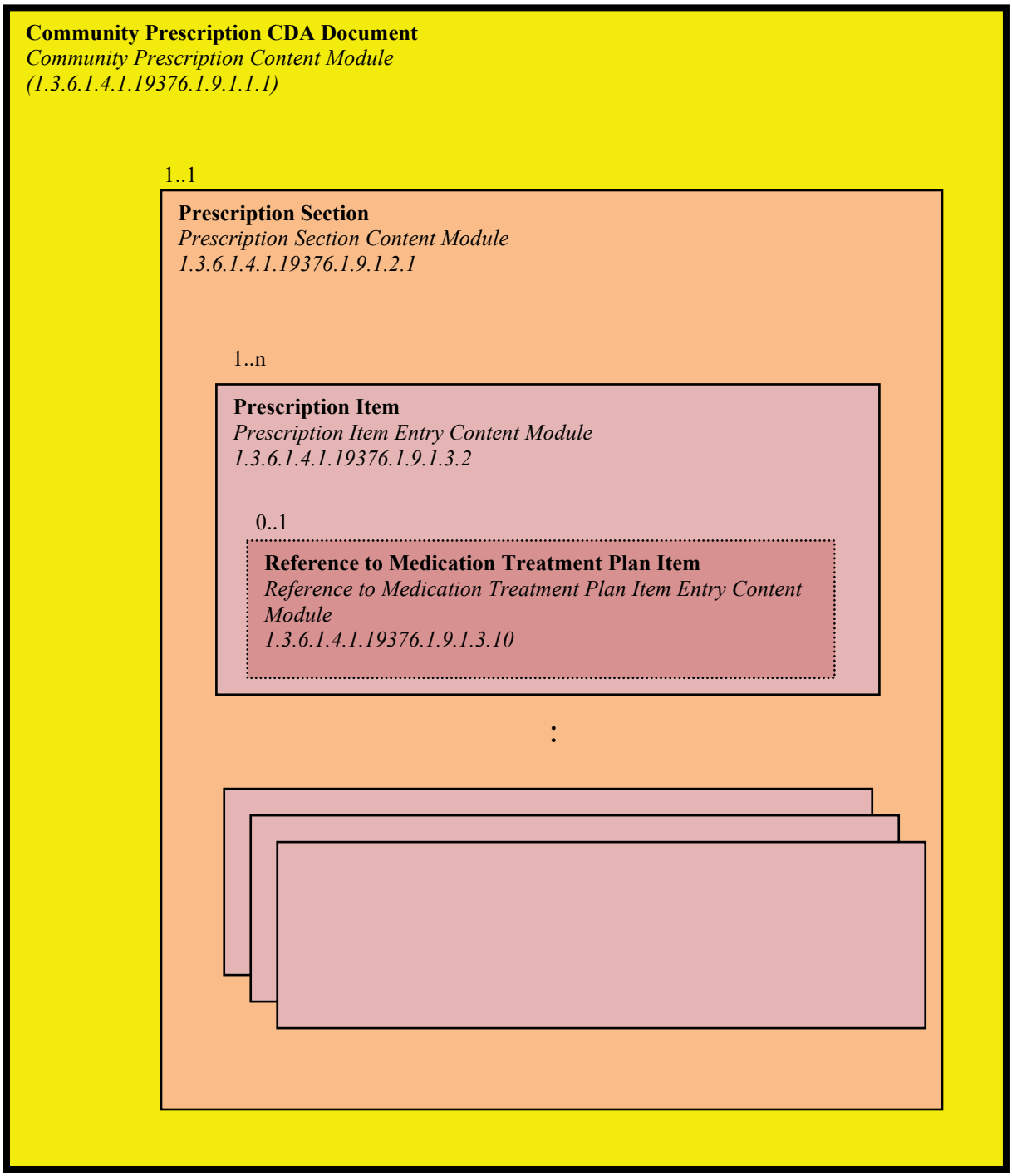
Because the information being transferred is in XML, it will be common that different Pharmacy systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and a Content Consumer must support rendering the information as seen by the sending provider, allowing both providers to see what was sent in its original rendered form.

3.7 Content Modules

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in. These dependencies are reflected in the Bindings listed above.

All Community Prescriptions shall be structured and coded as required by the Community Prescription Document Content Module described in this profile. The inclusion of the specific coded attributes explicitly defined as optional, may be supported by specific implementations of Document Sources using an IHE identified coded terminology of their choice. The requirements and manner in which implementations support such capabilities is beyond the scope of this integration profile.

3.7.1 Structure of a Community Prescription Document



Volume 3 – Content Modules

5.0 Namespaces and Vocabularies

codeSystem	codeSystemName	Description
1.3.6.1.4.1.19376.1.9	IHE Pharmacy Object Identifiers	This is the root OID for all IHE Pharmacy objects
1.3.6.1.4.1.19376.1.5.3.4		Namespace OID used for IHE Extensions to CDA Release 2.0

See also the Namespaces and Vocabularies of the IHE PCC Technical Framework (PCC TF2/Namespaces and Vocabularies).

5.1 IHE Format Codes

Profile	Format Code	Media Type	Template ID
2010 Profiles			
Community Prescription (PRE)	urn:ihe:pharm:pre:2010	text/xml	1.3.6.1.4.1.19376.1.9.1.1.1

6.0 Pharmacy Content Modules

6.3 HL7 Version 3.0 Content Modules

6.3.1 CDA Document Content Modules

Add Section 6.3.1.1

6.3.1.1 Community Prescription Specification 1.3.6.1.4.1.19376.1.9.1.1.1

The Community Prescription specification includes a Prescription section to capture Prescription Items prescribed to a patient as well as supporting sections containing information related to this prescription (e.g., diagnosis, etc.).

Structure	Community Prescription
Format Code	urn:ihe:pharm:pre:2010
LOINC Code	57833-6 (Prescriptions)
Document Template ID	1.3.6.1.4.1.19376.1.9.1.1.1
Section name / template ID	Prescription 1.3.6.1.4.1.19376.1.9.1.2.1

Structure	Community Prescription
Entry name / template ID	Prescription Item 1.3.6.1.4.1.19376.1.9.1.3.2
Medicine Content Entry Module template ID	Medication of Prescription Item 1.3.6.1.4.1.19376.1.9.1.3.1

6.3.1.1.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:pharm:pre:2010**.

6.3.1.1.2 Parent Template

This document is an instance of the Medical Document template.

6.3.1.1.3 Standards

HL7V3 NE2009	HL7 V3 2009 Normative Edition
CDAR2	HL7 CDA Release 2.0
IHE PCC	Medical Documents Specification (1.3.6.1.4.1.19376.1.5.3.1.1.1)
XMLXSL	Associating Style Sheets with XML documents

6.3.1.1.4 Data Element Index

Data Elements	CDA Release 2.0
Patient Information	recordTarget/patientRole
Patient Administrative Identifiers	recordTarget/patientRole/id
Patient Name	recordTarget/patientRole/patient/name
Patient Gender	recordTarget/patientRole/patient/administrativeGenderCode
Patient Birth Date	recordTarget/patientRole/patient/birthTime
Patient Address	recordTarget/patientRole/addr
Patient Telecom	recordTarget/patientRole/telecom
HCP Person Information	author
HCP ID(s)	author/assignedAuthor/id
HCP Profession	author/functionCode
HCP Name	author/assignedAuthor/assignedPerson/name
HCP Telecom	author/assignedAuthor/telecom
HCP Specialty	author/assignedAuthor/code
HCP Organization	author/assignedAuthor/representedOrganization
HCP Organization Name	author/assignedAuthor/representedOrganization/name
HCP Organization Address	author/assignedAuthor/representedOrganization/addr
HCP Organization Telecom	author/assignedAuthor/representedOrganization/telecom

Data Elements	CDA Release 2.0
Service Event[2]	documentationOf/serviceEvent
Date of Service Event	documentationOf/serviceEvent/effectiveTime
Service Event Code	documentationOf/serviceEvent/code
Encounter in the healthcare institution[3]	componentOf/encompassingEncounter
ID of the encounter	componentOf/encompassingEncounter/id
Date of Admission/Encounter start date	componentOf/encompassingEncounter/effectiveTime/low
Date of Discharge/Encounter end date	componentOf/encompassingEncounter/effectiveTime/high
Authorization	authorization/consent
Patient contacts	guardian
Payers	PAYMENT SOURCES
General Medical Information Height, Weight	VITAL SIGNS
Allergies and Drug Sensitivities	ALLERGIES, ADVERSE REACTIONS, ALERTS
Active Problems	PROBLEM LIST
Resolved Problems	HISTORY OF PAST ILLNESS
Immunizations	HISTORY OF IMMUNIZATIONS
Pregnancy History	HISTORY OF PREGNANCIES
Prescription	PRESCRIPTIONS

6.3.1.1.5 Data Element Specification

Data Element Name	Opt	Template ID
Patient Information Name Personal Identification Gender Date of Birth HCP Person Information Name HCP Identification HCP Organization Information Name Address Organization Identifier Contact Information	R	1.3.6.1.4.1.19376.1.5.3.1.1.1

[2] Service Event is optional and may contain service event information of the medical event in which context the prescription has been taken.

[3] Encounter is optional and shall contain encounter information if applicable.

Data Element Name	Opt	Template ID
Patient Information Address Contact Information HCP Person Information Profession Specialty	R2	1.3.6.1.4.1.19376.1.5.3.1.1.1
Patient Information Marital Status Race Ethnicity Religious Affiliation HCP Person Information Contact Information	O	1.3.6.1.4.1.19376.1.5.3.1.1.1
Authorization	R2	1.3.6.1.4.1.19376.1.5.3.1.2.5
Patient Contacts	O[4]	1.3.6.1.4.1.19376.1.5.3.1.2.4
Payers	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7
Coded Vital Signs	O[5]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Allergies and Other Adverse Reactions	O	1.3.6.1.4.1.19376.1.5.3.1.3.13
Active Problems	O	1.3.6.1.4.1.19376.1.5.3.1.3.6
History of Past Illness	O	1.3.6.1.4.1.19376.1.5.3.1.3.8
Immunizations	O	1.3.6.1.4.1.19376.1.5.3.1.3.23
Pregnancy History	O[6]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Prescription	R	1.3.6.1.4.1.19376.1.9.1.2.1

Additional explanation:

The sections “Coded Vital Signs”, “Allergies and Drug Sensitivities”, “Active Problems”, “Resolved Problems”, “Immunizations”, “Pregnancy History” are considered as sections containing medical information of the patient.

Although real-world projects may require some of these information, no stricter constraints as optional (O) could been applied to these sections in the profile due to the large degree of diversity in business requirements and privacy issues among different current.

[4] In case the patient is governed by a guardian, this element is R and shall contain the information about the guardian

[5] The Coded Vital Signs section should contain at least the height and weight of the patient.

[6] In case the patient is currently pregnant, this element is R and shall contain information about the current pregnancy. It shall not be used to document past pregnancies.

The notion of "context conduction" is highly dependent on the type of information carried by content profiles and its interpretation may be rather diverse and complex. It is therefore recommended not to use contextConductionInd attribute in any element of this profile.

6.3.1.1.6 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below. A CDA Document may conform to more than one template. This content module inherits from the Medical Summary content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.1.1'/>
  <id root=' ' extension=' '/>
  <code code='57833-6' displayName='Prescription for medication'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Prescription</title>
  <effectiveTime value='20100719012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component>
    <structuredBody>
        :
    </structuredBody>
  </component>
</ClinicalDocument>
```

6.3.2 CDA Header Content Modules

6.3.2.1 Validity of document

<documentationOf>

<serviceEvent>

<effectiveTime>

…

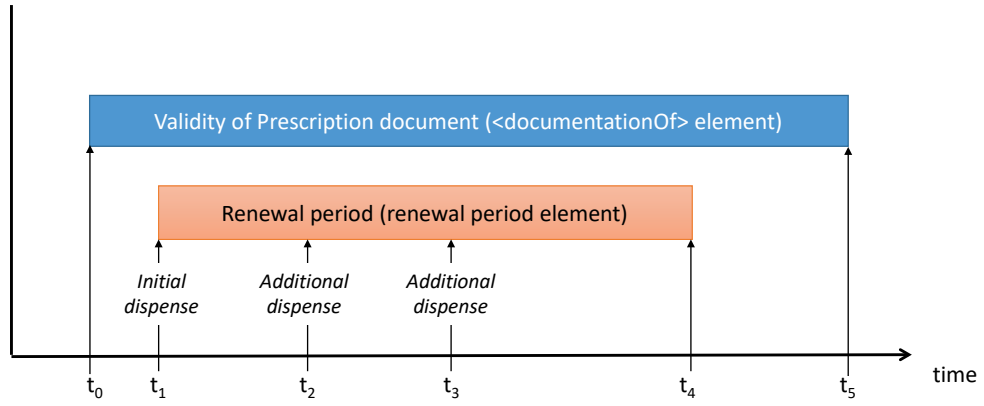
</effectiveTime>

</serviceEvent>

</documentationOf>

The validity of the Community Prescription document MAY be defined though the <documentationOf> element.

Note: While the <documentationOf> element defines the validity of the Community Prescription document, content elements "repeat number" and "renewal period" control the possible renewal of the dispense of the prescription as show in figure below:



The <documentationOf> element may define t_0 and t_5 (e.g., prescription is valid 1 year). The <repeatNumber> element may constrain the number of additional dispenses that may be performed (here 2, performed at t_2 and t_3).

Note: Project governance and legislations define, if just the first dispense or all dispenses must occur within the validity period of the prescription.

The renewal period element may define the time frame or the time period (defined by t_1 and t_4) during which dispense(s) may occur.

6.3.2.1.1 Validity of prescription

<effectiveTime>

<low value=" --- start of validity of the prescription ---"/>

<high value="--- end of validity of the prescription ---"/>

</effectiveTime>

This element SHALL be present and specify the start and end date of the validity period of the prescription, i.e., between which dates interval the prescription may be dispensed. In case the beginning or the ending date is unknown, the <low> or <high> sub-elements of this element SHALL be set to null flavor "UNK".

6.3.3 CDA Section Content Modules

Add Section 6.3.3.1

6.3.3.1 Prescription Section Content Module (1.3.6.1.4.1.19376.1.9.1.2.1)

Template ID	1.3.6.1.4.1.19376.1.9.1.2.1	
Parent Template	-	
General Description	The Prescription Section contains a description of the medications in a given prescription for the patient. It includes one or more Prescription Item entries as described in the Prescription Item Entry Content Module.	
LOINC Code	**Opt**	**Description**
57828-6	R	PRESCRIPTIONS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.9.1.3.2	R	Prescription Item Entry Content Module

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.2.1'/>
    <id root=' ' extension=' '/>
    <code code='57828-6' displayName='PRESCRIPTIONS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Prescriptions</title>
    <text>
      Text as described above
    </text>
    <author>
      :
    </author>
    <!-- 1..n Prescription Items -->
    <!-- Prescription Item 1 -->
    <entry>
        <substanceAdministration classCode='SBADM' moodCode='INT'>
            <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
            :
        </substanceAdministration>
    </entry>
    <!-- Prescription Item 2 -->
    <entry>
        <substanceAdministration classCode='SBADM' moodCode='INT'>
            <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
            :
        </substanceAdministration>
    </entry>
      :
  </section>
</component>
```

6.3.3.1.1 Parent Templates

This section content module has no parent structure. The value for ‘section/code’ SHALL be “57828-6”, “Prescriptions”.

6.3.3.1.2 Prescription Section ID

<id root=' ' extension=' '/>

A Prescription identifier SHALL be represented in the section <id> Element. The data type of the ID is II.

6.3.3.1.3 Section title

<title>…</title>

A Prescription Section title SHOULD be represented in the section <title> Element. According to CDA R2 rules for structured CDA body, "the absence of the Section.title component signifies an unlabeled section." (see HL7 Clinical Document Architecture, Release 2.0, 1.3.1 Recipient Responsibilities).

6.3.3.1.4 Text

<text>…</text>

A <text> element SHOULD be represented in the section and contain the narrative version of the Prescription Item. This narrative block SHALL present the information to the human reader and represent the Prescription Item information, using the various structures available in the CDA: tables, lists, paragraphs, hyperlinks, etc.

6.3.3.1.5 Prescriber

<author>…</author>

In the case where the prescriber or the timestamp of a prescription is different from the author and timestamp of the Community Prescription-document, the prescriber and timestamp of the prescription shall be represented by the <author> element of the section.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber Profession	CE	*author/functionCode*
Timestamp of prescribing	TS	*author/time*
Prescriber ID	II	*author/assignedAuthor/id*
Prescriber Specialty	CE	*author/assignedAuthor/code*
Prescriber Name	PN	*author/assignedAuthor/assignedPerson/name*
Prescriber Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Prescriber Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Prescriber Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4 CDA Entry Content Modules

Add Section 6.3.4.1

6.3.4.1 Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1)

A Medicine entry describes a medicine and is used within Medication Treatment Plan-, Prescription-, Dispense- or Medication Administration Items. It describes either a medicinal product, a generic/scientific name or a magistral preparation/compound medicine and contains information such as name, medication form, packaging information and active ingredients.

This entry uses the structure of the HL7 V3 R_Medication Universal Common Message Element (CMET), Release 2.

This structure is part of the HL7 V3 2009 Normative Edition (COCT_RM230100UV). The incorporation of this structure is done according to section ***1.4 CDA Extensibility*** of the HL7 CDA standard. Such an extension of the base CDA standard is an accepted practice in IHE (e.g., in the XD* Lab specification).

For the purposes of IHE Pharmacy this extension is necessary to satisfy the requirements for Prescription, Pharmaceutical Advice and Dispense data elements to represent required information which is not supported by the base CDA standard, such as packaging information, generic equivalent and ingredients.

The rules of section ***1.4 CDA Extensibility*** require the designation of a new XML namespace for the XML elements in this structure. For the purposes of documentation, the **namespace *urn:ihe:pharm*** shall be used.

The following specification and constraints are applied to the structures of the CMET.

6.3.4.1.1 Standards

This part describes the general structure for a Prescription Item. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.1.2 Parent Template

This entry content module has no parent structure.

6.3.4.1.3 Specification

```
<manufacturedMaterial classCode="MMAT" determinerCode="KIND">
    <templateId root="1.3.6.1.4.1.19376.1.9.1.3.1"/>
    <!-- National medicinal product code (brand-level) -->
    <code code=" " displayName=" " codeSystem=" " codeSystemName=" "/>
    <!-- Brand name -->
    <name>... </name>
    <!-- Pharmaceutical dose form -->
    <pharm:formCode code=" " displayName=" "
                    codeSystem=" " codeSystemName=" "/>
    <lotNumberText>...</lotNumberText>
    <pharm:expirationTime value=' '/>
    <!-- Container information -->
    <pharm:asContent classCode="CONT">
        <pharm:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">
            <!-- Medicinal product code (package-level) -->
            <pharm:code code=" " displayName=" " codeSystem=" " codeSystemName=" "/>
            <!-- Brand name (package) -->
            <pharm:name>...</pharm:name>
            <pharm:formCode code=" " displayName="  "
                   codeSystem=" " codeSystemName="  "/>
            <pharm:capacityQuantity value=" " unit=" "/>
            <pharm:asSuperContent>
                <pharm:containerPackagedMedicine classCode='CONT'
                           determinerCode='INSTANCE'>
                    <pharm:capacityQuantity value=' ' unit=' '/>
                </pharm:containerPackagedMedicine>
            </pharm:asSuperContent>
        </pharm:containerPackagedMedicine>
    </pharm:asContent>
    <!-- These are optional generic equivalents -->
    <pharm:asSpecializedKind classCode="GRIC">
         <pharm:generalizedMedicineClass classCode="MMAT">
              <pharm:code code=" " displayName="Generic Equivalent"
                    codeSystem=" " codeSystemName=" "/>
              <pharm:name>...</pharm:name>
         </pharm:generalizedMedicineClass>
    </pharm:asSpecializedKind>
    <!-- This is the list of active ingredients -->
    <pharm:ingredient classCode="ACTI">
         <!-- strength of ingredient -->
         <pharm:quantity>
            <numerator xsi:type="PQ" value=" " unit=" "/>
            <denominator xsi:type="PQ" value=" " unit=" "/>
         </pharm:quantity>
         <pharm:ingredient classCode="MMAT" determinerCode="KIND">
              <pharm:code code=" " displayName="Active Ingredient 1"
                    codeSystem=" " codeSystemName=" "/>
              <pharm:name>Active Ingredient 1</pharm:name>
         </pharm:ingredient>
    </pharm:ingredient>
    <pharm:ingredient classCode="ACTI">
         <!-- strength of ingredient -->
        <pharm:quantity>
            <numerator xsi:type="PQ" value=" " unit=" "/>
            <denominator xsi:type="PQ" value=" " unit=" "/>
         </pharm:quantity>
        <pharm:ingredient classCode="MMAT" determinerCode="KIND">
              <pharm:code code=" " displayName="Active Ingredient 2"
                    codeSystem=" " codeSystemName=" "/>
              <pharm:name>Active Ingredient 2</pharm:name>
        </pharm:ingredient>
    </pharm:ingredient>
</manufacturedMaterial>
```


6.3.4.1.3.1 Medicine Entry General Specification

<manufacturedMaterial classCode="MMAT" determinerCode="KIND">

…

</manufacturedMaterial>

The <manufacturedMaterial> element of the Medicine Entry contains elements using the XML namespace “pharm”.

The namespace “pharm” SHALL be defined at the level of the <manufacturedMaterial> element or at a higher level and SHALL contain the value “**urn:ihe:pharm**”.

Example:

```
<manufacturedMaterial xmlns:pharm="urn:ihe:pharm"
   classCode="MMAT" determinerCode="KIND">
   :
```

6.3.4.1.3.2 Medicine Entry Template ID

< templateId root='1.3.6.1.4.1.19376.1.9.1.3.1'/>

The Template ID for a Medicine Entry SHALL be provided.

6.3.4.1.3.3 Code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>
<originalText>
<reference value=' '/>
</originalText>
</code>

The <code> element of the <manufacturedMaterial> element SHALL be present and describes the code of the medication.

The medication may be either

- a brand/product or
- described as a generic/scientific name or
- a descriptor of a magistral preparation/compound medicine

The <originalText> shall contain a <reference> whose URI value points to the name and strength of the medication, or just the name alone if strength is not relevant.

If the medicine is uncoded (e.g., magistral preparations, compound medicine, …) nullFlavor=”NA” SHALL be used.

6.3.4.1.3.4 Name

< name>…</ name>

The element SHALL contain the name of the medication (e.g., “Adol 500mg Caplet”).

The medication may be either

- a brand/product or
- described as a generic/scientific name or
- a descriptor of a magistral preparation/compound medicine

If the medicine has no brand name (e.g., magistral preparations, compound medicine, …) nullFlavor=”NA” SHALL be used.

6.3.4.1.3.5 Form Code

<pharm:formCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

This code represents the pharmaceutical dose form (e.g., tablet, capsule, liquid) and SHOULD be present, if not implied by the product. It MAY be present if implied by the product. The value of this code affects the units used in the substance administration quantity element.

6.3.4.1.3.6 Lot Number

<lotNumberText>...</lotNumberText>

The <lotNumberText> element MAY be present and is a string representation of a lot number of this specific instance of the product.

The provided lot number SHALL refer to the primary packaged item described in the Packaging element.

6.3.4.1.3.7 Expiration Date

<pharm:expirationTime value=' '/>

The <pharm:expirationTime> element MAY be present and SHALL contain a value attribute containing the date (e.g., specific date, specific date including time) of expiration of this specific instance of the product.

The value given in the <pharm:expirationTime> element SHALL refer to the primary packaged item described in the Medicine Packaging element.

6.3.4.1.3.8 Packaging

```
<pharm:asContent classCode='CONT'>
  <pharm:containerPackagedMedicine classCode='CONT'
              determinerCode='INSTANCE'>
    <!-- Medicinal product code (package-level) -->
    <pharm:code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
```



```
      <!-- Brand name (package) -->
      <pharm:name>...</pharm:name>
      <pharm:formCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
      <pharm:capacityQuantity value=' ' unit=' '/>
      <pharm:asSuperContent>
        <pharm:containerPackagedMedicine classCode='CONT'
                determinerCode='INSTANCE'>
          <pharm:capacityQuantity value=' ' unit=' '/>
        </pharm:containerPackagedMedicine>
      </pharm:asSuperContent>
    </pharm:containerPackagedMedicine>
</pharm:asContent>
```

This structure describes the packaging of the medication and MAY be present. It represents the primary description of the packaging of the medicine (e.g., the medicine is packaged in ampoules of 50ml volume each) and may include additional packaging information of how many of the primary packaged items are within an outer package (e.g., 5 ampoules are packaged in a box).

The primary description of the package SHOULD be consistent with the given pharmaceutical dose form (<pharm:formCode> of the medication, see section “Medication Form Code”). Example: a consistent pharmaceutical dose form to the package form “Ampoules” would be e.g., “Solution for injection”.

In case the package describes a product, the <pharm:code> element provides the code for the product and SHOULD be present.

In case the package describes a product, and the package has a brand name, it SHOULD be described in the <pharm:name> element (e.g., Xylocaine 1% with Adrenaline Inj, 5 injections package).

The <pharm:formCode> element represents the form of the package (e.g., tablet container, bottle, ...) and SHOULD be present, if not implied by the product. It MAY be present if implied by the product. It SHALL be present if the <asSuperContent> element is present.

The <pharm:capacityQuantity> element SHALL be present and describes the capacity of the packaging.

If the capacityQuantity is given in countable units, the unit attribute SHALL NOT be present. If the capacityQuantity is given in non-countable units, the unit attribute SHALL be present and the value SHALL be out of the UCUM code system.

A <pharm:asSuperContent> element MAY be present to represent the quantity of the given primary packaged item (e.g., ampoule of 50ml) within an outer package (e.g., 5 ampoules in a box). It SHALL contain a <pharm:containerPackagedMedicine> element which SHALL contain a <pharm:capacityQuantity> element describing the quantity of the given primary packaged item present in the outer package. If the capacityQuantity is given in countable units, the unit attribute SHALL NOT be present. If the capacityQuantity is given in non-countable units, the unit attribute SHALL be present and the value SHALL be out of the UCUM code system.

Examples:

For example, to represent a medicinal product with pharmaceutical dose form ”Tablets”, available as a “Tablet container” with 30 tablets the <asContent> data elements would be set to:

```
<pharm:asContent classCode='CONT'>
  <pharm:containerPackagedMedicine classCode='CONT'
                determinerCode='INSTANCE'>
                :
    <pharm:formCode code=' ' displayName='Tablet container' codeSystem=' '
              codeSystemName=' '/>
    <pharm:capacityQuantity value='30'/> <!-- 30 tablets in the package -->
  </pharm:containerPackagedMedicine>
</pharm:asContent>
```

For example, to represent a medicinal product with pharmaceutical dose form ”Solution for injection”, available as “Ampoules” with 50ml volume, packaged as 5 ampoules per box, the <asContent> data elements would be set to:

```
<pharm:asContent classCode='CONT'>
  <pharm:containerPackagedMedicine classCode='CONT'
                determinerCode='INSTANCE'>
                :
    <pharm:formCode code=' ' displayName='Ampoules' codeSystem=' '
              codeSystemName=' '/>
    <pharm:capacityQuantity value='50' unit='ml'/> <!-- 50ml per ampoule -->
    <pharm:asSuperContent>
      <pharm:containerPackagedMedicine classCode='CONT'
                  determinerCode='INSTANCE'>
        <pharm:capacityQuantity value='5'/>   <!-- 5 ampoules in a box -->
      </pharm:containerPackagedMedicine>
    </pharm:asSuperContent>
  </pharm:containerPackagedMedicine>
</pharm:asContent>
```

Note: The “Ampoule” can be seen as a container representing a volume and as the “unit of use”/“unit of presentation”. In this example it only represents container packaging.

6.3.4.1.3.9 Generic Equivalent

```
<pharm:asSpecializedKind classCode='GRIC'>
  <pharm:generalizedMedicineClass classCode='MMAT'>
    <pharm:code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
    <pharm:name>…</pharm:name>
```



```
    </pharm:generalizedMedicineClass>
</pharm:asSpecializedKind>
```

The classCode of "GRIC" identifies this structure as the representation of a generic equivalent of the medication described in the current Medicine entry.

One or more elements MAY be present.

The <pharm:code> element contains the coded representation of the generic medicine, and the <pharm:name> element may be used for the plain text representation.

6.3.4.1.3.10 Active Ingredient List

```
<pharm:ingredient classCode='ACTI'>
  <pharm:quantity>
    <numerator xsi:type='PQ' value=' ' unit=' '/>
    <denominator xsi:type='PQ' value=' ' unit=' '/>
  </pharm:quantity>
  <pharm:ingredient classCode='MMAT' determinerCode='KIND'>
    <pharm:code code=' ' displayName=' '
                codeSystem='2.16.840.1.113883.6.73' codeSystemName='ATC WHO'/>
    <pharm:name>…</pharm:name>
  </pharm:ingredient>
</pharm:ingredient>
```

One or more active ingredients SHOULD be represented with this structure. The classCode of "ACTI" indicates that this is an active ingredient.

The <pharm:code> element SHOULD be present and contains the coded representation of the active ingredient. The WHO ATC terminology SHOULD be used to code the active ingredients, where applicable.

The <pharm:name> element SHALL be present and is used for the plain text representation.

The medication strength is represented as the ratio of the active ingredient(s) to a unit of medication. The <pharm:quantity> element SHOULD be present and represents the strength of the active ingredient(s) as the ratio of the active ingredient(s) to a unit of medication. The <pharm:quantity> element contains the numerator and denominator of the strength ratio.

The following example shows the strength of 10 mg of the ingredient per ml of the medication:

```
<pharm:quantity>
    <numerator xsi:type="PQ" value="10" unit="mg"/>
    <denominator xsi:type="PQ" value="1" unit="ml"/>
</pharm:quantity>
```

The following examples show the strength of the ingredient in 1 unit of the given medication.

2% of the ingredient (e.g., XYLOPHIL 2% GEL):


```
<pharm:quantity>
    <numerator xsi:type="PQ" value="2" unit="%"/>
    <denominator xsi:type="PQ" value="1"/>
</pharm:quantity>
```

5mg of the ingredient (e.g., XYZAL 5MG F.C.TABLET):

```
<pharm:quantity>
    <numerator xsi:type="PQ" value="5" unit="mg"/>
    <denominator xsi:type="PQ" value="1"/>
</pharm:quantity>
```

Add Section 6.3.4.2

6.3.4.2 Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2)

A Prescription Item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations. Prescription Item is the atomic entity for logistics, distribution and billing. It contains the prescribed medicine and dosage information as well as other information to the prescribed item such as patient- and fulfillment instructions and substitution handling.

6.3.4.2.1 Standards

This part describes the general structure for a Prescription Item. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition
CCD	ASTM/HL7 Continuity of Care Document
IHE PCC	Medications Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7)

6.3.4.2.2 Parent Template

This entry content module is based on the HL7 CCD template medication activity 2.16.840.1.113883.10.20.1.24 and inherits the structure of the Medication Entry Content Module, 1.3.6.1.4.1.19376.1.5.3.1.4.7.

6.3.4.2.3 Specification

This section makes use of the medicine and instruction entry content modules.

This specification relies on the PCC Medication Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification and only describes additional constraints.

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The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<substanceAdministration classCode='SBADM' moodCode='INT'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.3.6'/>
  <id root=' ' extension=' '/>
  <code code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
  <text><reference value='#med-1'/></text>
  <statusCode code='completed'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=' '/>
      <high value=' '/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
  </effectiveTime>
  <repeatNumber value=' '/>
  <routeCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
  <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
  <doseQuantity value=' ' unit=' '/>
  <rateQuantity value=' ' unit=' '/>
  <consumable>
    <manufacturedProduct" classCode="MANU">
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.2"/>
        <templateId root="2.16.840.1.113883.10.20.1.53"/>
        <manufacturedMaterial xmlns:pharm="urn:ihe:pharm
                              classCode="MMAT" determinerCode="KIND">
          :
          <!-- Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
          :
        </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>
  <!--
      Author(s) in case of usage elsewhere as in a PRE document
  -->
  <author>...</author>
  <author>...</author>
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
    <sequenceNumber value=''/>
      :
  </entryRelationship>
  <!-- An optional entry relationship that indicates the reason for use -->
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <!-- An optional entry relationship that refers to the corresponding MTP Item -->
  <entryRelationship typeCode='REFR'>
      <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.10'/>  <!-- PHARM -->
        ...
      </substanceAdministration>
  </entryRelationship>
  <!-- Reference to a related prescription activity (supply) -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
    :
  </entryRelationship>
<!-- An optional entry relationship that indicates the that the item is provisional until it is
validated -->
<entryRelationship typeCode='REFR'>
    <substanceAdministration classCode='SBADM' moodCode='PRP'>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>  <!-- PHARM -->
```

```
÷
    </substanceAdministration>
  </entryRelationship>
  <!-- Optional instructions for the patient -->
  <entryRelationship typeCode='SUBJ' inversionInd='true'>
    <act classCode='ACT' moodCode='INT'>
      <templateId root='2.16.840.1.113883.10.20.1.49'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
      <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
        codeSystemName='IHEActCode' />
      ...
  </entryRelationship>
  <!-- Optional instructions for Pharmacist -->
  <entryRelationship typeCode='SUBJ' inversionInd='true'>
    <act classCode='ACT' moodCode='INT'>
      <templateId root='2.16.840.1.113883.10.20.1.43'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
      <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
        codeSystemName='IHEActCode' />
      ...
  </entryRelationship>
  <!-- Amount of units of the consumable to dispense -->
  <entryRelationship typeCode='COMP'>
    <supply classCode='SPLY' moodCode='RQO'>
      <templateId root='1.3.6.1.4.1.19376.1.9.1.3.8'/> <!-- PHARM -->
      <independentInd value='false'/>
      <quantity value=' ' unit=' '/>
    </supply>
  </entryRelationship>
  <!-- Substitution permission -->
  <entryRelationship typeCode='COMP'>
    <act classCode="ACT" moodCode="DEF">
      <templateId root='1.3.6.1.4.1.19376.1.9.1.3.9.1'/> <!-- PHARM SubstitutionPermission -->
      <code code='E' codeSystem='2.16.840.1.113883.5.1070' displayName='equivalent'
            codeSystemName='HL7 Substance Admin Substitution'/>
      <statusCode code="completed"/>
    </act>
  </entryRelationship>
  <!-- Optional renewal Period -->
  <entryRelationship typeCode="COMP">
    <supply classCode="SPLY" moodCode="RQO">
      <templateId root="1.3.6.1.4.1.19376.1.9.1.3.15"/>
        ...
    </supply>
  </entryRelationship>
  <precondition>
    <criterion>
      <text><reference value=''></text>
    </criterion>
  </precondition>
</substanceAdministation>
```

6.3.4.2.3.1 Prescription Item Entry General Specification

<substanceAdministration classCode='SBADM' moodCode='INT'>
…
</substanceAdministration>

The moodCode SHALL be set to INT.

Note: Rational for using moodCode “INT”

Strictly speaking, according to HL7, the moodCode RQO ("request order") is a more appropriate substanceAdministration/moodCode for prescriptions than INT. RQO is a specialization of INT and should be used if the prescription is clearly a prescription in the meaning of an "order".

In some cases a prescription is clearly an "order" for execution (e.g., usually in hospital setting, where its execution is mostly driven by defined processes). In other cases a prescription given to a patient by a physician usually remains from that on in the authority of the patient him- or herself, relatives or other persons (e.g., in community setting). The patient usually decides in the end whether or not he/she retrieves the prescribed medication from the Community Pharmacy and takes it. Thus in some cases prescriptions might not clearly be seen as strict orders, but also as mere intents for the patient to take the medication. At least when collecting and summarizing Prescription Items in e.g., a Medication list, the ordering aspect of the prescription items gets almost entirely diminished.

Since the Prescription Item Entry does not always document a prescription in the strict sense, the more general moodCode "INT" is used.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.2 Prescription Item Entry TemplateID

<templateId root='2.16.840.1.113883.10.20.1.24'/> **<!-- CCD -->**

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/> **<!-- PCC -->**

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/> **<!-- PHARM -->**

A templateId of '1.3.6.1.4.1.19376.1.9.1.3.2' SHALL be present to indicate that this entry is conforming to the Prescription Item Entry Content Module.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.3 Prescription Item Entry Additional Template ID

<templateId root=' '/>

The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content.

The templateId must use one of the values in the table below for the root attribute.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.8	A <substanceAdministration> act that records tapered dose information in subordinate <substanceAdministration> act.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.10	A <substanceAdministration> act that records conditional dose information in subordinate <substanceAdministration> acts.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.4 Prescription Item ID

<id root=' ' extension=' '/>

This ID represents the Prescription Item ID and SHALL be present.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.5 Code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.6 Narrative Text

<text><reference value=' '/></text>

This element SHALL be present. The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication prescribed.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.7 Status Code

<statusCode code='completed'/>

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

Please note that this element does NOT represent the status of the Prescription Item (e.g., still open, already dispensed, etc.). There is no dedicated data element to record such a status, please refer to the Community Medication Prescription and Dispense (CMPD) Profile for more information.

6.3.4.2.3.8 Dosage Instructions

The Prescription Item SHALL contain dosage instructions according to the specification of the dosage instructions in the Dosage Instructions Content Module (1.3.6.1.4.1.19376.1.9.1.3.6).

Note: The following elements part of the Dosage Instructions:

- Prescription Item Entry Additional Template ID
- Effective Time (Duration of Treatment)

- Medication Frequency
- Route of Administration
- Approach Site Code
- Dose Quantity
- Rate Quantity
- Related Components

6.3.4.2.3.9 Number of repeats/refills

<repeatNumber value=' '/>

The <repeatNumber> element SHALL be present, and SHALL contain the number of allowed repeats/refills of the Prescription Item.

If the <repeatNumber> element has a value of zero no repeat/refill is allowed (single dispense). The total number of dispenses will be thus equal to the repeat number plus one.

If the repeatNumber is not limited (e.g., in case a renewal duration is defined), this element SHALL be set to nullFlavor='NI'.

6.3.4.2.3.10 Consumable

```
<consumable>
  <manufacturedProduct" classCode="MANU">
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.2"/>
    <templateId root="2.16.840.1.113883.10.20.1.53"/>
    <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
      :
      <!-- Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
      :
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

The <consumable> element SHALL be present, and SHALL contain a <manufacturedProduct> element.

The <manufacturedProduct> element SHALL contain a <manufacturedMaterial> element.

The <manufacturedMaterial> element SHALL contain a Medicine Entry, conforming to the Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1).

See PHARM TF-3, Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1) specification.

6.3.4.2.3.11 Prescriber

<author>…</author>

In the case that the Prescription Item is used within a Community Prescription document according to the "Community Prescription" (PRE) Profile this element SHALL NOT be present.

In all other cases (e.g., when used in a "Community Medication List" document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.) this element SHOULD be present and represent the prescriber and timestamp of the Prescription Item.

This first author element SHALL be present in case that the "Community Prescription document author" is present (see Section 6.3.4.2.3.12).

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the Community Prescription document or, if given, the <author> element of the Prescription section within the Community Prescription document.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber Profession	CE	*author/functionCode*
Timestamp of prescribing	TS	*author/time*
Prescriber ID	II	*author/assignedAuthor/id*
Prescriber Specialty	CE	*author/assignedAuthor/code*
Prescriber Name	PN	*author/assignedAuthor/assignedPerson/name*
Prescriber Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Prescriber Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Prescriber Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.2.3.12 Community Prescription document author

<author>…</author>

In the case that the Prescription Item is used within a Community Prescription document according to the "Community Prescription" (PRE) Profile this element SHALL NOT be present.

If the author of the Community Prescription document is already present in the "Prescriber" element (see section above) this element SHALL NOT be present.

In all other cases (e.g., when used in a "Community Medication List" document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.) this element MAY be present and represent the author and timestamp of the Community Prescription document.

The table below shows the meaning of the data elements of this <author> element. It SHALL be corresponding to the <author> element of the Community Prescription document header.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Community Prescription document author Profession	CE	*author/functionCode*
Timestamp of document creation	TS	*author/time*
Community Prescription document author ID	II	*author/assignedAuthor/id*
Community Prescription document author Specialty	CE	*author/assignedAuthor/code*
Community Prescription document author Name	PN	*author/assignedAuthor/assignedPerson/name*
Community Prescription document author Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Community Prescription document author Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Community Prescription document author Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.2.3.13 Reason

<entryRelationship typeCode='RSON'>

<act classCode='ACT' moodCode='EVN'>

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>

<id root=' ' extension=' '/>

```
    </act>
</entryRelationship>
```

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2.3.14 Reference to Medication Treatment Plan Item

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.10'/> <!-- PHARM -->
    …
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entryRelationship>
```

If the Prescription Item is related to a Medication Treatment Plan Item, the reference to it SHALL be present IF KNOWN and SHALL contain a Reference to Medication Treatment Plan Item Entry, conforming to the Reference to Medication Treatment Plan Item Entry template (1.3.6.1.4.1.19376.1.9.1.3.10). See PHARM TF-3, Reference to Medication Treatment Plan Item Entry Module (1.3.6.1.4.1.19376.1.9.1.3.10) specification.

6.3.4.2.3.15 Reference to a related prescription activity (supply)

~~<entryRelationship typeCode='REFR'>~~
~~ <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>~~
~~ …~~
~~</entryRelationship>~~

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

This element SHALL NOT be present.

6.3.4.2.3.16 Validation Step

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='PRP'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/> <!-- PHARM -->
```



```
      <consumable>
        <manufacturedProduct>
          <manufacturedMaterial nullFlavor='NA'/>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
</entryRelationship>
```

When present, this entry relationship SHALL contain a Validation Step (1.3.6.1.4.1.19376.1.9.1.3.16) entry.

The Validation Step acts as a flag, which renders the present Prescription Item as "provisional" unless there is a Pharmaceutical Advice Item present, which is related to that Prescription Item and contains the outcome of the validation in the Observation Code element (see Workflow scenario 2 in the Pharmacy CMPD Profile Section 4.4 CMPD Process Flow).

See PHARM TF-3, Reference to Validation Step Content Module (1.3.6.1.4.1.19376.1.9.1.3.16) specification.

6.3.4.2.3.17 Patient Medication Instructions

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
  <act classCode='ACT' moodCode='INT'>
    <templateId root='2.16.840.1.113883.10.20.1.49'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
    <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
      codeSystemName='IHEActCode' />
    ...
</entryRelationship>
```

At most one instruction MAY be provided for each <substanceAdministration> entry. When present, this entry relationship SHALL contain a Patient Medication Instructions (1.3.6.1.4.1.19376.1.5.3.1.4.3) entry.

Patient Medication Instructions (used in a Prescription Item) are comments from "prescriber to patient" and may contain the following information:

- Human readable dosage instructions (e.g., a representation of the structured dosage instructions as narrative text, any special dosage instructions which could not have been represented in structured way, etc.)
- General comments by the prescriber to the patient (e.g., "take with food", etc.)

6.3.4.2.3.18 Fulfillment Instructions

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
  <act classCode='ACT' moodCode='INT'>
   <templateId root='2.16.840.1.113883.10.20.1.43'/>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
   <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
    codeSystemName='IHEActCode' />
   ...
 </entryRelationship>
```

At most one instruction MAY be provided for each <substanceAdministration> entry.-When present, this entry relationship SHALL contain a Medication Fulfillment Instructions (1.3.6.1.4.1.19376.1.5.3.1.4.3.1) entry.

Fulfillment Instructions (used in a Prescription Item) are comments from "prescriber to dispenser" and may contain the following information:

- A proposal of a product/brand including information about substitution in case of prescribing Generic/Scientific names (e.g., Prescriber prescribes the generic "Paracetamol" but proposes the product "Adol 500mg Caplet" to be dispensed because the patient is used to that medicine)
- Information to the preparation of compound medicine (e.g., "20 capsules of phenytoin, 20 ml glycerin, 2ml alcohol, Q.S. Syrup to 200ml")
- General comments by the prescriber to the dispenser (e.g., if the patient is very old: "Patient is instructed about the dosing, but please repeat the instruction to ensure that the patient understood how to intake the medicine")

6.3.4.2.3.19 Amount of units of the consumable to dispense

```
<entryRelationship typeCode='COMP'>
  <supply classCode='SPLY' moodCode='RQO'>
    …
  </supply>
</entryRelationship>
```

This element MAY be present and describes the amount of units to be dispensed. If present, it shall contain a quantity conforming to the Amount of units of the consumable Entry template (1.3.6.1.4.1.19376.1.9.1.3.8). See PHARM TF-3, Amount of units of the consumable Entry Module (1.3.6.1.4.1.19376.1.9.1.3.8) specification.

6.3.4.2.3.20 Substitution permission

```
<entryRelationship typeCode='COMP'>
  <act classCode="ACT" moodCode="DEF">
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.9.1'/>
    …
  </act>
</entryRelationship>
```

One or more <entryRelationship> elements, each containing a Substitution Permission Entry, MAY be present and describe the substitution permission. If present, it SHALL contain a Substitution Permission Entry conforming to the Substitution Permission Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.9.1).

See PHARM TF-3, Substitution Permission Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.9.1) specification.

6.3.4.2.3.21 Renewal Period

```
<entryRelationship typeCode="COMP">
  <supply classCode="SPLY" moodCode="RQO">
    <templateId root="1.3.6.1.4.1.19376.1.9.1.3.15"/> <!-- PHARM -->
      …
  </supply>
</entryRelationship>
```

The Prescription Item MAY contain a renewal period according to the specification of the Renewal Period Content Module (1.3.6.1.4.1.19376.1.9.1.3.15).

6.3.4.2.3.22 ID of parent container (Community Prescription document)

```
<reference typeCode='XCRPT'>
  <externalDocument>
    <id root=' ' extension=' '/>
  </externalDocument>
</reference>
```

In the case that the Prescription Item is used within a Community Prescription document according to the “Community Prescription” (PRE) Profile this element SHALL NOT be present.

In all other cases (e.g., when used in a “Community Medication List” document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries,

etc.) this element SHOULD be present and contain the identifier of the Community Prescription document, the Prescription Item initially has been created.

6.3.4.2.3.23 Precondition Criterion

<precondition>

<criterion>

<text><reference value=' '></text>

</criterion>

</precondition>

In a CDA document, the preconditions for use of the medication are recorded in the <precondition> element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.

This element MAY be present.

See PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.6 Dosage Instructions Content Module (1.3.6.1.4.1.19376.1.9.1.3.6)

Dosage Instructions are a set of data elements which together represent the dosage instructions to a medication such as duration of treatment, medication frequency, dose quantity, route of administration, etc.

Dosage Instructions may be provided structured and/or narrative. This section describes *structured* dosage instructions.

If dosage instructions are provided *narrative only*, the Dosage Instructions data elements SHALL NOT be present as a whole.

6.3.4.6.1 Standards

This part describes the general structure for a Dosage Instructions. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition
CDAR2	HL7 CDA Release 2.0

6.3.4.6.2 Parent Template

This content module has no parent structure.

6.3.4.6.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
      :
  <templateId root='1.3.6.1.4.1.19376.1.9.1.3.6'/>
      :
  <effectiveTime xsi:type='IVL_TS'>
      <low value=' '/>
      <high value=' '/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    …
  </effectiveTime>
      :
  <routeCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
  <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
  <doseQuantity value=' ' unit=' '/>
  <rateQuantity value=' ' unit=' '/>
      :
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
    <sequenceNumber value=''/>
       :
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
       :
  </entryRelationship>
      :
</substanceAdministation>
```

6.3.4.6.3.1 Dosage Instructions General Specification

< substanceAdministration classCode='SBADM' moodCode='INT|EVN'>

…

</substanceAdministration>

The Dosage Instructions are part of a <substanceAdministration> element.

The <substanceAdministration> element itself as well as additional constraints applying to this <substanceAdministration> element (e.g., other applying content module constraints such as IHE PHARM “Prescription Item”) are specified in the parent specification using this content module.

6.3.4.6.3.2 Dosage Instructions TemplateID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.6'/> <!-- PHARM -->

The <templateId> element identifies this <entry> as a particular type of event, allowing for validation of the content.

The templateId SHALL be set to the value 1.3.6.1.4.1.19376.1.9.1.3.6.

6.3.4.6.3.3 Dosage Instructions Additional Template ID

<templateId root=' '/>

This templateId declares which type of dosage instructions ("normal dosing", "split dosing", etc.) is used.

The templateId SHALL be present.

In case (structured) dosage instructions are not provided (e.g., because they are only provided as narrative text), this element SHALL be set to "Normal Dosing".

The templateId SHALL use one of the values in the table below for the root attribute.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.8	A <substanceAdministration> act that records tapered dose information in subordinate <substanceAdministration> act.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.10	A <substanceAdministration> act that records conditional dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

The constraints defined for this element in PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.4 Effective Time (Duration of Treatment)

<effectiveTime xsi:type='IVL_TS'>

In case the (structured) dosage instructions include a dose regime[7] this element SHALL be present and specify the entire duration of the medication treatment. In case the Duration of Treatment is unknown the <low> and <high> sub-elements of this element SHALL be set to null flavor "UNK".

If dosage instructions are provided *narrative <u>only</u>*, this element SHALL NOT be present.

In all other cases this element MAY be present.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

[7] For the scope of this Content Module, "dose regime" groups the data elements Medication Frequency, Dose Quantity and Rate Quantity, provided in a certain type of dosing ("Normal dosing", "Split dosing", etc.)

6.3.4.6.3.5 Medication frequency

<effectiveTime operator='A'

xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS' />

In case the (structured) dosage instructions include a dose regime using “Normal Dosing”, this element SHALL be present and SHALL NOT be null flavor.

If dosage instructions are provided *narrative only*, this element SHALL NOT be present.

In all other cases this element MAY be present.

The constraints defined for this element in PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.6 Route of Administration

<routeCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

If dosage instructions are provided *narrative only*, this element SHALL NOT be present.

In all other cases this element MAY be present.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.7 Approach Site Code

<approachSiteCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>

If dosage instructions are provided *narrative only*, this element SHALL NOT be present.

In all other cases this element MAY be present.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.8 Dose Quantity

<doseQuantity> <low value=' ' unit=' '/><high value=' ' unit=' '/> </doseQuantity>

or

<doseQuantity value=' ' unit=' '/>

In case the (structured) dosage instructions include a dose regime using “Normal Dosing”, this element SHALL be present and SHALL NOT be null flavor.

If dosage instructions are provided *narrative only*, this element SHALL NOT be present.

In all other cases this element MAY be present.

In case low and high values and units are the same, the quantity data type may be used. Otherwise the range representation shall be used.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.9 Rate Quantity

<rateQuantity> <low value=' ' unit=' '/><high value=' ' unit=' '/> </rateQuantity>

or

<rateQuantity value=' ' unit=' '/>

In case the (structured) dosage instructions include a dose regime using “Normal Dosing”, this element SHALL be present and SHALL NOT be null flavor.

If dosage instructions are provided *narrative only*, this element SHALL NOT be present.

In all other cases this element MAY be present.

In case low and high values and units are the same, the quantity data type may be used. Otherwise the range representation shall be used.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.6.3.10 Related components

```
<entryRelationship typeCode='COMP'>
  <sequenceNumber value=''/>
   :
   <consumable>
    <manufacturedProduct>
     <manufacturedMaterial nullFlavor='NA'/>
    </manufacturedProduct>
   </consumable>
   :
</entryRelationship>
```

In case the (structured) dosage instructions include a dose regime using “Normal Dosing”, subordinate <substanceAdministration> entries SHALL NOT be present.

If dosage instructions are provided *narrative only*, subordinate <substanceAdministration> entries SHALL NOT be present.

In case the (structured) dosage instructions include a dose regime using other types than “Normal Dosing”, one or more subordinate <substanceAdministration> entries SHALL be present.

In case subordinate <substanceAdministration> entries are present, the <consumable> element of subordinate <substanceAdministration> entries SHALL NOT contain a medicine, but the <manufacturedProduct/manufacturedMaterial> element SHALL be set to nullFlavor='NA'.

The constraints defined for this element in PCC TF-2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification apply to this element.

6.3.4.7 Amount of units of the consumable Content Module (1.3.6.1.4.1.19376.1.9.1.3.8)

The Amount of units of the consumable Content Module describes the quantity of the enclosing <consumable> element.

6.3.4.7.1 Standards

This part describes the general structure for an Amount of units of the consumable Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.7.2 Parent Template

This content module has no parent structure.

6.3.4.7.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='COMP'>
    <supply classCode='SPLY' moodCode='RQO'>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.8'/> <!-- PHARM -->
        <independentInd value='false'/>
        <quantity value=' ' unit=' '/>
    </supply>
</entryRelationship>
```

6.3.4.7.3.1 Amount of units of the consumable General Specification

<entryRelationship typeCode='COMP'>

<supply classCode='SPLY' moodCode='RQO'>

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.8'/>

<independentInd value='false'/>

…

</supply>

</entryRelationship>

6.3.4.7.3.2 Amount of units of the consumable Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.8'/>

The Template ID for an Amount of units of the consumable Content Module SHALL be provided.

6.3.4.7.3.3 Amount of units of the consumable independentInd

<independentInd value='false'/>

The <independentInd> SHALL be present and SHALL contain a value set to “false”.

6.3.4.7.3.4 Amount of units of the consumable Quantity

<quantity value=' ' unit=' '/>

The Amount of units of the consumable Content Module describes the quantity of the enclosing <consumable> element.

- If the enclosing <consumable> - element also contains package information, the <quantity> element SHALL contain the amount of primary packaged items of the medication. The value shall refer to the primary layer of the package information given in the <pharm:asContent> element of the consumable (e.g., if the value is 2 and the <pharm:asContent> element describes a blister containing 30 tablets, this means that 2 blisters (with each 30 tablets in it) have been prescribed). Eventually present sub- or super layers of packaging (subContent, asSuperContent elements below the asContent element) are not affected. In this case the unit attribute SHALL NOT be present.
- If the enclosing <consumable> - element does not contain package information, the <quantity> element SHALL contain the amount of consumable units of the medication. In this case the unit attribute MAY be present, if the quantity is in non-countable units. The value of the unit SHALL be out of the UCUM code system.

6.3.4.8 Substitution Permission Content Module (1.3.6.1.4.1.19376.1.9.1.3.9.1)

An <entryRelationship> element, containing exactly one element describing the substitution permission.

6.3.4.8.1 Standards

This part describes the general structure for a Substitution Permission Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.8.2 Parent Template

This content module has no parent structure.

6.3.4.8.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='COMP'>
    <act classCode="ACT" moodCode="DEF">
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.9.1'/> <!-- PHARM SubstitutionPermission -->
        <code code='E' codeSystem='2.16.840.1.113883.5.1070' displayName='equivalent'
              codeSystemName='HL7 Substance Admin Substitution'/>
        <statusCode code="completed"/>
    </act>
</entryRelationship>
```

6.3.4.8.3.1 Substitution Permission General Specification

<entryRelationship typeCode='COMP'>

<act classCode="ACT" moodCode="DEF">

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.9.1'/>

…

</act>

</entryRelationship>

6.3.4.8.3.2 Substitution Permission Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.9.1'/>

The Template ID for a Substitution Permission Content Module SHALL be provided.

6.3.4.8.3.3 Substitution Permission code

<code code='E' codeSystem='2.16.840.1.113883.5.1070' displayName='equivalent'
codeSystemName='HL7 Substance Admin Substitution'/>

The <code> element identifies what sort of change is permitted between the therapy that was ordered and the therapy that will be provided. It SHALL be coded in HL7 terminology for substance substitution.

6.3.4.8.3.4 Substitution Permission statusCode

<statusCode code="completed"/>

The <statusCode> element SHALL be set to “completed”.

6.3.4.9 Reference to Medication Treatment Plan Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.10)

An <entryRelationship> element, containing one and only one reference to a Medication Treatment Plan Item.

6.3.4.9.1 Standards

This part describes the general structure for a Reference to a Medication Treatment Plan Item Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.9.2 Parent Template

This content module has no parent structure.

6.3.4.9.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.10'/>
    <id root=' ' extension=' '/>     <!-- Medication Treatment Plan Item Id -->
    <code code='MTPItem'
          codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
          displayName='Medication Treatment Plan Item'
          codeSystemName='IHE Pharmacy Item Type List'/>
    <consumable>
      <manufacturedProduct>
         <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
    <!-- Author of referenced item -->
    <author>
      :
    </author>
    <!-- Embedding of referenced item -->
    <entryRelationship typeCode='REFR'>
      <substanceAdministration classCode='SBADM' moodCode='INT'>
        <templateId root='2.16.840.1.113883.10.20.1.24'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.7'/>
           :
      </substanceAdministration>
    </entryRelationship>
    <!-- ID of parent container of referenced item -->
    <reference typeCode='XCRPT'>
      <externalDocument>
        <id root=' ' extension=' '/>
      </externalDocument>
    </reference>
  </substanceAdministration>
</entryRelationship>
```

6.3.4.9.3.1 Reference to Medication Treatment Plan Item General Specification

<entryRelationship typeCode='REFR'>
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
<templateId root='1.3.6.1.4.1.19376.1.9.1.3.10'/>
…
<consumable>
<manufacturedProduct>
<manufacturedMaterial nullFlavor='NA'/>
</manufacturedProduct>
</consumable>
</substanceAdministration>
</entryRelationship>

6.3.4.9.3.2 Reference to Medication Treatment Plan Item Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.10'/>

The Template ID for a Reference to Medication Treatment Plan Item Content Module SHALL be provided.

6.3.4.9.3.3 Reference to Medication Treatment Plan Item ID

<id root=' ' extension=' '/> <!—Medication Treatment Plan Item Id →

This ID represents the referenced Medication Treatment Plan Item Id and SHALL be present.

6.3.4.9.3.4 Reference to Medication Treatment Plan Item code

<code co'e='MTPI'em'
codeSyst'm='1.3.6.1.4.1.19376.1.9.'.2'
displayNa'e=' Medication Treatment Plan I'em'
codeSystemNa'e='IHE Pharmacy Item Type L'st'/>

This code indicates that the referenced item is a Medication Treatment Plan Item. It SHALL be present.

6.3.4.9.3.5 Author of the referenced item

<author>…</author>

This element SHOULD be present and represent the author of the referenced item. It SHALL contain the author and the timestamp of the referenced item.

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the containing document of the referenced item, of if given, the <author> element of the section within the containing document of the referenced item.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Profession	CE	*author/functionCode*
Timestamp of referenced item	TS	*author/time*
Author of referenced item ID	II	*author/assignedAuthor/id*
Author of referenced item Specialty	CE	*author/assignedAuthor/code*
Author of referenced item Name	PN	*author/assignedAuthor/assignedPerson/name*
Author of referenced item Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Author of referenced item Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.9.3.6 Embedding of referenced item

<entryRelationship typeCode='REFR'>

<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>

<templateId root='2.16.840.1.113883.10.20.1.24'/>

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.7'/>

:

</substanceAdministration>

</entryRelationship>

An unchanged copy of the referenced Medication Treatment Plan Item MAY be present and SHALL conform to the Medication Treatment Plan Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.7).

Note: In case the referenced item contains internal references (e.g., an IHE PCC "Internal Reference" entry (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)), a complete copy of this element could result in a broken link to the information stated in another narrative text section, if this section is not available in the targeted document. In this case the complete copy SHOULD be modified to avoid such broken links (e.g., by setting the internal reference to nullFlavor=MSK: masked, confidential, not published).

6.3.4.9.3.7 ID of parent container of referenced item

<reference typeCode='XCRPT'>

<externalDocument>

<id root=' ' extension=' '/>

</externalDocument>

</reference>

The identifier of the document, the referenced item has been initially created (parent container) SHOULD be present. The presence of the parent container document id in this reference content module relieves the technical efforts in case the parent container document has to be queried and retrieved for some reason.

6.3.4.10 Reference to Prescription Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.11)

An <entryRelationship> element, containing one and only one reference to a Prescription (PRE) Item.

6.3.4.10.1 Standards

This part describes the general structure for a Reference to a Prescription Item Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.10.2 Parent Template

This content module has no parent structure.

6.3.4.10.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='INT'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.11'/>
    <id root=' ' extension=' '/>      <!-- Prescription Item Id -->
    <code code='PREItem'
          codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
          displayName='Prescription Item'
          codeSystemName='IHE Pharmacy Item Type List'/>
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
    <!-- Author of referenced item -->
    <author>
      :
    </author>
    <!-- Embedding of referenced item -->
    <entryRelationship typeCode='REFR'>
      <substanceAdministration classCode='SBADM' moodCode='INT'>
        <templateId root='2.16.840.1.113883.10.20.1.24'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
              :
      </substanceAdministration>
    </entryRelationship>
    <!-- ID of parent container of referenced item -->
    <reference typeCode='XCRPT'>
      <externalDocument>
        <id root=' ' extension=' '/>
      </externalDocument>
    </reference>
  </substanceAdministration>
</entryRelationship>
```

6.3.4.10.3.1 Reference to Prescription Item General Specification

<entryRelationship typeCode='REFR'>
** <templateId root='1.3.6.1.4.1.19376.1.9.1.3.11'/>**
** <substanceAdministration classCode='SBADM' moodCode='INT'>**
**   …**
**   <consumable>**
**   <manufacturedProduct>**
**   <manufacturedMaterial nullFlavor='NA'/>**
**   </manufacturedProduct>**
**   </consumable>**
** </substanceAdministration>**
</entryRelationship>

6.3.4.10.3.2 Reference to Prescription Item Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.11'/>

The Template ID for a Reference to Prescription Item Content Module SHALL be provided.

6.3.4.10.3.3 Reference to Prescription Item ID

<id root=' ' extension=' '/> <!-- Prescription Item Id -->

This ID represents the referenced Prescription Item Id and SHALL be present.

6.3.4.10.3.4 Reference to Prescription code

<code code=’PREItem'
codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
displayName='Prescription Item'
codeSystemName='IHE Pharmacy Item Type List'/>

This code indicates that the referenced item is a Prescription Item. It SHALL be present.

6.3.4.10.3.5 Author of the referenced item

<author>…</author>

This element SHOULD be present and represent the author of the referenced item. It SHALL contain the author and the timestamp of the referenced item.

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the containing document of the referenced item, of if given, the <author> element of the section within the containing document of the referenced item.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Profession	CE	*author/functionCode*
Timestamp of referenced item	TS	*author/time*
Author of referenced item ID	II	*author/assignedAuthor/id*
Author of referenced item Specialty	CE	*author/assignedAuthor/code*
Author of referenced item Name	PN	*author/assignedAuthor/assignedPerson/name*
Author of referenced item Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Author of referenced item Organization Name	ON	*author/assignedAuthor/representedOrganization/name*

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.10.3.6 Embedding of referenced item

<entryRelationship typeCode='REFR'>

<substanceAdministration classCode='SBADM' moodCode='INT'>

<templateId root='2.16.840.1.113883.10.20.1.24'/>

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>

:

</substanceAdministration>

</entryRelationship>

An unchanged copy of the referenced Prescription Item MAY be present and SHALL conform to the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2).

Note: In case the referenced item contains internal references (e.g., an IHE PCC "Internal Reference" entry (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)), a complete copy of this element could result in a broken link to the information stated in another narrative text section, if this section is not available in the targeted document. In this case the complete copy SHOULD be modified to avoid such broken links (e.g., by setting the internal reference to nullFlavor=MSK: masked, confidential, not published).

6.3.4.10.3.7 ID of parent container of referenced item

<reference typeCode='XCRPT'>

<externalDocument>

<id root=' ' extension=' '/>

</externalDocument>

</reference>

The identifier of the document, the referenced item has been initially created (parent container) SHOULD be present. The presence of the parent container document id in this reference content module relieves the technical efforts in case the parent container document has to be queried and retrieved for some reason.

6.3.4.11 Reference to Dispense Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.12)

An <entryRelationship> element, containing exactly one reference to a Dispense (DIS) Item.

6.3.4.11.1 Standards

This part describes the general structure for a Reference to a Dispense Item Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.11.2 Parent Template

This content module has no parent structure.

6.3.4.11.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <supply classCode='SPLY' moodCode='EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.12'/>
    <id root=' ' extension=' '/>     <!-- Dispense Item Id -->
    <code code='DISItem'
          codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
          displayName='Dispense Item'
          codeSystemName='IHE Pharmacy Item Type List'/>
    <!-- Author of referenced item -->
    <author>
      :
    </author>
    <!-- Embedding of referenced item -->
    <entryRelationship typeCode='REFR'>
      <supply classCode='SPLY' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.34'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4'/>
          :
      </supply>
    </entryRelationship>
    <!-- ID of parent container of referenced item -->
    <reference typeCode='XCRPT'>
      <externalDocument>
        <id root=' ' extension=' '/>
      </externalDocument>
    </reference>
  </supply>
</entryRelationship>
```

6.3.4.11.3.1 Reference to Dispense Item General Specification

<entryRelationship typeCode='REFR'>

<supply classCode='SPLY' moodCode='EVN'>

…

</supply>

</entryRelationship>

6.3.4.11.3.2 Reference to Dispense Item Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.12'/>

The Template ID for a Reference to Dispense Item Content Module SHALL be provided.

6.3.4.11.3.3 Reference to Dispense Item ID

<id root=' ' extension=' '/> <!-- Dispense Item Id -->

This ID represents the referenced Dispense Item Id and SHALL be present.

6.3.4.11.3.4 Reference to Dispense Item code

<code code='DISItem'
codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
displayName='Dispense Item'
codeSystemName='IHE Pharmacy Item Type List'/>

This code indicates that the referenced item is a Dispense Item. It SHALL be present.

6.3.4.11.3.5 Author of the referenced item

<author>…</author>

This element SHOULD be present and represent the author of the referenced item. It SHALL contain the author and the timestamp of the referenced item.

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the containing document of the referenced item, of if given, the <author> element of the section within the containing document of the referenced item.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Profession	CE	*author/functionCode*
Timestamp of referenced item	TS	*author/time*

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item ID	II	*author/assignedAuthor/id*
Author of referenced item Specialty	CE	*author/assignedAuthor/code*
Author of referenced item Name	PN	*author/assignedAuthor/assignedPerson/name*
Author of referenced item Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Author of referenced item Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Author of referenced item Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.11.3.6 Embedding of referenced item

<entryRelationship typeCode='REFR'>
<supply classCode='SPLY' moodCode='EVN'>
<templateId root='2.16.840.1.113883.10.20.1.34'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
<templateId root='1.3.6.1.4.1.19376.1.9.1.3.4'/>
:
</supply>
</entryRelationship>

An unchanged copy of the referenced Dispense Item MAY be present and SHALL conform to the Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4).

Note: In case the referenced item contains internal references (e.g., an IHE PCC "Internal Reference" entry (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)), a complete copy of this element could result in a broken link to the information stated in another narrative text section, if this section is not available in the targeted document. In this case the complete copy SHOULD be modified to avoid such broken links (e.g., by setting the internal reference to nullFlavor=MSK: masked, confidential, not published).

6.3.4.11.3.7 ID of parent container of referenced item

<reference typeCode='XCRPT'>
<externalDocument>


```
    <id root=' ' extension=' '/>
  </externalDocument>
</reference>
```

The identifier of the document, the referenced item has been initially created (parent container) SHOULD be present. The presence of the parent container document id in this reference content module relieves the technical efforts in case the parent container document has to be queried and retrieved for some reason.

6.3.4.12 Reference to Pharmaceutical Advice Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.13)

An <entryRelationship> element, containing one and only one reference to a Pharmaceutical Advice (PADV) Item.

6.3.4.12.1 Standards

This part describes the general structure for a Reference to a Pharmaceutical Advice Item Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.12.2 Parent Template

This content module has no parent structure.

6.3.4.12.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.13'/>
    <id root=' ' extension=' '/>     <!-- Pharmaceutical Advice Item Id -->
    <code code='PADVItem'
        codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
        displayName='Pharmaceutical Advice Item'
        codeSystemName='IHE Pharmacy Item Type List'/>
    <!-- Author of referenced item -->
    <author>
      :
    </author>
    <!-- Embedding of referenced item -->
    <entryRelationship typeCode='REFR'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.34'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4'/>
          :
      </observation>
    </entryRelationship>
    <!-- ID of parent container of referenced item -->
    <reference typeCode='XCRPT'>
      <externalDocument>
        <id root=' ' extension=' '/>
      </externalDocument>
    </reference>
  </observation>
</entryRelationship>
```

6.3.4.12.3.1 Reference to Pharmaceutical Advice Item General Specification

<entryRelationship typeCode='REFR'>

<observation classCode='OBS' moodCode='EVN'>

…

</observation>

</entryRelationship>

6.3.4.12.3.2 Reference to Pharmaceutical Advice Item Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.13'/>

The Template ID for a Reference to Pharmaceutical Advice Item Content Module SHALL be provided.

6.3.4.12.3.3 Reference to Pharmaceutical Advice Item ID

<id root=' ' extension=' '/> <!-- Pharmaceutical Advice Item Id -->

This ID represents the referenced Pharmaceutical Advice Item Id and SHALL be present.

6.3.4.12.3.4 Reference to Pharmaceutical Advice Item code

<code code='PADVItem'
codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
displayName='Pharmaceutical Advice Item'
codeSystemName='IHE Pharmacy Item Type List'/>

This code indicates that the referenced item is a Pharmaceutical Advice Item. It SHALL be present.

6.3.4.12.3.5 Author of the referenced item

<author>…</author>

This element SHOULD be present and represent the author of the referenced item. It SHALL contain the author and the timestamp of the referenced item.

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the containing document of the referenced item, of if given, the <author> element of the section within the containing document of the referenced item.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Profession	CE	*author/functionCode*
Timestamp of referenced item	TS	*author/time*
Author of referenced item ID	II	*author/assignedAuthor/id*
Author of referenced item Specialty	CE	*author/assignedAuthor/code*
Author of referenced item Name	PN	*author/assignedAuthor/assignedPerson/name*
Author of referenced item Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Author of referenced item Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Author of referenced item Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.12.3.6 Embedding of referenced item

<entryRelationship typeCode='REFR'>

```
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.3.3'/>
    :
</observation>
</entryRelationship>
```

An unchanged copy of the referenced Pharmaceutical Advice Item MAY be present and SHALL conform to the Pharmaceutical Advice Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.3).

Note: In case the referenced item contains internal references (e.g., an IHE PCC "Internal Reference" entry (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)), a complete copy of this element could result in a broken link to the information stated in another narrative text section, if this section is not available in the targeted document. In this case the complete copy SHOULD be modified to avoid such broken links (e.g., by setting the internal reference to nullFlavor=MSK: masked, confidential, not published).

6.3.4.12.3.7 ID of parent container of referenced item

```
<reference typeCode='XCRPT'>
  <externalDocument>
    <id root=' ' extension=' '/>
  </externalDocument>
</reference>
```

The identifier of the document, the referenced item has been initially created (parent container) SHOULD be present. The presence of the parent container document id in this reference content module relieves the technical efforts in case the parent container document has to be queried and retrieved for some reason.

6.3.4.13 Reference to Medication Administration Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.14)

An <entryRelationship> element, containing one and only one reference to a Medication Administration (CMA) Item.

6.3.4.13.1 Standards

This part describes the general structure for a Reference to a Medication Administration Item Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.13.2 Parent Template

This content module has no parent structure.

6.3.4.13.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.14'/>
    <id root=' ' extension=' '/>     <!-- Medication Administration Item Id -->
    <code code='CMAItem'
        codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
        displayName='Medication Administration Item'
        codeSystemName='IHE Pharmacy Item Type List'/>
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
    <!-- Author of referenced item -->
    <author>
      :
    </author>
    <!-- Embedding of referenced item -->
    <entryRelationship typeCode='REFR'>
      <substanceAdministration classCode='SBADM' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.24'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>
          :
      </substanceAdministration>
    </entryRelationship>
    <!-- ID of parent container of referenced item -->
    <reference typeCode='XCRPT'>
      <externalDocument>
        <id root=' ' extension=' '/>
      </externalDocument>
    </reference>
  </substanceAdministration>
</entryRelationship>
```

6.3.4.13.3.1 Reference to Medication Administration Item General Specification

<entryRelationship typeCode='REFR'>
** <substanceAdministration classCode='SBADM' moodCode='EVN'>**
**   …**
**   <consumable>**
**   <manufacturedProduct>**
**   <manufacturedMaterial nullFlavor='NA'/>**
**   </manufacturedProduct>**
**   </consumable>**
** </substanceAdministration>**
</entryRelationship>

6.3.4.13.3.2 Reference to Medication Administration Item Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.14'/>

The Template ID for a Reference to Medication Administration Item Content Module SHALL be provided.

6.3.4.13.3.3 Reference to Medication Administration Item ID

<id root=' ' extension=' '/> <!-- Medication Administration Item Id -->

This ID represents the referenced Medication Administration Item Id and SHALL be present.

6.3.4.13.3.4 Reference to Medication Administration Item code

<code code='CMAItem'
codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
displayName='Medication Administration Item'
codeSystemName='IHE Pharmacy Item Type List'/>

This code indicates that the referenced item is a Medication Administration Item. It SHALL be present.

6.3.4.13.3.5 Author of the referenced item

<author>…</author>

This element SHOULD be present and represent the author of the referenced item. It SHALL contain the author and the timestamp of the referenced item.

The table below shows the meaning of the data elements of this <author> element. It SHOULD be corresponding to the <author> element of the containing document of the referenced item, of if given, the <author> element of the section within the containing document of the referenced item.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Profession	CE	*author/functionCode*
Timestamp of referenced item	TS	*author/time*
Author of referenced item ID	II	*author/assignedAuthor/id*
Author of referenced item Specialty	CE	*author/assignedAuthor/code*
Author of referenced item Name	PN	*author/assignedAuthor/assignedPerson/name*
Author of referenced item Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Author of referenced item Organization Name	ON	*author/assignedAuthor/representedOrganization/name*

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Author of referenced item Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

6.3.4.13.3.6 Embedding of referenced item

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.24'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>
      :
  </substanceAdministration>
</entryRelationship>
```

An unchanged copy of the referenced Medication Administration Item MAY be present and SHALL conform to the Medication Administration Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.16).

Note: In case the referenced item contains internal references (e.g., an IHE PCC "Internal Reference" entry (1.3.6.1.4.1.19376.1.5.3.1.4.4.1)), a complete copy of this element could result in a broken link to the information stated in another narrative text section, if this section is not available in the targeted document. In this case the complete copy SHOULD be modified to avoid such broken links (e.g., by setting the internal reference to nullFlavor=MSK: masked, confidential, not published).

6.3.4.13.3.7 ID of parent container of referenced item

```
<reference typeCode='XCRPT'>
  <externalDocument>
    <id root=' ' extension=' '/>
  </externalDocument>
</reference>
```

The identifier of the document, the referenced item has been initially created (parent container) SHOULD be present. The presence of the parent container document id in this reference content module relieves the technical efforts in case the parent container document has to be queried and retrieved for some reason.

6.3.4.14 Renewal Period Content Module (1.3.6.1.4.1.19376.1.9.1.3.15)

Renewal Period Content Module describes the possible renewal of a Prescription Item in terms of duration or period of time (start / end date).

6.3.4.14.1 Standards

This part describes the general structure for a Renewal period. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition
CDAR2	HL7 CDA Release 2.0

6.3.4.14.1 Parent Template

This content module has no parent structure.

6.3.4.14.2 Specification

The chapters below identify and describe the fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode="COMP">
  <supply classCode="SPLY" moodCode="RQO">
    <templateId root="1.3.6.1.4.1.19376.1.9.1.3.15"/>
    <!-- allowed renewal period for the Prescription Item -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20170601"/> <!-- optional -->
      <high value="20170801"/>
          <!--   OR   -->
      <low value="20170601"/> <!-- optional -->
      <width value="3" unit="mo"/>
    </effectiveTime>
  </supply>
</entryRelationship>
```

6.3.4.14.2.1 Renewal Period General Specification

<entryRelationship typeCode="COMP">

<supply classCode="SPLY" moodCode="RQO">

<templateId root="1.3.6.1.4.1.19376.1.9.1.3.15"/> <!-- PHARM -->

<effectiveTime xsi:type="IVL_TS">

…

</effectiveTime>

</supply>

</entryRelationship>

6.3.4.14.2.2 Renewal Period Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.15'/>

The Template ID for the Renewal Period SHALL be provided.

6.3.4.14.2.3 Renewal Period effectiveTime

<effectiveTime xsi:type="IVL_TS">

<low value="…"/> <!-- optional -->

<high value="…"/>

</effectiveTime>

-- or --

<effectiveTime xsi:type="IVL_TS">

<low value="…"/> <!-- optional -->

<width value="…" unit="…"/>

</effectiveTime>

The renewal period SHALL be defined by the “effectiveTime” element.

In case the renewal period is bound by a precise date, the first form of interval SHALL be used. When using this form, the “high” value (ending date) SHALL be specified and the “low” value (starting date) MAY be specified.

In case the renewal period is known in terms of duration, the second form of interval SHALL be used. When using this form the “width” (period of time) SHALL be specified and the “low” (starting date) MAY be specified.

6.3.4.15 Validation Step Content Module (1.3.6.1.4.1.19376.1.9.1.3.16)

An <entryRelationship> element, containing one and only one Validation Step.

The Validation Step acts as a flag, which renders the present Prescription Item as “provisional” unless there is a Pharmaceutical Advice Item present, which is related to that Prescription Item and contains the outcome of the validation in the Observation Code element (see Workflow scenario 2 in IHE Pharmacy CMPD Profile Section 4.4 CMPD Process Flow).

6.3.4.15.1 Standards

This part describes the general structure for a Validation Step Content Module. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

6.3.4.15.2 Parent Template

This content module has no parent structure.

6.3.4.15.3 Specification

The chapters below identify and describe these fields, and indicate the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SMADM' moodCode='PRP'>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>
    <consumable>
      <manufacturedProduct>
         <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entryRelationship>
```

6.3.4.15.3.1 Validation Step General Specification

<entryRelationship typeCode='REFR'>
<substanceAdministration classCode='SBADM' moodCode='PRP'>
<templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>
<consumable>
…
</consumable>
</substanceAdministration>
</entryRelationship>

6.3.4.15.3.2 Reference to Validation Step Template ID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.16'/>

The Template ID for a Reference to Validation Step Content Module SHALL be provided.

6.3.4.15.3.3 Consumable

```
<consumable>
 <manufacturedProduct>
  <manufacturedMaterial nullFlavor='NA'/>
 </manufacturedProduct>
</consumable>
```

The consumable element SHALL be present and SHALL contain nullFlavor “NA” in the manufacturedMaterial sub-element.

6.5 PHARM Value Sets

Add Section 6.5.3

6.5.3 IHE Pharmacy Item Type List

The Pharmacy Item Type List is used in the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2), the Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4) and in the Pharmaceutical Advice Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.3) for explicitly indicating to which kind of item a reference (entryRelationship with typeCode='REFR') points to.

code: **see column "Code"**

codeSystem: **1.3.6.1.4.1.19376.1.9.2.2**

codeSystemName: **IHE Pharmacy Item Type List**

Code	Display Name
MTPItem	Medication Treatment Plan Item
PREItem	Prescription Item
DISItem	Dispense Item
PADVItem	Pharmaceutical Advice Item
CMAItem	Medication Administration Item

Appendices to Volume 3

Appendix A Validating CDA Documents using the Framework

A.1 Validating Documents

For validation of document content modules please refer to PCC TF-2: Appendix B.1.

A.2 Validating Sections

For validation of section content modules please refer to PCC-TF 2: Appendix B.2.

A.3 Phases of Validation and Types of Errors

For the phases of validation and types of errors please refer to PCC TF-2: Appendix B.3.

Appendix B Extensions to CDA Release 2

B.1 IHE PHARM Extensions

All Extensions to CDA Release 2.0 created by the IHE PHARM Technical Committee are in the namespace urn:ihe:pharm.

The approach used to create extension elements created for the PHARM Technical Framework is the same as was used for the PCC Technical Framework, the HL7 Care Record Summary (see Appendix E) and the ASTM/HL7 Continuity of Care Document (see Section 7.2).

B.1.1 Used for Medicine Entry Content Module

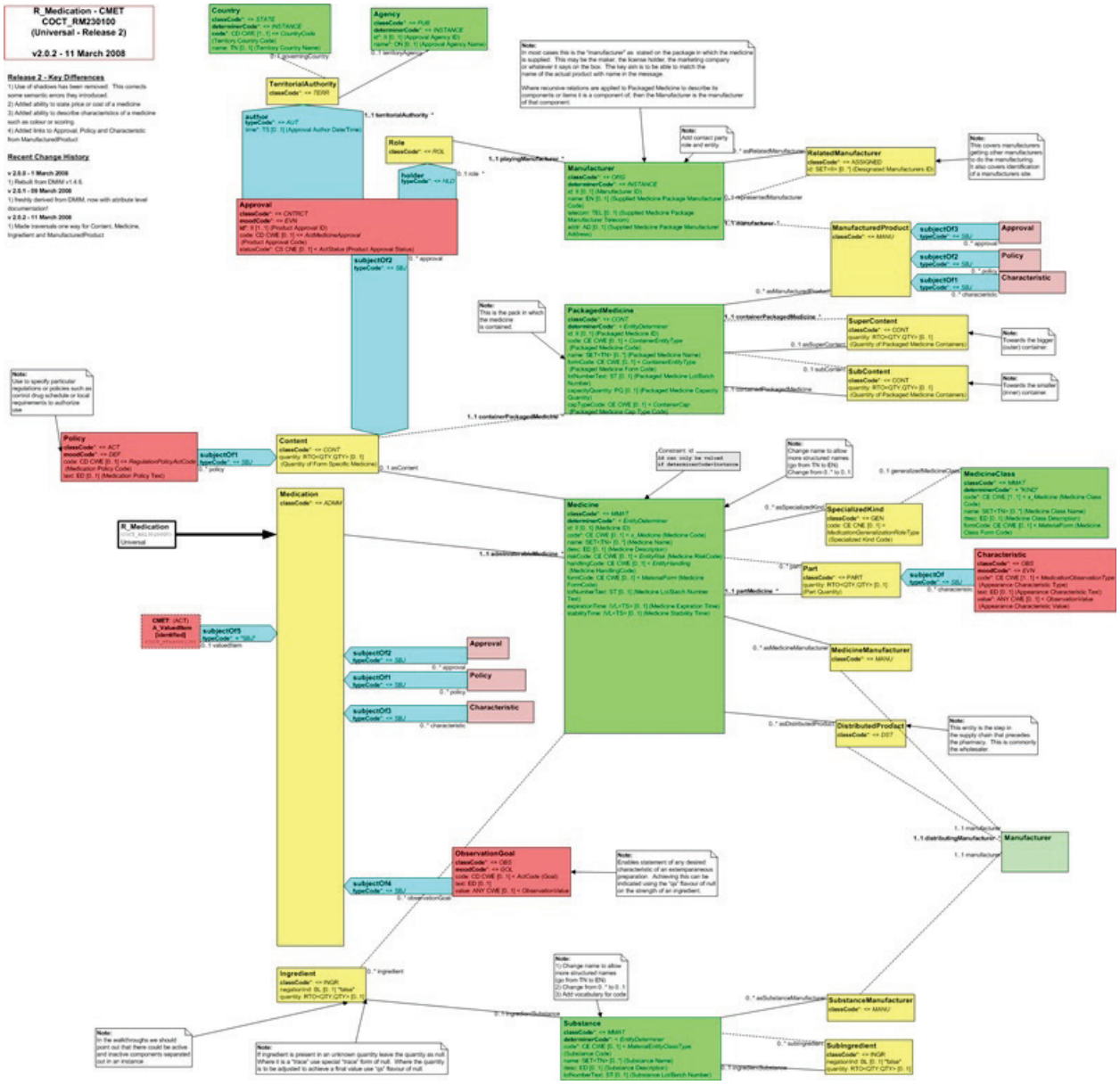
The extensions of CDA Release 2 used for the Medicine Entry Content Module are derived of a medication structure based on a standard HL7 V3 Common Message Element Type (CMET) created by the HL7 Pharmacy group. The used CMET is **"R_Medication Universal" (COCT_MT230100UV), Release 2** and fits within the overall entry by extending the "Manufactured Product" structure of the CDA "substanceAdministration" branch.

This structure is part of the HL7 V3 2009 Normative Edition (COCT_RM230100UV). The incorporation of this structure is done according to Section ***1.4 CDA Extensibility*** of the HL7 CDA standard. Such an extension of the base CDA standard is an accepted practice in IHE (e.g., in the XD* Lab specification).

The rules of Section ***1.4 CDA Extensibility*** require the designation of a new XML namespace for the XML elements in this structure. For the purposes of documentation, the **namespace *urn:ihe:pharm*** shall be used.

```
<manufacturedMaterial xmlns:pharm="urn:ihe:pharm" classCode="MMAT" determinerCode="KIND">
    <templateId root="1.3.6.1.4.1.19376.1.9.1.3.1"/>
    <!-- National medicinal product code (brand-level) -->
    <code code=" " displayName=" " codeSystem=" " codeSystemName=" "/>
    <!-- Brand name -->
    <name>... </name>
    <!-- Pharmaceutical dose form -->
    <pharm:formCode code=" " displayName=" "
                    codeSystem=" " codeSystemName=" "/>
    <lotNumberText>...</lotNumberText>
    <pharm:expirationTime value=' '/>
    <!-- Container information -->
    <pharm:asContent classCode="CONT">
        <pharm:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">
            <!-- Medicinal product code (package-level) -->
            <pharm:code code=" " displayName=" " codeSystem=" " codeSystemName=" "/>
            <!-- Brand name (package) -->
            <pharm:name>...</pharm:name>
            <pharm:formCode code=" " displayName="  "
                   codeSystem=" " codeSystemName="  "/>
            <pharm:capacityQuantity value=" " unit=" "/>
            <pharm:asSuperContent>
                <pharm:containerPackagedMedicine classCode='CONT'
                             determinerCode='INSTANCE'>
                    <pharm:capacityQuantity value=' ' unit=' '/>
                </pharm:containerPackagedMedicine>
            </pharm:asSuperContent>
        </pharm:containerPackagedMedicine>
    </pharm:asContent>
    :
</manufacturedMaterial>
```

The detailed usage is shown in the specification of the Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1) within the PHARM Technical Framework.



Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

- Community Prescription (PRE) Document Content Module
  - 1.3.6.1.4.1.19376.1.9.1.1.1
- Prescription Section Content Module
  - 1.3.6.1.4.1.19376.1.9.1.2.1
- Medicine Entry Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.1
- Prescription Item Entry Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.2
- Dosage Instructions Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.6
- Amount of units of the consumable Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.8
- Substitution Permission Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.9.1
- Reference to Medication Treatment Plan Item Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.10
- Reference to Prescription Item Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.11
- Reference to Dispense Item Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.12
- Reference to Pharmaceutical Advice Item Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.13
- Reference to Medication Administration Item Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.14
- Renewal Period Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.15
- Validation Step Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.16