Integrating the Healthcare Enterprise

5

IHE Pharmacy
Technical Framework Supplement

Pharmacy Prescription
(PRE)

15

Trial Implementation

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Foreword

This is a supplement to the forthcoming 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 submitted for Trial Implementation as of September 27, 2012 and will be
available for testing at subsequent IHE Connectathons. The supplement may be amended based
on the results of testing. Following successful testing it will be incorporated into the forthcoming
Pharmacy Technical Framework. Comments are invited and may be submitted at
http://www.ihe.net/pharmacy/pharmacycomments.cfm or by email to pharmacy@ihe.net.

This supplement introduces a new forthcoming technical framework and where indicated amends
text by addition (**bold underline**) or removal (**bold strikethrough**), as well as addition of large
new sections introduced by editor's instructions to "add new text" or similar, which for
readability are not bolded or underlined. "Boxed" instructions like the sample below indicate to
the Volume Editor how to integrate the relevant section(s) into the relevant Technical
Framework volume:

Replace Section X.X by the following:

General information about IHE can be found at: www.ihe.net

Information about the IHE Pharmacy domain can be found at:
http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at:
http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of IHE Technical Frameworks can be found at:
http://www.ihe.net/Technical_Framework/index.cfm

CONTENTS

50

90

Introduction

The Pharmacy Prescription Document Profile (PRE) describes the content and format of a 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 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 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?
- 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".

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)

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[1] The first seven documents can be located on the IHE Website at http://www.ihe.net/Technical_Framework/index.cfm. The remaining documents can be obtained from their respective publishers.

Volume 1 – Profiles

120

Add the following to section 1.n

1.n Copyright Permissions

Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights
125 reserved. Material drawn from these documents is credited where used.

Add the following to section 2.5

2.5 Dependencies of the Pharmacy Integration Profiles

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

130 *Add the following to section 2.7*

2.7 History of Annual Changes

Add Section 3

3 Pharmacy Prescription Content Profile

135   The Pharmacy Prescription Document Profile (PRE) describes the content and format of a 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.

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

3.1 Purpose and Scope

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

A 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
150   of a clinical decision.

This profile defines the content and format of such a 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.

155

3.2 Process Flow

3.2.1 Use Case 1: Placing a prescription

160   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
165   preparing the prescription. After the prescription is completely assembled it shall be submitted to the Community Pharmacy Prescription and Dispense system to be validated and dispensed.

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

3.3 Actors/Transactions

170   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 Actor. A Document Consumer, a Document
175   Recipient or a Portable Media Importer may embody the Content Consumer Actor. 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

180

Figure 3.3-1: Actor Diagram

185

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.

190

Table 3.4-1: Pharmacy 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) Section Import Option (See Note 1) Discrete Data Import Option (See Note 1)	PCC TF-2: 3.1.2 PCC TF-2: 3.1.3 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

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

3.5.1 Community Pharmacy 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
200 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.

205 ## 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.

210 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
215 verify document integrity and authorizations (DSG).

8

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.

220   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.

225   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.

230   ## 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 Pharmacy Prescriptions shall be structured and coded as required by the Pharmacy
235   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.

240

3.7.1 Structure of a Pharmacy Prescription Document

Pharmacy Prescription CDA Document
Pharmacy Prescription Content Module
(1.3.6.1.4.1.19376.1.9.1.1.1)

1..1

Prescription
Prescription Section Content Module
1.3.6.1.4.1.19376.1.9.1.2.1

1..n

Prescription Item
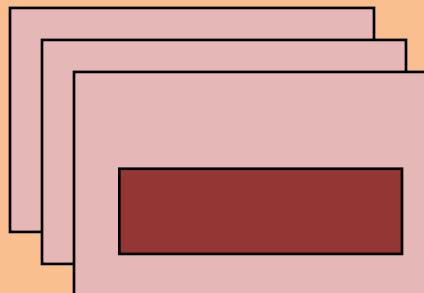*Prescription Item Entry Content Module*
1.3.6.1.4.1.19376.1.9.1.3.2

Includes exactly one

Medication of the Prescription Item
Medicine Entry Content Module
1.3.6.1.4.1.19376.1.9.1.3.1

:

245

Glossary

Add the following terms to the Glossary:

ICA

250   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
255   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
260   ingredients and packaging information.

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).

265   **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
270   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,
275   distribution and billing.

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

280   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			
Pharmacy Prescription (PRE)	urn:ihe:pharm:pre:2010	text/xml	1.3.6.1.4.1.19376.1.9.1.1.1

285

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

290   **6.3.1.1 Pharmacy Prescription Specification 1.3.6.1.4.1.19376.1.9.1.1.1**

This section defines the base set of constraints used by almost all medical document profiles described the PCC Technical Framework.

Structure	Pharmacy 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

12

Structure	Pharmacy 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

295   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
CCD	ASTM/HL7 Continuity of Care Document
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 Address	author/assignedAuthor/addr
HCP Telecom	author/assignedAuthor/telecom
HCP Specialty	author/assignedAuthor/code
HCP Represented 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	HISTORY OF MEDICATION USE

300

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 Address HCP Identification Profession Specialty	R	1.3.6.1.4.1.19376.1.5.3.1.1.1

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[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
HCP Organization Information Name Address Organization Identifier Contact Information		
Patient Information Address Contact Information	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 Drug Sensitivities	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
Resolved Problems	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:

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

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[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.

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.

310 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
315 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>Pharmacy 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

6.3.3 CDA Section Content Modules

340 *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	CCD 3.9 (2.16.840.1.113883.10.20.1.8) 1.3.6.1.4.1.19376.1.5.3.1.3.19	
General Description	The prescription section shall contain a description of the medications in a given prescription for the patient. It shall include entries for each Prescription Item 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>
345     <section>
          <templateId root='2.16.840.1.113883.10.20.1.8'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
          <templateId root='1.3.6.1.4.1.19376.1.9.1.2.1'/>
          <!-- The section ID is the Prescription ID -->
350       <id root=' ' extension=' '/>
          <code code='57828-6' displayName='PRESCRIPTIONS'
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Prescriptions</title>
          <text>
355         Text as described above
          </text>
          <author>
           :
          </author>
360       <!-- Each entry is a Prescription Item -->
          <!-- Prescription Item 1 -->
          <entry>
             :
            <!-- Required element indicating the prescription entry content module -->
365           <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
             :
          </entry>
          <!-- Prescription Item 2 -->
          <entry>
370          :
            <!-- Required element indicating the prescription entry content module -->
              <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
             :
          </entry>
375     </section>
      </component>
```

6.3.3.1.1 Parent Templates

The parents of this template are CCD 3.9 and PCC 1.3.6.1.4.1.19376.1.5.3.1.3.19 except the requirement CCD-CONF-301 ("The value for 'section/code' SHALL be "10160-0" "History of medication use").

17

6.3.3.1.2 Prescription ID

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

A Prescription identifier SHALL be represented in the section <id> Element. The data type of the ID is II. Although HL7 allows for multiple identifiers, one and only one shall be used.

385

> If this section is used in a Prescription document, this identifier shall be set equal to the document ID (ClinicalDocument/id).

6.3.3.1.3 Prescriber

390 **<author>…</author>**

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

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`

395

6.3.4 CDA Entry Content Modules

Add section 6.3.4.1

6.3.4.1 Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2)

400 **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
CCD	ASTM/HL7 Continuity of Care Document
IHE PCC	Medications Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7)

405 **6.3.4.1.2 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.

6.3.4.1.3 Specification

410 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.

The chapters below identify and describe these fields, and indicate the constraints on whether or
415 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'/>
420     <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'/>
        <id root=' ' extension=' '/>
        <code code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
        <text><reference value='#med-1'/></text>
425     <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'>
430       :
        </effectiveTime>
        <routeCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
        <doseQuantity value=' ' unit=' '/>
        <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
435     <rateQuantity value=' ' unit=' '/>
        <consumable>
          :
          <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
          :
440     </consumable>
        <author>
          <functionCode/>
          <time/>
          <assignedAuthor>
445         <id root=' ' extension=' '/>
            <code code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
            <assignedPerson><name></name></assignedPerson>
            <representedOrganization>...</representedOrganization>
          </assignedAuthor>
450     </author>
        <!-- 0..* entries describing the components -->
        <entryRelationship typeCode='COMP' >
          <sequenceNumber value=''/>
            :
455     </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'/>
460         <id root='' extension=''/>
          </act>
        </entryRelationship>
        <!-- Reference to a related prescription activity (supply) -->
        <entryRelationship typeCode='REFR'>
465       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
            :
        </entryRelationship>
        <!-- Optional instructions for the patient -->
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
470       <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' />
475         ...
        </entryRelationship>
        <!-- Optional instructions for Pharmacist -->
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
          <act classCode='ACT' moodCode='INT'>
480         <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' />
```

20

```
485      ...
       </entryRelationship>
       <!-- Amount of units of the consumable to dispense -->
       <entryRelationship typeCode='COMP'>
         <supply classCode='SPLY' moodCode='RQO'>
           <independentInd value='false'/>
490          <quantity value=' ' unit=' '/>
         </supply>
       </entryRelationship>
       <!-- Substitution handling -->
       <entryRelationship typeCode='SUBJ' inversionInd='true'>
495        <observation classCode='OBS' moodCode='EVN'>
           <code code='SUBST' displayName='Substitution'
                 codeSystem='2.16.840.1.113883.5.6' codeSystemName='HL7 ActClass'/>
           <value xsi:type='CE' code=' ' displayName=' '
                 codeSystem='2.16.840.1.113883.5.1070'
500              codeSystemName='HL7 Substance Admin Substitution'/>
         </observation>
       </entryRelationship>
       <precondition>
         <criterion>
505          <text><reference value=''></text>
         </criterion>
       </precondition>
     </substanceAdministation>
```

6.3.4.1.3.1 Prescription Item Entry General Specification

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

   …

</substanceAdministration>

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.2 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 -->**

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.3 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.

21

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.

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

530 **6.3.4.1.3.4 Prescription Item ID**

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

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.5 Substance Administration Code

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.6 Substance Administration Reference Value

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

540 **6.3.4.1.3.7 Substance Administration Status Code**

<statusCode code='completed'/>

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.8 Substance Administration Effective Time

<effectiveTime xsi:type='IVL_TS'>

545 See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.9 Medication frequency

<effectiveTime operator='A'

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

550   See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.10 Route of Administration

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.11 Approach Site Code

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.12 Dose Quantity

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

560   ### 6.3.4.1.3.13 Rate Quantity

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

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.14 Consumable
<consumable>

565   **:**

    <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->

    :

</consumable>

The <consumable> element SHALL be present, and shall contain a <medication> entry,
570   conforming to the Medicine Entry template (1.3.6.1.4.1.19376.1.9.1.3.1).

See PHARM-TF2, Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) specification.

6.3.4.1.3.15 Author

<author>…</author>

In the case where the prescriber or the timestamp of a Prescription Item is different from the
575 author and timestamp of the prescription-section, the prescriber of the Prescription Item MAY be
represented by the <author> element of the <u>entry</u>.

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`

6.3.4.1.3.16 Related components

580 **<entryRelationship typeCode='COMP'>**

    <sequenceNumber value=''/>

     :

</entryRelationship>

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

585 ### 6.3.4.1.3.17 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=' '/>

590   **</act>**

</entryRelationship>

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.1.3.18 Reference to a related prescription activity (supply)

~~<entryRelationship typeCode='REFR'>~~

595   ~~<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>~~

  ~~:~~

 ~~</entryRelationship>~~

See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

This element shall not be present.

600 ### 6.3.4.1.3.19 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'/>

605   **<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. If
610 provided, it shall conform to the requirements listed for Patient Medication Instructions. The
instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional
dosing), and may contain other information (take with food, et cetera).

6.3.4.1.3.20 Fulfillment Instructions

<entryRelationship typeCode='SUBJ' inversionInd='true'>

615   **<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' />

620   **...**

 </entryRelationship>

25

An entry relationship MAY be present to provide the fulfillment instructions. When present, this entry relationship shall contain a [Medication Fulfillment Instructions](#)

625 (1.3.6.1.4.1.19376.1.5.3.1.4.3.1) entry.

6.3.4.1.3.21 Amount of units of the consumable to dispense

<entryRelationship typeCode='COMP'>

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

     <independentInd value='false'/>

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

   </supply>

</entryRelationship>

This element SHALL be present and describes the amount of units to be dispensed.

The medication in the consumable - element describes a manufactured medication (e.g.,
635 "Paracetamol 30mg"). It also may contain package information (e.g., "Paracetamol 30mg, 30 tablets package"). The following rules shall indicate to which the <quantity> element relates to (either manufactured medication or package):

- If the manufactured medication also contains package information, the <quantity> element is considered to contain the amount of packages of the medication. In this case the unit attribute
640   shall be not present.

- If the manufactured medication does not contain package information, the <quantity> element is considered to 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 SHALL be out of the UCUM code system.

645 ### 6.3.4.1.3.22 Substitution handling

<entryRelationship typeCode='COMP'>

   <supply classCode="SPLY"

       moodCode="RQO">

   <independentInd value="false" />

650   **<pharm:subjectOf4>**

     <pharm:substitutionPermission

       classCode="SUBST"

       moodCode="PERM">

       <pharm:code code=' '

655   **displayName=' '**

---

codeSystem='2.16.840.1.113883.5.1070'

codeSystemName='HL7 Substance Admin Substitution'/>

    </pharm:substitutionPermission>

   </pharm:subjectOf4>

660   **</supply>**

</entryRelationship>

One or more <entryRelationship> elements, each containing one and only one <pharm:subjectOf4> element, MAY be present and describe the substitution handling.

665   The <value> 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.

http://www.hl7.org/v3ballot/html/infrastructure/vocabulary/substanceAdminSubstitution.htm

670   **6.3.4.1.3.23 Precondition Criterion**

<precondition>

  <criterion>

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

  </criterion>

675   **</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.

680   See PCC TF2, Medication Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7) specification.

6.3.4.2 Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1)

The Medicine Entry content module describes a medication used in a <substanceAdministration> or <supply> act. 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 a 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:medication* shall be used.

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

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

6.3.4.2.2 Parent Template

This entry content module has no parent structure.

6.3.4.2.3 Specification

```
<manufacturedProduct xmlns:pharm="urn:ihe:pharm:medication" 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">
        <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=" "/>
        <!-- Container information -->
        <pharm:asContent classCode="CONT">
            <pharm:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">
                <!-- National 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:lotNumberText>...</pharm:lotNumberText>
                <pharm:capacityQuantity value=" " unit=" "/>
            </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>
              <pharm:numerator xsi:type="PQ" value=" " unit=" "/>
              <pharm: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>
              <pharm:numerator xsi:type="PQ" value=" " unit=" "/>
              <pharm: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>
</manufacturedProduct>
```

6.3.4.2.3.1 Medication Template ID

< templateId root='1.3.6.1.4.1.19376.1.9.1.3.1'/>

770

The Template ID for a Medicine Entry SHALL be provided.

6.3.4.2.3.2 Medication Code (brand-level)

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>
** <originalText>**

775   **<reference value=' '/>**

  </originalText>

</code>

The <code> element of the <manufacturedMaterial> element SHALL be present and describes
780 the code of the branded medication (without packaging).

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

6.3.4.2.3.3 Medication Brand Name

< name>…</ name>

785 The element SHALL contain the brand name of the medication without packaging information
(e.g.,"Paracetamol 30mg").

6.3.4.2.3.4 Medication Form Code

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

This code represents the pharmaceutical dose form (e.g. tablet, capsule, liquid) and SHOULD be
790 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.

6.3.4.2.3.5 Medication Packaging

<pharm:asContent classCode='CONT'>
** <pharm:containerPackagedMedicine classCode='CONT'**
795   **determinerCode='INSTANCE'>**
    <!-- National medicinal product code (package-level) -->
    <pharm:code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
    <!-- Brand name (package) -->
    <pharm:name>...</pharm:name>
800   **<pharm:formCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>**

30

```
        <pharm:lotNumberText>...</pharm:lotNumberText>
        <pharm:capacityQuantity value=' ' unit=' '/>
      </pharm:containerPackagedMedicine>
  </pharm:asContent>
```

805 This structure describes the packaging of the medication and MAY be present.

The <pharm:code> element provides the code for the particular package and SHOULD be present.

If the package has a brand name, it SHOULD be described in the <pharm:name> element (e.g., Paracetamol 30mg, 30 tablets package).

810 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.

The <pharm:lotNumberText> element MAY be present and is a string representation of a possible lot number.

815 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.

820 For example, to represent 30 tablets, the pharmaceutical dose form (<pharm:formCode> of the medication, see chapter "Medication Form Code") must indicate tablets as the form, value attribute of the <pharm:capacityQuantity> element must be set to the value of 30, and the unit attribute must not be present.

6.3.4.2.3.6 Medication Generic Equivalent

825
```
<pharm:asSpecializedKind classCode='GRIC'>
   <pharm:generalizedMedicineClass classCode='MMAT'>
     <pharm:code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
     <pharm:name>…</pharm:name>
   </pharm:generalizedMedicineClass>
```
830
```
</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
835 <pharm:name> element may be used for the plain text representation.

6.3.4.2.3.7 Medication Active Ingredient List

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

850 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 SHALL be present and contains the coded representation of the ingredient and the <pharm:name> element SHALL be present and is used for the plain text representation. The WHO ATC terminology SHOULD be used to code the ingredients, where applicable.

855 The medication strength is represented as the ratio of the active ingredient(s) to a unit of medication. The <pharm:quantity> element SHALL 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:

860

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

865

32

Appendix A Validating CDA Documents using the Framework

A.1 Validating Documents

870   For validation of document content modules please refer to PCC-TF2, Appendix A.1.

A.2 Validating Sections

For validation of section content modules please refer to PCC-TF2, Appendix A.2.

A.3 Phases of Validation and Types of Errors

For the phases of validation and types of errors please refer to PCC-TF2, Appendix A.3.

875   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:medication.

The approach used to create extension elements created for the PHARM Technical Framework is
880   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)
885   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
890   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:medication*** shall be used.

895

```
<manufacturedProduct xmlns:pharm="urn:ihe:pharm:medication" classCode="MANU">
    <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=" "/>
        <!-- Container information -->
        <pharm:asContent classCode="CONT">
            <pharm:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">
                <!-- National 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:lotNumberText>...</pharm:lotNumberText>
                <pharm:capacityQuantity value=" " unit=" "/>
            </pharm:containerPackagedMedicine>
        </pharm:asContent>
      :
```

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905

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915

920

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.

The model for this extension is shown in the following diagram. The current version of the
model is shown at:

925 http://www.hl7.org/v3ballot/html/domains/uvct/editable/COCT_RM230100UV.htm