

Integrating the Healthcare Enterprise



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**IHE Pharmacy
Technical Framework Supplement**

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**Pharmacy Dispense
(DIS)**

15

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

30 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 published on October 23, 2015 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the forthcoming
35 Pharmacy Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/Pharmacy_Public_Comments.

This supplement describes changes to the existing technical framework documents.

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

40

<i>Amend Section X.X by the following:</i>
--

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.

45

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

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

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

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

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Introduction

125 The Pharmacy Dispense Document Profile (DIS) describes the content and format of a dispense document generated during the process in which a health care professional (in most cases, but not necessarily always, a pharmacist) hands out a medication to a patient.

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

130 This supplement also references other documents¹. 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](#)
- 135 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

140 Open Issues and Questions

- How to deal with dispenses which should be performed on behalf of a prescription which is not available yet?
- Dispense 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”.

145 Closed Issues

- Dispense Item Entry Content Module: epSOS introduced an entryRelationship Element for indicating that a Substitution has occurred during dispense. Shall this concept be included in this specification too? Yes, it has been included (see CP-PHARM-019).

¹ The first seven documents can be located on the IHE Website at http://ihe.net/Technical_Frameworks/. The remaining documents can be obtained from their respective publishers.

150

Volume 1 – Profiles

Add the following to Section 1.n

1.n Copyright Permission

155 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 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 Dispense (DIS)	PCC	Content definition	This profile includes Section and Entry Content Modules of the Patient Care Coordination (PCC) domain.
-------------------------	-----	--------------------	--

160

Add the following to Section 2.7

2.7 History of Annual Changes

Add Section 3

3 Pharmacy Dispense Content Profile

165 The Pharmacy Dispense Document Profile (DIS) describes the content and format of a dispense document generated during the process in which a health care professional (in most cases, but not necessarily always, a pharmacist) hands out a medication to a patient.

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

170 **3.1 Purpose and Scope**

The Community Pharmacy Prescription and Dispense workflow includes the stage of dispensing medication by a health care professional, usually a pharmacist, to the patient.

175 A dispense document is the documentation of the performed dispense. It contains the referred prescription (if available), the actual dispensed medication and other additional information concerning the dispense act.

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

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

180

185 **3.2 Process Flow**

3.2.1 Use Case 1: Dispensing a prescribed item

A patient enters the community pharmacy and requests a Prescription Item to be dispensed. The dispense act refers to the initially prescribed item and leads to a medication product actually dispensed.

190 Usually the pharmacist uses the pharmacy information system for preparing the dispense. After the dispense is completely assembled it shall be submitted to the Community Pharmacy Prescription and Dispense system.

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

195 **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 Actor. A Document Consumer, a Document 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.

205



Figure 3.3-1: Actor Diagram

210 **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: Pharmacy Dispense 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	

215

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.

220

3.5.1 Community Pharmacy Dispense 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.

225

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

230

The DIS 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 DIS.

235

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).

240

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 DIS Profile does have a few security considerations of its own.

245 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.

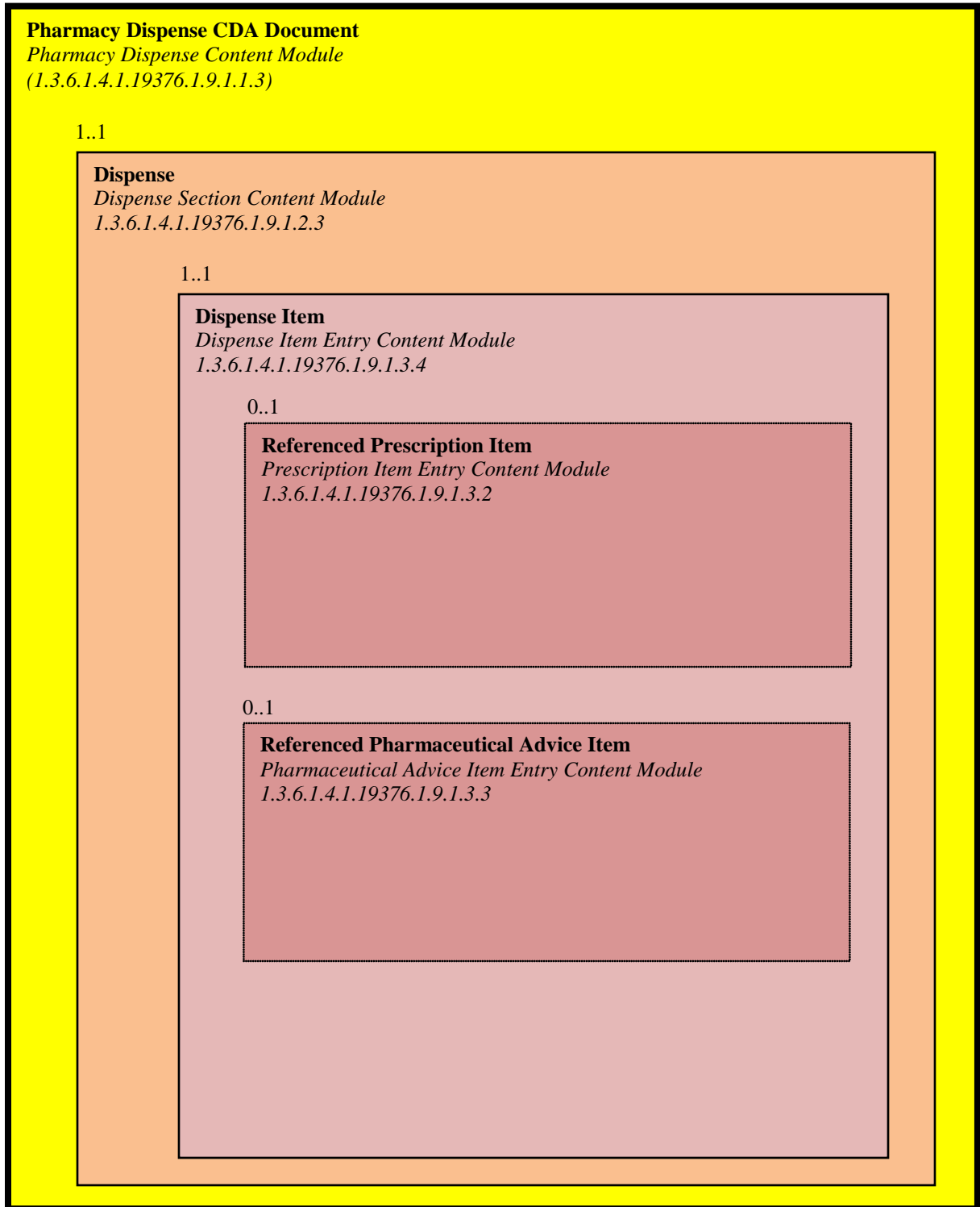
250 Because the information being transferred is in XML, it will be common that different Pharmacy systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and 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

255 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.

260 All Pharmacy Dispenses shall be structured and coded as required by the Pharmacy Dispense 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 Pharmacy Dispense Document



Glossary

The glossary of the Pharmacy Prescription is applicable to this supplement and described in the “Pharmacy Prescription (PRE)” supplement.

270

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

275 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 Dispense (DIS)	urn:ihe:pharm:dis:2010	text/xml	1.3.6.1.4.1.19376.1.9.1.1.3

280 6.0 Pharmacy Content Modules

6.3 HL7® Version 3.0 Content Modules

6.3.1 CDA® Document Content Modules

Add Section 6.3.1.3

6.3.1.3 Pharmacy Dispense Specification 1.3.6.1.4.1.19376.1.9.1.1.3

285 The Pharmacy Dispense specification includes a Dispense section to capture a Dispense Item representing a dispensed medication to a patient as well as supporting sections containing information related to this dispensation (e.g., diagnosis, etc.).

Structure	Pharmacy Dispense
Format Code	urn:ihe:pharm:dis:2010
LOINC Code	60593-1 (Medication dispensed)
Document Template ID	1.3.6.1.4.1.19376.1.9.1.1.3
Section name / template ID	Dispense 1.3.6.1.4.1.19376.1.9.1.2.3

Structure	Pharmacy Dispense
Entry name / template ID	Dispense Item 1.3.6.1.4.1.19376.1.9.1.3.4
Medicine Content Entry Module template ID	Medication of Dispense Item 1.3.6.1.4.1.19376.1.9.1.3.1

6.3.1.3.1 Format Code

290 The XSDDocumentEntry format code for this content is **urn:ihe:pharm:dis:2010**.

6.3.1.3.2 Parent Template

This document is an instance of the Medical Document template (1.3.6.1.4.1.19376.1.5.3.1.1.1).

6.3.1.3.3 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

295

6.3.1.3.4 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 Represented Organization	author/assignedAuthor/representedOrganization
HCP Organization Name	author/assignedAuthor/representedOrganization/name
HCP Organization Address	author/assignedAuthor/representedOrganization/addr

Data Elements	CDA Release 2.0
HCP Organization Telecom	author/assignedAuthor/representedOrganization/telecom
Service Event²	documentationOf/serviceEvent
Date of Service Event	documentationOf/serviceEvent/effectiveTime
Service Event Code	documentationOf/serviceEvent/code
Encounter in the healthcare institution³	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 Other Adverse Reactions	ALLERGIES, ADVERSE REACTIONS, ALERTS
Active Problems	PROBLEM LIST
History of Past Illness	HISTORY OF PAST ILLNESS
Immunizations	HISTORY OF IMMUNIZATIONS
Pregnancy History	HISTORY OF PREGNANCIES
Dispense	MEDICATION DISPENSED.BRIEF

6.3.1.3.5 Data Element Specification

Data Element Name	Opt	Template ID
<u>Patient Information</u> Name Personal Identification Gender Date of Birth <u>HCP Person Information</u> Name HCP Identification <u>HCP Organization Information</u> Name	R	1.3.6.1.4.1.19376.1.5.3.1.1.1

² Service Event is optional and may only be used if the dispense has been taken without a prescription. In this case it may contain service event information of the medical event in which context the dispense act has been taken.

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

Data Element Name	Opt	Template ID
Address Organization Identifier Contact Information		
<u>Patient Information</u> Address Contact Information <u>HCP Person Information</u> Profession Specialty	R2	1.3.6.1.4.1.19376.1.5.3.1.1.1
<u>Patient Information</u> Marital Status Race Ethnicity Religious Affiliation <u>HCP Person Information</u> 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
<u>Dispense</u>	R	1.3.6.1.4.1.19376.1.9.1.2.3

300

Additional explanation:

The sections “Coded Vital Signs”, “Allergies and Other Adverse Reactions”, “Active Problems”, “History of Past Illness”, “Immunizations”, and “Pregnancy History” are considered as sections containing medical information of the patient.

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.

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

6.3.1.3.6 Conformance

310 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.

315

```

<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='1.3.6.1.4.1.19376.1.9.1.1.3' />
  <id root=' ' extension=' ' />
  <code code='60593-1' displayName='Medication dispensed'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
  <title>Pharmacy Dispense</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>
    
```

320

325

330

335

6.3.2 CDA® Header Content Modules

6.3.3 CDA® Section Content Modules

Add Section 6.3.3.3

6.3.3.3 Dispense Section Content Module (1.3.6.1.4.1.19376.1.9.1.2.3)

340

Template ID	1.3.6.1.4.1.19376.1.9.1.2.3	
Parent Template	CCD 3.9 (2.16.840.1.113883.10.20.1.8)	
General Description	The Dispense Section contains a description of a medication dispensed for the patient. It includes exactly one Dispense Item entry as described in the Dispense Item Entry Content Module.	
LOINC Code	Opt	Description
60590-7	R	MEDICATION DISPENSED.BRIEF
Entries	Opt	Description
1.3.6.1.4.1.19376.1.9.1.3.4	R	Dispense Item Entry Content Module

345

350

355

360

365

```

<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.8' />
    <templateId root='1.3.6.1.4.1.19376.1.9.1.2.3' />
    <!-- The section ID is the Dispense ID -->
    <id root=' ' extension=' ' />
    <code code='60590-7' displayName='MEDICATION DISPENSED.BRIEF'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <title>Medication dispensed</title>
    <text>
      Text as described above
    </text>
    <author>
      :
    </author>
    <!-- Dispensed medication -->
    <entry>
      :
      <!-- Required element indicating the Dispense entry content module -->
      <supply>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4' />
        :
      </supply>
    </entry>
  </section>
</component>

```

6.3.3.3.1 Parent Templates

370

The parent of this template is CCD® 3.9 except the requirement CCD-CONF-301 (“The value for 'section/code' SHALL be “10160-0” “History of medication use”).

6.3.3.3.2 Dispense ID

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

375 A Dispense 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.

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

380 6.3.3.3.3 Dispenser

<author>...</author>

In the case the Dispenser or the timestamp of a Dispense is different from the author and timestamp of the Dispense-document, the Dispenser and timestamp of the Dispense SHALL be represented by the <author> element of the section.

385

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

6.3.4 CDA® Entry Content Modules

Add Section 6.3.4.5

6.3.4.5 Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4)

390 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.

6.3.4.5.1 Standards

395 This part describes the general structure for a Dispense 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) Supply Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7.3)

6.3.4.5.2 Parent Template

400 This entry content module inherits the structure of the Supply Entry Content Module, 1.3.6.1.4.1.19376.1.5.3.1.4.7.3.

6.3.4.5.3 Specification

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

This specification relies on the PCC Supply Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification and only describes additional constraints.

405 The sections 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.

```

410 <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' />
    <id root='' extension='' />
    <code code='' displayName='' codesystem='2.16.840.1.113883.5.4'
415     codeSystemName='ActCode' />
    <text><reference value=' ' /></text>
    <repeatNumber value='' />
    <quantity value='' unit='' />
    <product>
420     :
     <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
     :
    </product>
    <performer typeCode='PRF' />
    <!--
425     1. author element
       Author of the prescription this dispense references to
       in case of usage elsewhere as in a DIS document
    -->
    <author>
430     :
    </author>
    <!--
     2. author element
435     Dispenser of the Dispense Item
       in case of usage elsewhere as in a DIS document
    -->
    <author>
440     :
    </author>
    <!--
       referenced Prescription Item by which this dispense was performed
445     must not be present if the dispense was performed without prescription
    -->
    <entryRelationship typeCode='REFR'>
     <substanceAdministration classCode="SBADM" moodCode="INT">
450       <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>
    <!--
455     referenced pharmaceutical advice by which this dispense was performed
       must not be present if the dispense was performed without prescription
    -->
    <entryRelationship typeCode='REFR'>
     <observation classCode='OBS' moodCode='EVN'>
460       <templateId root='1.3.6.1.4.1.19376.1.9.1.3.3' />
       :
     </act>
    </entryRelationship>
    <!-- Optional instructions for the patient -->
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
465     <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' />
       ...
470     </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' />

```

```

475         <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='IHEActionCode' />
         ...
480     </entryRelationship>
     <!-- Optional dosage instructions, if differs from Prescription Item -->
     <entryRelationship typeCode="COMP">
       <substanceAdministration moodCode="INT" classCode="SBADM">
         <effectiveTime xsi:type='IVL_TS'>
485           <low value=' '/>
           <high value=' '/>
         </effectiveTime>
         <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPRTS'>
           :
490         </effectiveTime>
         <routeCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
         <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
         <doseQuantity value=' ' unit=' '/>
         <rateQuantity value=' ' unit=' '/>
495         <consumable>
           <manufacturedProduct>
             <manufacturedMaterial nullFlavor='NA' />
           </manufacturedProduct>
         </consumable>
500       </substanceAdministration>
     </entryRelationship>
  </supply>

```

6.3.4.5.3.1 Dispense Item Entry General Specification

```

505 <supply classCode='SPLY' moodCode='EVN'>
  ...
</supply>

```

The <supply> element SHALL be present and represents the actual dispense. The moodCode attribute shall be EVN to reflect that a medication has been dispensed.

6.3.4.5.3.2 Dispense Item Entry TemplateID

```

510 <templateId root='2.16.840.1.113883.10.20.1.34' />           <!-- CCD -->
     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />     <!-- PCC -->
     <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4' />         <!-- PHARM -->

```

See PCC TF2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

6.3.4.5.3.3 Dispense Item ID

```

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

```

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

See PCC TF2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

6.3.4.5.3.4 Code

```

<code code="" displayName="" codesystem='2.16.840.1.113883.5.4'

```

520 `codeSystemName='ActCode'/>`

In case the Dispense Item references an underlying Prescription Item the code of a Dispense Item SHOULD be set to a value out of the value-set below (which is a sub-set of the HL7® value-set “ActPharmacySupplyType”, 2.16.840.1.113883.1.11.16208) and is indicating whether the Dispense Item is just partly fulfilling or fully fulfilling the underlying Prescription Item.

525 Full dispense

A full dispense is a dispense fully fulfilling an underlying prescription “at once”.

- In this case the code “**First Fill - Complete**” SHALL be set.
- The code “**First Fill - Complete**” is also induced if the element is not present.

Partial dispense

530 A partial dispense is a dispense partly fulfilling an underlying prescription.

- In the case that this dispense is the first partial dispense, the code SHALL be set to “**First Fill - Part Fill**”.
- In the case that this dispense is not the first partial dispense, but not fulfilling the underlying prescription, the code SHALL be set to “**Refill - Part Fill**”.

535 • In the case that this dispense is the last partial dispense, finally fulfilling the underlying prescription, the code SHALL be set to “**Refill - Complete**”.

code	displayName
Full dispense	
FFC	First Fill - Complete
Partial dispense	
FFP	First Fill - Part Fill
RFP	Refill - Part Fill
RFC	Refill - Complete

Example

540 The Prescriber issues a long-term Prescription Item for a medication with a treatment duration of 6 months intended to be partially dispensed by the Pharmacist every month. The following dispense process occurs:

545 The Dispenser records the first partial dispense of the medication with code “First Fill - Part Fill”, indicating that the Prescription Item is just partly fulfilled and further Dispensations are expected.

The Dispenser records the following 4 partial dispenses of the medication with code “Refill - Part Fill”.

The Dispenser records the last (6th) partial dispense with code “Refill - Complete” indicating that the Prescription Item is now fully fulfilled.

550 **6.3.4.5.3.5 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 dispensed.

555 **6.3.4.5.3.6 Repeat Number**

`<repeatNumber value=' '/>`

The repeatNumber SHALL NOT be present.

6.3.4.5.3.7 Quantity Value

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

560 The supply entry SHALL be present and indicate the quantity supplied.

The medication in the `<product>` element describes either (1) a manufactured medication (e.g., “Adol 500mg Caplet”) or (2) a descriptor of a magistral preparation/compound medicine. It also may contain package information (e.g., “Adol 500mg Caplet, 30 tablets package”) in the `<pharm:asContent>` element. The following rules shall indicate to which the `<quantity>` element relates to (either manufactured medication or package):

565

- If the `<product>` - element also contains package information, the `<quantity>` element SHALL contain the amount of packages of the medication. The value shall refer to the primary layer of the package information given in the `<pharm:asContent>` element of the product (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 dispensed). 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.

570

- If the `<product>` - 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.

575

- If no medication has been dispensed for any reason, but the act is still considered as completed (non-dispense) this SHALL be recorded with the value of quantity set to zero and unit being not present.

580

See PCC TF2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

6.3.4.5.3.8 Product

<product>

585 :
 <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
 :

</product>

590 The <product> element SHALL be present, and SHALL contain a <manufacturedProduct> element, conforming to the Medicine Entry Content Module. This element represents the actual medication dispensed.

See PHARM-TF3, Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) specification.

6.3.4.5.3.9 Dispenser

<performer typeCode='PRF'>... </performer>

The <performer> element SHALL NOT be present.

595 Note: The Dispenser will be recorded in a second author element. See chapter 6.3.4.5.3.11.
 See PCC TF2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

6.3.4.1.3.10 Author of the Prescription Item to the dispense

<author>...</author>

600 In the case that the Dispense Item is used within a Dispense document according to the “Pharmacy Dispense” (DIS) Profile this element SHALL NOT be present.

605 In all other cases (e.g., when used in a “Pharmacy Medication List” document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.) this first author element SHOULD be present and represent the prescriber of the Dispense Item (if applicable). It SHALL contain the author and the timestamp of the Prescription document in which the Prescription Item this Dispense Item references to was described (or, if given, the author of the Prescription section within the Prescription document).

610 This first author element SHALL be present in case that the “Dispenser” is present (see chapter 6.3.4.5.3.11). In case it is present, but does not contain Prescriber information (e.g., because the dispense was an OTC medication without prescription), the first author element SHALL be nullFlavor=”NA”.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber Profession	CE	<i>author/functionCode</i>
Timestamp of prescribing	TS	<i>author/time</i>

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber ID	II	<i>author/assignedAuthor/id</i>
Prescriber Specialty	CE	<i>author/assignedAuthor/code</i>
Prescriber Name	PN	<i>author/assignedAuthor/assignedPerson/name</i>
Prescriber Organization Identifier	II	<i>author/assignedAuthor/representedOrganization/id</i>
Prescriber Organization Name	ON	<i>author/assignedAuthor/representedOrganization/name</i>
Prescriber Organization Address	AD	<i>author/assignedAuthor/representedOrganization/addr</i>

6.3.4.5.3.11 Dispenser

<author>...</author>

615 In the case that the Dispense Item is used within a Dispense document according to the “Pharmacy Dispense” (DIS) Profile this element SHALL NOT be present.

In all other cases (e.g., when used in a “Pharmacy Medication List” document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.) this second author element SHOULD be present and represent the dispenser of the Dispense Item. It SHALL contain the author and the timestamp of the Dispense document in which the Dispense Item was described (or, if given, the author of the Dispense section within the Dispense document).

620 This second author element SHALL be present in case that the “Author of the Prescription Item to the dispense” is present (see chapter 6.3.4.5.3.10).

625

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Dispenser Profession	CE	<i>author/functionCode</i>
Timestamp of the Dispense	TS	<i>author/time</i>
Dispenser ID	II	<i>author/assignedAuthor/id</i>
Dispenser Specialty	CE	<i>author/assignedAuthor/code</i>
Dispenser Name	PN	<i>author/assignedAuthor/assignedPerson/name</i>
Dispenser Organization Identifier	II	<i>author/assignedAuthor/representedOrganization/id</i>
Dispenser Organization Name	ON	<i>author/assignedAuthor/representedOrganization/name</i>

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Dispenser Organization Address	AD	<i>author/assignedAuthor/representedOrganization/addr</i>

6.3.4.5.3.12 Reference to Prescription Item

... Prescription Item Id only ...

<entryRelationship typeCode='REFR'>

```

630 <substanceAdministration classCode='SBADM' moodCode='INT'>
      <id root=' ' extension=' '/>      <!-- Prescription Item Id -->
      <code code='PREItem'
            codeSystem='1.3.6.1.4.1.19376.1.9.2.2'
            displayName='Prescription Item'
635     codeSystemName='IHE Pharmacy Item Type List'/>
      <consumable>
        <manufacturedProduct>
          <manufacturedMaterial nullFlavor='NA'/>
        </manufacturedProduct>
640 </consumable>
      </substanceAdministration>
</entryRelationship>

```

... or complete copy of Prescription item ...

<entryRelationship typeCode='REFR'>

```

645 <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'/>
      :
650 </substanceAdministration>
</entryRelationship>

```

The reference to the Prescription Item this dispense is related to SHALL be present, containing either (1) the Id of the Prescription Item referenced or (2) a whole Prescription Item Entry described in the Pharmacy Prescription (PRE) Content Profile.

655 (1) In case the reference **contains just the Id of the Prescription Item** the following constraints SHALL be met:

- The Id (<id> element) SHALL be present and SHALL contain the Id of the referenced Prescription Item.
- The type of the Id (<code> element) SHOULD be present and SHALL contain the code “PREItem” out of the **IHE Pharmacy Item Type List** value-set.
- The <consumable> element SHALL be present and SHALL contains a <manufacturedProduct/manufacturedMaterial> element which is nullFlavored to “NA”.

660

(2) In case the reference **contains a whole Prescription Item Entry** the following constraints SHALL be met:

- The Prescription Item SHALL be declared as an unchanged copy of the referenced Prescription Item according to the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2), with the following exception:
- In case the Prescription Item contains a “reason for the use of the medication”⁷, according to the specification of an “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 internal information referenced, if this information is not available in the Dispense document. In this case the complete copy SHALL be modified and all reason(s) set to nullFlavor=MSK (“masked”: masked, confidential, not published).

670

675 Example: nullFlavored reason of a Prescription Item Entry:

```
<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 nullFlavor="MSK"/>  
    <code nullFlavor="NA"/>  
  </act>
```

680

Dispensing without prescription: This element must not be present if the dispense was performed without prescription.

685 **6.3.4.5.3.13 Reference to Pharmaceutical Advice**

... Pharmaceutical Advice Item Id only ...

⁷ see chapter “Reason” of the Pharmacy Prescription (PRE) Profile

<entryRelationship typeCode='REFR'>

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

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

690

**<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'/'>**

</observation>

695

</entryRelationship>

... or complete copy of Pharmaceutical Advice item ...

<entryRelationship typeCode='REFR'>

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

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.3'/'>

700

:

</observation>

</entryRelationship>

The reference to the Pharmaceutical Advice this dispense is related to SHOULD be present IF KNOWN, containing either (1) the Id of the Pharmaceutical Advice Item referenced or (2) a whole Pharmaceutical Advice Item Entry described in the Pharmacy Pharmaceutical Advice (PADV) Content Profile.

705

Note: Implementations may rely on the policy that prescriptions are implicitly approved for being dispensed (this is comparable to explicitly issue a related Pharmaceutical Advice with Observation Code “OK”). In this case the Pharmaceutical Advice by which this dispense was performed is “not known” and thus this element may be omitted.

710

Dispensing without prescription: This element SHALL NOT be present if the dispense was performed without prescription because no Pharmaceutical Advice is available in this case.

(1) In case the reference **contains just the Id of the Pharmaceutical Advice Item** the following constraints SHALL be met:

715

- The Id (<id> element) SHALL be present and SHALL contain the Id of the referenced Pharmaceutical Advice Item.
- The type of the Id (<code> element) SHOULD be present and SHALL contain the code “PADVItem” out of the **IHE Pharmacy Item Type List** value-set.

(2) In case the reference **contains a whole Pharmaceutical Advice Item Entry** the following constraints SHALL be met:

720

- The Pharmaceutical Advice Item SHALL be declared as an unchanged copy of the referenced Pharmaceutical Advice Item according to the Pharmaceutical Advice Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.3).

725 **6.3.4.5.3.14 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' />
730   <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
      codeSystemName='IHEActCode' />
    ...
  </entryRelationship>

```

735 At most one instruction MAY be provided for each <supply> 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 Dispense Item) are comments from “dispenser to patient” and may contain the following information:

- 740 • 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 dispenser to the patient (e.g., “take with food”, etc.)

6.3.4.5.3.15 Fulfillment Notes

```

<entryRelationship typeCode='SUBJ' inversionInd='true'>
745   <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' />
750   ...
  </entryRelationship>

```

At most one instruction MAY be provided for each <supply> 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.

755 Fulfillment Notes (used in a Dispense Item) are comments from the dispenser regarding the dispensing act and may contain the following information:

- Comments of the dispenser regarding the dispensation act (e.g., "I warned the patient about ...")

See PCC TF2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

760 **6.3.4.5.3.16 Dosage Instructions**

```

<entryRelationship typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="INT">
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.6'/>
      :
765   <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
770   :
  </substanceAdministration>
</entryRelationship>

```

The dosage instructions are provided in a <substanceAdministration> element containing the dosage instructions data elements.

775 This element MAY be present.

This information SHOULD be declared in the following cases:

- The Dispense Item is used within a Dispense document and the dosage instructions are different from the underlying prescription (e.g., because the dispensed drug changes from the prescribed one). It may be declared either structured in this element or in the Narrative Text element.
- The Dispense Item is used outside of a Dispense document (e.g., it is used in a “Pharmacy Medication List” document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.)

785 A <substanceAdministration> element SHALL contain a moodCode attribute set to ‘INT’ to reflect that the given instructions in the Dosage Instructions is intended to be followed.

A <substanceAdministration> element SHALL contain a <consumable> element, which SHALL contain a <manufacturedProduct/manufacturedMaterial> element with a nullFlavor="NA" attribute.

790 A <substanceAdministration> element SHALL contain dosage instructions, given “as a whole” 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) as defined in the Pharmacy Prescription (PRE) Profile.

Note: The following elements part of the Dosage Instructions:

- Prescription Item Entry Additional Template ID
- Effective Time (Duration of Treatment)
- 795 • Medication Frequency
- Route of Administration
- Approach Site Code
- Dose Quantity
- Rate Quantity
- 800 • Related Components

6.3.4.5.3.17 ID of parent container (Dispense document)

```
<reference typeCode='XCRPT'>
```

```
  <externalDocument>
```

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

```
805  </externalDocument>
```

```
</reference>
```

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

810 In all other cases (e.g., when used in a “Pharmacy 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 Dispense document, the Dispense Item initially has been created.

6.3.4.5.3.18 Substitution act

```
<pharm:component1>
```

```
815  <pharm:substitutionMade
```

```
    classCode="SUBST"
```

```
    moodCode="EVN">
```



```
<pharm:code code=' '  
    displayName=' '  
    codeSystem='2.16.840.1.113883.5.1070'  
    codeSystemName='HL7 Substance Admin Substitution'/>  
</pharm:substitutionMade>  
</pharm:component1>
```

820

825

At most one <pharm:component1> element MAY be present to inform that a substitution occurred. When present, this element SHALL contain one and only one substitution event.

The <code>-element of the substitution event identifies what sort of change has occurred. It SHALL be coded in HL7® terminology for substance substitution.

Technical note: A part of an HL7® Medication Dispense (PORX_MT020070UV) is used to express Substitution Handling.

830

6.5 PHARM Value Sets

Add Section 6.5.2

6.5.2 IHE Dispense Code List

835 The Dispense Code List is used in the Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4) for coding if the dispense was partial or full.

codeSystem: **2.16.840.1.113883.5.4**

codeSystemName: **ActCode**

840

code	displayName
Full dispense	
FFC	First Fill - Complete
Partial dispense	
FFP	First Fill - Part Fill
RFP	Refill - Part Fill
RFC	Refill - Complete

Appendices

Appendices A.1 to A.4 are applicable to this profile as described in the “Pharmacy Prescription (PRE)” supplement.