Integrating the Healthcare Enterprise

IHE Pharmacy
Technical Framework Supplement

Pharmacy Dispense
(DIS)

Trial Implementation

Date: September 29, 2014

Author: IHE Pharmacy Technical Committee

Email: pharmacy@ihe.net

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.

Copyright © 2014: IHE International, Inc.

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

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

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

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

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

Copyright © 2014: IHE International, Inc.

CONTENTS

Introduction 5
Open Issues and Questions 5
Closed Issues 5
Volume 1 – Profiles 6
1.n Copyright Permission 6
2.5 Dependencies of the Pharmacy Integration Profiles 6
2.7 History of Annual Changes 6
3 Pharmacy Dispense Content Profile 7
3.1 Purpose and Scope 7
3.2 Process Flow 8
3.2.1 Use Case 1: Dispensing a prescribed item 8
3.3 Actors/Transactions 8
Figure 3.3-1: Actor Diagram 8
3.4 Options 8
Table 3.4-1: Pharmacy Dispense Actors and Options 9
3.5 Groupings 9
3.5.1 Community Pharmacy Dispense and Dispense 9
3.6 Security Considerations 9
3.7 Content Modules 10
3.7.1 Structure of a Pharmacy Dispense Document 11
Glossary 12
Volume 3 – Content Modules 13
5.0 Namespaces and Vocabularies 13
5.1 IHE Format Codes 13
6.0 Pharmacy Content Modules 13
6.3 HL7 Version 3.0 Content Modules 13
6.3.1 CDA Document Content Modules 13
6.3.1.3 Pharmacy Dispense Specification 1.3.6.1.4.1.19376.1.9.1.1.3 13
6.3.1.3.1 Format Code 14
6.3.1.3.2 Parent Template 14
6.3.1.3.3 Standards 14
6.3.1.3.4 Data Element Index 14
6.3.1.3.5 Data Element Specification 15
6.3.1.3.6 Conformance 17
6.3.2 CDA Header Content Modules 18
6.3.3 CDA Section Content Modules 18
6.3.3.3 Dispense Section Content Module (1.3.6.1.4.1.19376.1.9.1.2.3) 18
6.3.3.3.1 Parent Templates 18
6.3.3.3.2 Dispense ID 19
6.3.3.3.3 Dispenser 19
6.3.4 CDA Entry Content Modules 19

 Copyright © 2014: IHE International, Inc.

6.3.4.5 Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4) 19
6.3.4.5.1 Standards 20
6.3.4.5.2 Parent Template 20
6.3.4.5.3 Specification 20
6.3.4.5.3.1 Dispense Item Entry General Specification 22
6.3.4.5.3.2 Dispense Item Entry TemplateID 22
6.3.4.5.3.3 Dispense Item ID 22
6.3.4.5.3.4 Code 22
6.3.4.5.3.5 Narrative Text 24
6.3.4.5.3.6 Repeat Number 24
6.3.4.5.3.7 Quantity Value 24
6.3.4.5.3.8 Product 25
6.3.4.5.3.9 Dispenser 25
6.3.4.1.3.10 Author of the Prescription Item to the dispense 25
6.3.4.5.3.11 Reference to Prescription Item 26
6.3.4.5.3.12 Reference to Pharmaceutical Advice 28
6.3.4.5.3.13 Patient Medication Instructions 28
6.3.4.5.3.14 Fulfillment Notes 29
6.3.4.5.3.15 Dosage Instructions 30
6.3.4.5.3.16 Substitution act 31
6.5 PHARM Value Sets 32
6.5.2 IHE Dispense Code List 32
Appendices 33

 Copyright © 2014: IHE International, Inc.

Introduction

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).

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

- 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".

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.

Copyright © 2014: IHE International, Inc.

Volume 1 – Profiles

Add the following to Section 1.n

1.n Copyright Permission

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.

Add the following to Section 2.7

2.7 History of Annual Changes

Add Section 3

Copyright © 2014: IHE International, Inc.

3 Pharmacy Dispense Content Profile

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).

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.

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.

 Copyright © 2014: IHE International, Inc.

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.

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.

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.

Figure 3.3-1: Actor Diagram

3.4 Options

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

Copyright © 2014: IHE International, Inc.

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	

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

3.5 Groupings

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

3.5.1 Community 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.

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

3.6 Security Considerations

The 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.

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

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

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

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

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

 Copyright © 2014: IHE International, Inc.

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

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

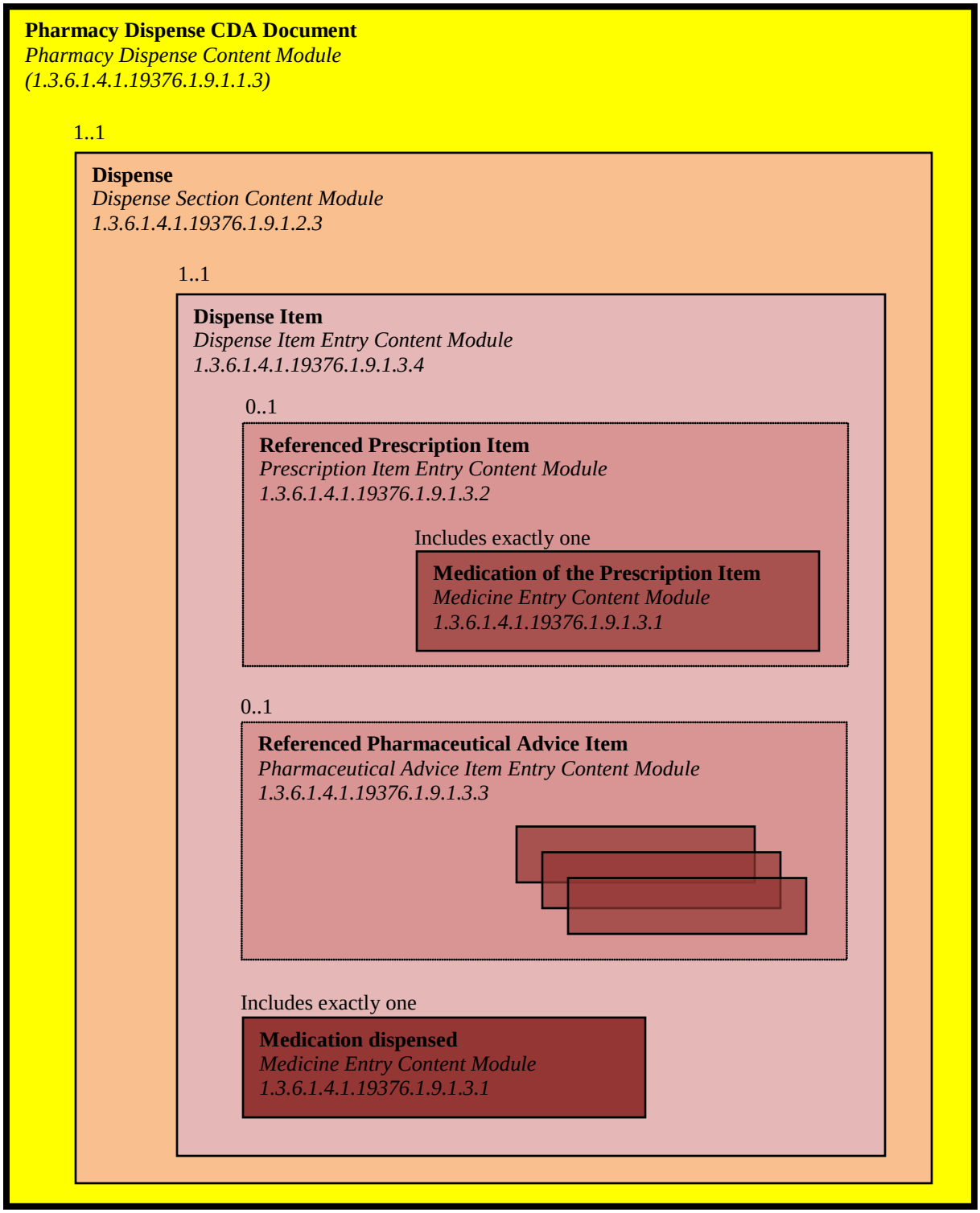
3.7 Content Modules

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

All 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.

 Copyright © 2014: IHE International, Inc.

3.7.1 Structure of a Pharmacy Dispense Document



Copyright © 2014: IHE International, Inc.

Glossary

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

 Copyright © 2014: IHE International, Inc.

Volume 3 – Content Modules

5.0 Namespaces and Vocabularies

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

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

5.1 IHE Format Codes

Profile	Format Code	Media Type	Template ID
2010 Profiles			
Pharmacy Dispense (DIS)	urn:ihe:pharm:dis:2010	text/xml	1.3.6.1.4.1.19376.1.9.1.1.3

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

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

Copyright © 2014: IHE International, Inc.

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

The XDSDocumentEntry 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).

290 #### 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

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

Copyright © 2014: IHE International, Inc.

Data Elements	CDA Release 2.0
HCP Organization Telecom	author/assignedAuthor/representedOrganization/telecom
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 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

295

6.3.1.3.5 Data Element Specification

Data Element Name	Opt	Template ID
Patient Information Name Personal Identification Gender Date of Birth HCP Person Information Name HCP Identification Profession Specialty	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.

 Copyright © 2014: IHE International, Inc.

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 Specialty	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
Dispense	R	1.3.6.1.4.1.19376.1.9.1.2.3

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.

Copyright © 2014: IHE International, Inc.

Although real-world projects may require some of this 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.

6.3.1.3.6 Conformance

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

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.1.3'/>
  <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>
```

 Copyright © 2014: IHE International, Inc.

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)

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

```
<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

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”).

 Copyright © 2014: IHE International, Inc.

6.3.3.3.2 Dispense ID

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

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).

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.

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

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)

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.

Copyright © 2014: IHE International, Inc.

6.3.4.5.1 Standards

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

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.

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.

Copyright © 2014: IHE International, Inc.

```
<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'
        codeSystemName='ActCode'/>
  <text><reference value=' '/></text>
  <repeatNumber value=''/>
  <quantity value='' unit=''/>
  <product>
    :
    <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
    :
  </product>
  <!--
       Dispenser of the Dispense Item in case of usage elsewhere as in a DIS document
  -->
  <performer typeCode='PRF'>
    :
  </performer>
  <!--
       Author of the prescription this dispense references to
       in case of usage elsewhere as in a DIS document
  -->
  <author>
     :
  </author>
  <!--
       referenced Prescription Item by which this dispense was performed
       must not be present if the dispense was performed without prescription
  -->
  <entryRelationship typeCode='REFR'>
    <substanceAdministration classCode="SBADM" moodCode="INT">
      <templateId root='2.16.840.1.113883.10.20.1.24'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
      <templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>
      ...
    </substanceAdministration>
  </entryRelationship>
  <!--
       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'>
      <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'>
       <act classCode='ACT' moodCode='INT'>
            <templateId root='2.16.840.1.113883.10.20.1.49'/>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
            <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
                  codeSystemName='IHEActCode' />
            ...
  </entryRelationship>
  <!-- Optional instructions for Pharmacist -->
  <entryRelationship typeCode='SUBJ' inversionInd='true'>
       <act classCode='ACT' moodCode='INT'>
            <templateId root='2.16.840.1.113883.10.20.1.43'/>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
            <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
                  codeSystemName='IHEActCode' />
            ...
```

 Copyright © 2014: IHE International, Inc.

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

6.3.4.5.3.1 Dispense Item Entry General Specification

<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

<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

<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'
codeSystemName='ActCode'/>

 Copyright © 2014: IHE International, Inc.

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.

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

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**".
- 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

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:

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 (6^{th}) partial dispense with code "Refill - Complete" indicating that the Prescription Item is now fully fulfilled.

 Copyright © 2014: IHE International, Inc.

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.

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=' '/>

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):

- 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.
- 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.
- 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.

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

 Copyright © 2014: IHE International, Inc.

6.3.4.5.3.8 Product

<product>

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

</product>

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>

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 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).

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

Data element	HL7 V3 Data Type	CDA Header position (relative XPath expression)
Dispensation Time	TS	*performer/time*
Dispenser Identifier	II	*performer/assignedEntity/id*
Dispenser Name	PN	*performer/assignedEntity/assignedPerson/name*
Dispenser Organization Identifier	II	*performer/assignedEntity/representedOrganization/id*
Dispenser Organization Name	ON	*performer/assignedEntity/representedOrganization/name*
Dispenser Organization Address	AD	*performer/assignedEntity/representedOrganization/addr*

6.3.4.1.3.10 Author of the Prescription Item to the dispense

<author>…</author>

 Copyright © 2014: IHE International, Inc.

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 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).

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*

6.3.4.5.3.11 Reference to Prescription Item

… Prescription Item Id only …

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='INT'>
   <id root=' ' extension=' '/>       <!-- Prescription Item Id -->
   <consumable>
    <manufacturedProduct>
     <manufacturedMaterial nullFlavor='NA'/>
    </manufacturedProduct>
   </consumable>
  </substanceAdministration>
```

 Copyright © 2014: IHE International, Inc.

</entryRelationship>

… or complete copy of Prescription item …

<entryRelationship typeCode='REFR'>

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

<templateId root='2.16.840.1.113883.10.20.1.24'/>

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.2'/>

:

</substanceAdministration>

</entryRelationship>

The reference to the Prescription Item by which this dispense was performed SHALL be present, containing a Prescription Item Entry described in the Pharmacy Prescription (PRE) Content Profile.

This Prescription Item Entry SHALL contain at least the Prescription Item Id (<id> element) and SHOULD be a complete copy (including the <id> element) of the Prescription Item by which this dispense was performed.

In case the Prescription Item by which this dispense was performed 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. Such broken links shall be avoided by either:

- also copying the referred information to the Dispense document (e.g., the Active Problems section of the Prescription, to provide the referenced diagnosis) or
- modifying the complete copy and set all reason(s) to nullFlavor=MSK (“masked”: masked, confidential, not published).

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"/>
```

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

 Copyright © 2014: IHE International, Inc.

```
</act>
```

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

6.3.4.5.3.12 Reference to Pharmaceutical Advice

… Pharmaceutical Advice Item Id only …

```
<entryRelationship typeCode='REFR'>
  <observation classCode='OBS' moodCode='EVN'>
    <id root=' ' extension=' '/>        <!-- Pharmaceutical Advice Item Id -->
    <code nullFlavor='NA'/>
  </observation>
</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'/>
      :
  </observation>
</entryRelationship>
```

The reference to the Pharmaceutical Advice by which this dispense was performed SHOULD be present IF KNOWN, containing a Pharmaceutical Advice Item Entry described in the Pharmacy Pharmaceutical Advice (PADV) Content Profile. The Pharmaceutical Advice Item Entry SHALL contain at least the Pharmaceutical Advice Item Id (<id> element) and SHOULD be a complete copy (including the <id> element) of the one referenced to.

Note: Implementations may rely on the policy that prescriptions are implicitly approved for being dispensed (this is compareable 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.

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.

6.3.4.5.3.13 Patient Medication Instructions

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
  <act classCode='ACT' moodCode='INT'>
```

 Copyright © 2014: IHE International, Inc.

```
<templateId root='2.16.840.1.113883.10.20.1.49'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
<code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
 codeSystemName='IHEActCode' />
...
</entryRelationship>
```

At most one instruction MAY be provided for each <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:

- 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.)

6.3.4.5.3.14 Fulfillment Notes

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

At most one instruction MAY be provided for each <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.

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.

 Copyright © 2014: IHE International, Inc.

6.3.4.5.3.15 Dosage Instructions

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

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

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.)

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.

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

 Copyright © 2014: IHE International, Inc.

- Effective Time (Duration of Treatment)
- Medication Frequency
- Route of Administration
- Approach Site Code
- Dose Quantity
- Rate Quantity
- Related Components

6.3.4.5.3.16 Substitution act

```
<pharm:component1>
  <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>
```

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.

 Copyright © 2014: IHE International, Inc.

6.5 PHARM Value Sets

Add Section 6.5.2

6.5.2 IHE Dispense Code List

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**

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

Copyright © 2014: IHE International, Inc.

Appendices

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

Copyright © 2014: IHE International, Inc.