Integrating the Healthcare Enterprise

IHE Pharmacy
Technical Framework Supplement

Pharmacy Dispense
(DIS)

Trial Implementation

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Foreword

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

This supplement is published on October 11, 2013 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.

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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.

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

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.

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.

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.

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.

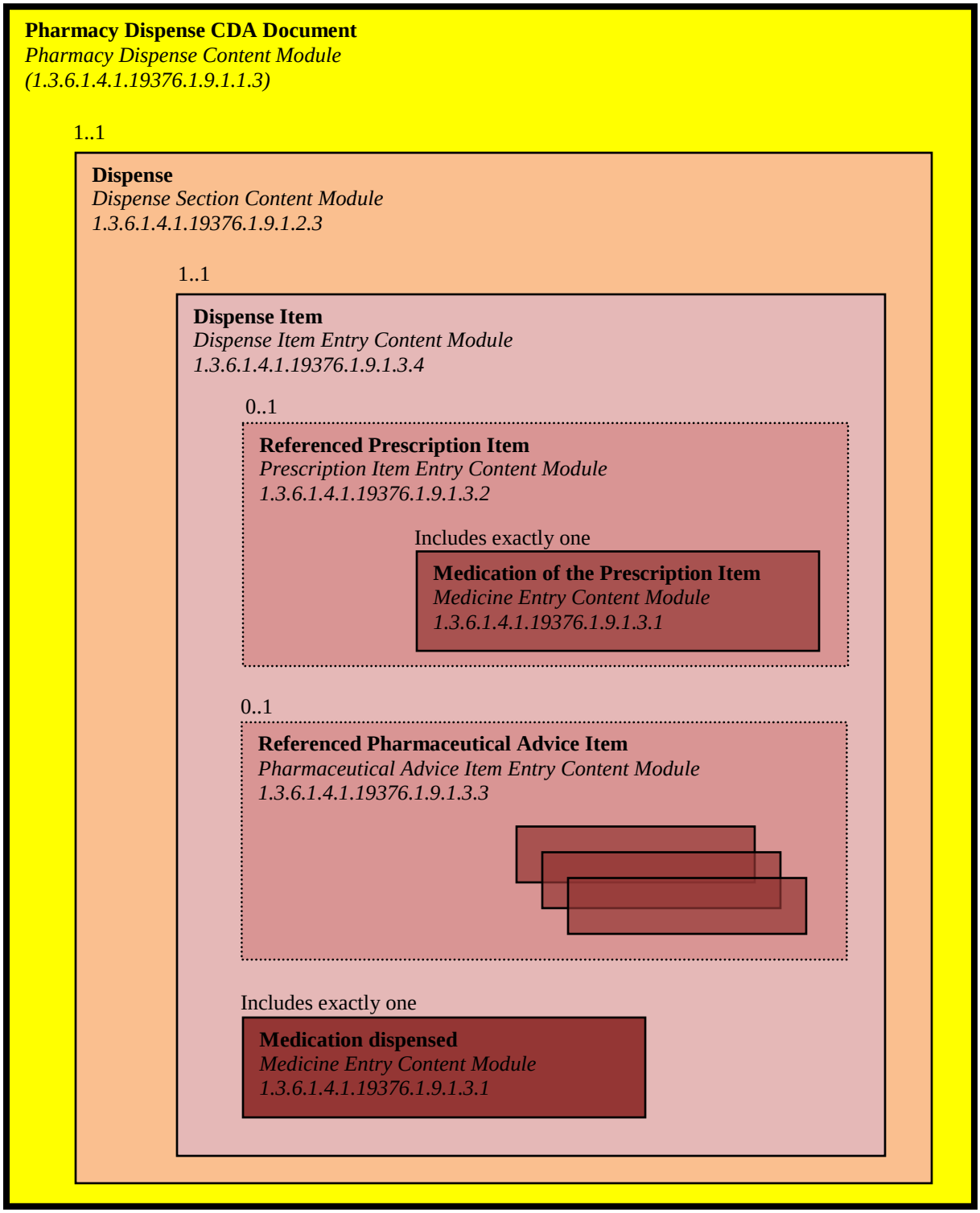
Because the information being transferred is in XML, it will be common that different Pharmacy systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and a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

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.

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

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

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
Entry name / template ID	Dispense Item

Structure	Pharmacy Dispense
	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).

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 Address	author/assignedAuthor/addr
HCP Telecom	author/assignedAuthor/telecom
HCP Specialty	author/assignedAuthor/code
HCP Represented Organization	author/assignedAuthor/representedOrganization
HCP Organization Name	author/assignedAuthor/representedOrganization/name
HCP Organization Address	author/assignedAuthor/representedOrganization/addr

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

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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 Address HCP Identification Profession	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
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.

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>
```


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 dispensation section shall contain a description of a medication dispensed for the patient. It shall include exactly one dispensed medication 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>
    <!-- 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”).

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).

6.3.4 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)

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.

```
    <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=''/>
      <repeatNumber value=''/>
      <quantity value='' unit=''/>
      <product>
        :
        <!-- Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
        :
      </product>
      <author>
        <time value=''/>
        <assignedAuthor>
          <id root='' extension=''/>
          <addr></addr>
          <telecom use='' value=''/>
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedAuthor>
      </author>
      <performer typeCode='PRF'>
            <time value=''/>
            <assignedEntity>
                  <id root='' extension=''/>
                  <addr></addr>
                  <telecom use='' value=''/>
                  <assignedPerson><name></name></assignedPerson>
                  <representedOrganization><name></name></representedOrganization>
            </assignedEntity>
      </performer>
      <!--
           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' />
                ...
    </entryRelationship>
    <!-- Optional dosing information, 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=' '/>
          <doseQuantity value=' ' unit=' '/>
          <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
          <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 Repeat Number

~~**<repeatNumber value=' '/>**~~

The repeatNumber shall not be present.

6.3.4.5.3.5 Quantity Value

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

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

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

- If the manufactured medication also contains package information, the <quantity> element is considered to contain the amount of packages of the medication. In this case the unit attribute SHALL NOT be present.
- If the manufactured medication does not contain package information, the <quantity> element is considered to contain the amount of consumable units of the medication. In this case the unit attribute MAY be present, if the quantity is in non-countable units. The value SHALL be out of the UCUM code system.

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

6.3.4.5.3.6 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-TF2, Medicine Entry Module (1.3.6.1.4.1.19376.1.9.1.3.1) specification.

6.3.4.5.3.7 Author

~~**<author>… </author>**~~

The <author> element shall not be present.

6.3.4.5.3.8 Dispenser

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

In the case where the dispenser of a Prescription Item is different from the author of the dispense document, the dispenser SHALL be represented by the <performer> element of the entry and the author SHALL be represented in the author Element of the 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 Name	PN	*performer/assignedEntity/assignedPerson/name*
Dispenser Identifier	II	*performer/assignedEntity/id*
Dispenser Organization Identifier	II	*performer/assignedEntity/representedOrganization/id*
Dispenser Organization Name	ON	*performer/assignedEntity/representedOrganization/name*
Dispenser Organization Address	AD	*performer/assignedEntity/representedOrganization/addr*

6.3.4.5.3.9 Reference to 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 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"/>
  </act>
```

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

6.3.4.5.3.10 Reference to Pharmaceutical Advice

```
<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 SHALL be present, containing a Pharmaceutical Advice Item Entry described in the Pharmacy Pharmaceutical Advice (PADV) Content Profile. The Pharmaceutical Advice Item Entry is a complete copy (including the <id> element) of the one referenced to.

[7] see chapter "Reason" of the Pharmacy Prescription (PRE) profile

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

6.3.4.5.3.11 Patient Medication Instructions

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

At most one instruction MAY be provided for each <supply> entry. If provided, it shall conform to the requirements listed for "Patient Medication Instructions". The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).

This element SHOULD be provided if the Patient Fulfillment Instructions at the point of dispense are newly created or differ from the ones provided in the Prescription Item.

6.3.4.5.3.12 Fulfillment Instructions

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

At most one entry relationship MAY be present to provide the fulfillment instructions. 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.

This element SHOULD be provided, if the Medication Fulfillment Instructions at the point of dispense are newly created or differ from the one's provided in the Prescription Item.

6.3.4.5.3.13 Dosing information

```
<entryRelationship typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="INT">
    <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=' '/>
    <doseQuantity value=' ' unit=' '/>
    <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
    <rateQuantity value=' ' unit=' '/>
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
    </consumable>
    <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
        :
    </entryRelationship>
  </substanceAdministration>
</entryRelationship>
```

In case the pharmacist describes different dosing information (e.g., because the dispensed drug changes from the prescribed one) this dosing information SHOULD be stated here.

If this element is used, the different dosing information SHALL be given “as a whole” according to the specification of the dosing information in the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2).

6.3.4.5.3.14 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.

Appendix

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