

Integrating the Healthcare Enterprise



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IHE Pharmacy Technical Framework Supplement

10

Community Dispense (DIS)

15

Rev. 1.8 – Trial Implementation

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

Foreword

This is a supplement to the 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, 2017 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.

40 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.

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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

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<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

- 130 The Community 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 Medication Prescription and Dispense” Integration Profile (CMPD).
- 135 This supplement also references other documents¹. The reader should have already read and understood these documents:
1. [PHARM Common parts document](#)
 2. [PHARM Community Medication Prescription and Dispense Integration Profile \(CMPD\)](#)
 3. [PCC Technical Framework Volume 1](#)
 4. [PCC Technical Framework Volume 2](#)
 5. [IT Infrastructure Technical Framework Volume 1](#)
 6. [IT Infrastructure Technical Framework Volume 2](#)
 7. [IT Infrastructure Technical Framework Volume 3](#)
 8. HL7®² and other standards documents referenced in this document

145 **Open Issues and Questions**

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

Closed Issues

- 150
- 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).
 - Dispense Section Content Module: It is still in discussion, if it's allowed to state the CCD®³ template as “parent”, or if we have to weaken it to “derived from”.
 - The Section Content Module has been decoupled from the CCD parent.

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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.

² HL7 is the registered trademark of Health Level Seven International.

³ CCD is the registered trademark of Health Level Seven International.

Volume 1 – Profiles

Add the following to Section 1.n

1.n Copyright Permission

160 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

Community Dispense (DIS)	PCC	Content definition	This profile includes Section and Entry Content Modules of the Patient Care Coordination (PCC) domain.
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165

Add the following to Section 2.7

2.7 History of Annual Changes

170 In the 2016-2017 cycle of the IHE Pharmacy initiative, the following major changes were introduced to this supplement (please see the list of this year's change proposals for the complete set of changes at ftp://ftp.ihe.net/Pharmacy/Technical_Framework/CP%20Overview):

- Profile has been renamed from “Pharmacy Dispense” to “Community Dispense”
- Parent template CCD on section level removed
- Constraint that section id has to be equal to document id has been removed
- Title and text elements have been added on section level
- 175 • Reporting of authors into the entry-level refined
- References to items of previous process stages (Medication Treatment Plan Items, Prescription Items, ...) refined and reorganized at “Reference to ...” Content Modules in located in PRE profile
- Substitution act structure refined
- 180 • Pharm-Namespace “ihe:pharm:medication” changed to “ihe:pharm” (see Medicine Entry Content Module located in PRE profile)

Important note: Due to the nature of some of the changes, this profile version is no longer downward compatible to the former versions.

185

Add Section 3

3 Community Dispense Content Profile

190 The Community 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 Medication Prescription and Dispense” Integration Profile (CMPD).

3.1 Purpose and Scope

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

A Community 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 Community Dispense document.

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

205

3.2 Process Flow

3.2.1 Use Case 1: Dispensing a prescribed item

210 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.

215 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 Medication Prescription and Dispense system.

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

3.3 Actors/Transactions

220 There are two actors in this profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer. The sharing or transmission
225 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.



230

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.

235

Table 3.4-1: Community Dispense Actors and Options

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

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

3.5 Groupings

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

3.5.1 Community Medication Prescription and Dispense

- 245 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.

- 250 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

- 255 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.

- 260 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.

- 265 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.
- 270 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.
- 275 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.

- 280 All Community Dispenses shall be structured and coded as required by the Community 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 content profile.

3.7.1 Structure of a Community Dispense Document

Community Dispense CDA Document
Community Dispense Content Module
(1.3.6.1.4.1.19376.1.9.1.1.3)

1..1

Dispense Section
Dispense Section Content Module
1.3.6.1.4.1.19376.1.9.1.2.3

1..1

Dispense Item
Dispense Item Entry Content Module
1.3.6.1.4.1.19376.1.9.1.3.4

0..1

Reference to Medication Treatment Plan Item
Reference to Medication Treatment Plan Item Entry Content Module
1.3.6.1.4.1.19376.1.9.1.3.10

0..1

Reference to Prescription Item
Reference to Prescription Item Entry Content Module
1.3.6.1.4.1.19376.1.9.1.3.11

0..1

Referenced Pharmaceutical Advice Item
Pharmaceutical Advice Item Entry Content Module
1.3.6.1.4.1.19376.1.9.1.3.13

Glossary

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

Volume 3 – Content Modules

5.0 Namespaces and Vocabularies

295

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® ⁴ 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

300

Profile	Format Code	Media Type	Template ID
2010 Profiles			
Community 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

305

Add Section 6.3.1.3

6.3.1.3 Community Dispense Specification 1.3.6.1.4.1.19376.1.9.1.1.3

The Community 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.).

310

Structure	Community Dispense
Format Code	urn:ihe:pharm:dis:2010
LOINC Code	60593-1 (Medication dispensed.extended)

⁴ CDA is the registered trademark of Health Level Seven International.

Structure	Community Dispense
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 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).

315 6.3.1.3.3 Standards

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

6.3.1.3.4 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

Data Elements	CDA Release 2.0
HCP Organization	author/assignedAuthor/representedOrganization
HCP Organization Name	author/assignedAuthor/representedOrganization/name
HCP Organization Address	author/assignedAuthor/representedOrganization/addr
HCP Organization Telecom	author/assignedAuthor/representedOrganization/telecom
Service Event⁵	documentationOf/serviceEvent
Date of Service Event	documentationOf/serviceEvent/effectiveTime
Service Event Code	documentationOf/serviceEvent/code
Encounter in the healthcare institution⁶	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

320

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	R	1.3.6.1.4.1.19376.1.5.3.1.1.1
<u>HCP Person Information</u> Name		

⁵ 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.

⁶ Encounter is optional and shall contain encounter information if applicable.

Data Element Name	Opt	Template ID
HCP Identification <u>HCP Organization Information</u> Name 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 ⁷	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 ⁸	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 ⁹	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

Additional explanation:

⁷ In case the patient is governed by a guardian, this element is R and shall contain the information about the guardian

⁸ The Coded Vital Signs section should contain at least the height and weight of the patient.

⁹ 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.

325 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.

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.

330 **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.extended'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
  <title>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

360

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	-	
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

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' />
    <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>
    <!-- exactly one Dispense Item -->
    <entry>
      <supply>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4' />
        :
      </supply>
    </entry>
  </section>
</component>

```

370

375

380

385

6.3.3.3.1 Parent Templates

390

This section content module has no parent structure. The value for ‘section/code’ SHALL be “60593-1”, “Medication dispensed.extended”.

6.3.3.3.2 Dispense Section ID

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

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

395 **6.3.3.3.3 Section title**

`<title>...</title>`

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

6.3.3.3.4 Text

`<text>...</text>`

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

6.3.3.3.5 Dispenser

`<author>...</author>`

410 In the case the Dispenser or the timestamp of a Dispense is different from the author and timestamp of the Community 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	<code>author/functionCode</code>
Timestamp of the Dispense	TS	<code>author/time</code>
Dispenser ID	II	<code>author/assignedAuthor/id</code>
Dispenser Specialty	CE	<code>author/assignedAuthor/code</code>
Dispenser Name	PN	<code>author/assignedAuthor/assignedPerson/name</code>
Dispenser Organization Identifier	II	<code>author/assignedAuthor/representedOrganization/id</code>
Dispenser Organization Name	ON	<code>author/assignedAuthor/representedOrganization/name</code>
Dispenser Organization Address	AD	<code>author/assignedAuthor/representedOrganization/addr</code>

6.3.4 CDA Entry Content Modules

Add Section 6.3.4.5

415 **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.

6.3.4.5.1 Standards

- 420 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

- 425 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.

430

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.

```

435 <supply classCode='SPLY' moodCode='EVN'>
436   <templateId root='2.16.840.1.113883.10.20.1.34' />
437   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />
438   <templateId root='1.3.6.1.4.1.19376.1.9.1.3.4' />
439   <id root='' extension='' />
440   <code code='' displayName='' codesystem='2.16.840.1.113883.5.4'
441     codeSystemName='ActCode' />
442   <text><reference value=' ' /></text>
443   <repeatNumber value=''/>
444   <quantity value='' unit='' />
445   <product>
446     <manufacturedProduct classCode="MANU">
447       <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.2" />
448       <templateId root="2.16.840.1.113883.10.20.1.53" />
449       <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
450         :
451         <!-- Medicine Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.1) -->
452         :
453       </manufacturedMaterial>
454     </manufacturedProduct>
455   </product>
456   <performer typeCode='PRF' />
457   <!--
458     Author(s) in case of usage elsewhere as in a DIS document
459   -->
460   <author>...</author>
461   <author>...</author>
462   <!--
463     referenced Medication Treatment Plan Item by which this dispense was performed
464     must not be present if the dispense was performed without planning
465   -->
466   <entryRelationship typeCode='REFR'>
467     <substanceAdministration classCode="SBADM" moodCode="INT">
468       <templateId root='1.3.6.1.4.1.19376.1.9.1.3.10' />
469       ...
470     </substanceAdministration>
471   </entryRelationship>
472   <!--
473     referenced Prescription Item by which this dispense was performed
474     must not be present if the dispense was performed without prescription
475   -->
476   <entryRelationship typeCode='REFR'>
477     <substanceAdministration classCode="SBADM" moodCode="INT">
478       <templateId root='1.3.6.1.4.1.19376.1.9.1.3.11' />
479       ...
480     </substanceAdministration>
481   </entryRelationship>
482   <!--
483     referenced pharmaceutical advice by which this dispense was performed
484     must not be present if the dispense was performed without prescription
485   -->
486   <entryRelationship typeCode='REFR'>
487     <observation classCode='OBS' moodCode='EVN'>
488       <templateId root='1.3.6.1.4.1.19376.1.9.1.3.13' />
489       :
490     </observation>
491   </entryRelationship>
492   <!-- Optional instructions for the patient -->
493   <entryRelationship typeCode='SUBJ' inversionInd='true'>
494     <act classCode='ACT' moodCode='INT'>
495       <templateId root='2.16.840.1.113883.10.20.1.49' />
496       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3' />
497       <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
498         codeSystemName='IHEActCode' />
499       ...
500     </act>
501   </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' />
        ...
    </act>
</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

535 <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.

540 **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 TF-2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

545 **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 TF-2, 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

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

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.

560 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

570 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:

- 575 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”.
- 580 The Dispenser records the last (6th) partial dispense with code “Refill - Complete” indicating that the Prescription Item is now fully fulfilled.

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

- 590 **<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 595 <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 600 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 605 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.

- 610
 - 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 TF-2, 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>

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

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

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

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

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

6.3.4.5.3.9 Performer

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

The <performer> element SHALL NOT be present.

Note: The Dispenser will be recorded in a second author element. See chapter 6.3.4.5.3.12.

635 See PCC TF-2, Supply Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.7.3) specification.

6.3.4.5.3.10 Dispenser

<author>...</author>

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

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

645 This element SHALL be present in case that the “Community Dispense document author” is present (see chapter 6.3.4.5.3.11)

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

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>

650

6.3.4.5.3.11 Community Dispense document author

<author>...</author>

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

655 If the author of the Community Dispense document is already present in the “Dispenser” element (see chapter above) this element SHALL NOT be present.

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

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

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

6.3.4.5.3.12 Reference to Medication Treatment Plan Item

665 <entryRelationship typeCode='REFR'>
 <substanceAdministration classCode='SBADM' moodCode='INT'>
 <templateId root='1.3.6.1.4.1.19376.1.9.1.3.10' /> <!-- PHARM -->
 ...
 </substanceAdministration>

670 </entryRelationship>

If the dispense is related to a Medication Treatment Plan Item, the reference to it SHALL be present IF KNOWN and SHALL contain a Reference to Medication Treatment Plan Item Entry, conforming to the Reference to Medication Treatment Plan Item Entry template (1.3.6.1.4.1.19376.1.9.1.3.10).

675 See PHARM TF-3, Reference to Medication Treatment Plan Item Entry Module (1.3.6.1.4.1.19376.1.9.1.3.10) specification.

6.3.4.5.3.13 Reference to Prescription Item

<entryRelationship typeCode='REFR'>

```
<substanceAdministration classCode='SBADM' moodCode='INT'>
680   <templateId root='1.3.6.1.4.1.19376.1.9.1.3.11'/_> <!-- PHARM -->
    ...
</substanceAdministration>
</entryRelationship>
```

685 The reference to the Prescription Item this dispense is related to SHALL be present IF KNOWN and SHALL contain a reference to a Prescription Item Entry, conforming to the Reference to Prescription Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.11).

See PHARM TF-3, Reference to Prescription Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.11) specification.

6.3.4.5.3.14 Reference to Pharmaceutical Advice Item

```
690   <entryRelationship typeCode='REFR'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.9.1.3.13'/_> <!-- PHARM -->
        ...
      </observation>
695   </entryRelationship>
```

A dispense may be related to a Pharmaceutical Advice, which was given on items on higher (e.g., PADV on underlying prescription), equal (e.g., PADVs on previous partial dispenses), or lower (e.g., PADVs on administrations of previous partial dispenses) steps of this dispense act.

Examples:

- 700 • a Pharmaceutical Advice to the underlying prescription of this dispense, indicating that the dispense is authorized
- a Pharmaceutical Advice to the underlying prescription of this dispense, indicating that the dosage instructions or medication have changed

705 The reference to a Pharmaceutical Advice Item this dispense is related to SHOULD be present IF KNOWN and SHALL contain a reference to a Pharmaceutical Advice Item, conforming to the Reference to Pharmaceutical Advice Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.13).

See PHARM TF-3, Reference to Pharmaceutical Advice Item Content Module (1.3.6.1.4.1.19376.1.9.1.3.13) specification.

6.3.4.5.3.15 Patient Medication Instructions

```
710   <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. 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.)

6.3.4.5.3.16 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 fulfillment note 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 issues happened during the dispense act or up until the creation of the DIS report. Due to the nature of the Medication Fulfillment Instructions (1.3.6.1.4.1.19376.1.5.3.1.4.3.1) Content Module, these comments are limited to narrative text only.

Examples:

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

Note: Comments regarding the dispense act about issues happening after the creation of the DIS report should be documented by a Community Pharmaceutical Advice (PADV) related to this administration. PADV may also be used for comments regarding the dispense act happened during the administration act or up until the creation of the DIS report, e.g., in case narrative description of the issue is not sufficient.

6.3.4.5.3.17 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:

- 770 • The Dispense Item is used within a Community 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 Community Dispense document (e.g., it is used in a “Community Medication List” document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.)
- 775 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.

780 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 Community Prescription (PRE) Profile.

Note: The following elements part of the Dosage Instructions:

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

6.3.4.5.3.18 ID of parent container (Community Dispense document)

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

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

800 In all other cases (e.g., when used in a "Community Medication List" document according to the PML Profile or in medication sections of other documents as for example Discharge Summaries, etc.) this element SHOULD be present and contain the identifier of the Community Dispense document, the Dispense Item initially has been created.

6.3.4.5.3.19 Substitution act

```
805 <entryRelationship typeCode="COMP">
  <act classCode="ACT" moodCode="EVN">
    <templateId root="1.3.6.1.4.1.19376.1.9.1.3.9.2"/> <!-- SubstitutionAct -->
    <code code="E">
```

- ```

codeSystem="2.16.840.1.113883.5.1070"
810 codeSystemName="HL7 Substance Admin Substitution"
 displayName="equivalent"/>
 <statusCode code="completed"/>
 </act>
</entryRelationship>
815 At most one substitution act element MAY be present to inform that a substitution occurred.
When present, this element SHALL contain exactly one substitution event.
The Template ID for a Substitution Act (1.3.6.1.4.1.19376.1.9.1.3.9.2) SHALL be provided.
The <code>-element of the substitution event identifies what sort of change has occurred. It
SHALL be coded in HL7 terminology for substance substitution.

```
- 820

## 6.5 PHARM Value Sets

*Add Section 6.5.2*

### 6.5.2 IHE Dispense Code List

- 825 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      |

830

## Appendices

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

## Volume 3 Namespace Additions

835    *Add the following terms to the IHE Namespace:*

- Community Dispense (DIS) Document Content Module
  - 1.3.6.1.4.1.19376.1.9.1.1.3
- Dispense Section Content Module
  - 1.3.6.1.4.1.19376.1.9.1.2.3
- Dispense Item Entry Content Module
  - 1.3.6.1.4.1.19376.1.9.1.3.4

840