Integrating the Healthcare Enterprise

IHE Pharmacy
Technical Framework Supplement

Pharmacy Pharmaceutical Advice (PADV)

Trial Implementation

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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.

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.

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Introduction

The Pharmacy Pharmaceutical Advice Document Profile (PADV)[1] describes the content and format of a pharmaceutical advice document generated during the process in which a health care professional (in most cases, but not necessarily always, a pharmacist) validates a Prescription Item of a prescription against pharmaceutical knowledge and regulations. The validation can be with regard to conflicts with other Prescription Items or current medication of the patient or other reasons which affect the further processing of the Prescription Item (may be dispensed, dispensed with change, etc.).

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[2]. 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

Closed Issues

- Shall the pharmaceutical advice document also be applicable to be related to Dispense Items (instead of Prescription Items) for e.g., cancelling already dispensed items.
    - Yes, this possibility was introduced in CP-PHARM-054

[1] From the clinical work practice perspective, a prescription is reviewed by a clinical pharmacist. The review may or may not result in recommendation(s) or advice(s) to the prescribing clinician to modify the prescription. Hence semantically more accurate this profile could be referenced as Pharmacist Pharmaceutical Review Document Profile. However, given the pervasive use of this profile, it is agreed through the international review that this profile name remains unchanged.

[2] 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 Pharmaceutical Advice (PADV)	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 X

3 Pharmacy Pharmaceutical Advice Content Profile

The Pharmacy Pharmaceutical Advice Document Profile (PADV) describes the content and format of a pharmaceutical advice generated during the process in which a health care professional (in most cases, but not necessarily always, a pharmacist) validates a Prescription Item of a prescription against pharmaceutical knowledge and regulations. The validation can be with regard to conflicts with other Prescription Items or current medication of the patient or other reasons which affect the further processing of the Prescription Item (may be dispensed, dispensed with change, etc.).

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 validation of a prescription by a health care professional, usually different from the prescriber, possibly also supported by expert systems.

A Pharmaceutical Advice document is the outcome of the validation or review of one Prescription- or Dispense Item. It contains the overall result of the validation or review which affects the further processing as well as additional information such as Intolerances, Contra-indications and Allergies (ICAs) and all other information which was discovered during validation.

A Pharmaceutical Advice document is also used to manage Prescription- or Dispense Items (e.g., change, cancel, etc.) as well as to document Medication Interaction Checking Issues and their resolutions.

This profile defines the content and format of such a Pharmaceutical Advice 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: Validating a prescribed item

A patient enters the community pharmacy and requests a Prescription Item to be dispensed. The requested Prescription Item has not yet been validated by the Pharmaceutical Adviser.

Usually the pharmacist uses the pharmacy information system for validating the Prescription Item. After the process the result of the validation is stated in a Pharmaceutical Advice document. If the result was successful, the prescription is allowed to be dispensed by a Medication Dispenser.

3.2.2 Use Case 2: Reviewing and manage a dispensed item (stopping)

After getting Penicillin prescribed by a physician, the patient retrieves the prescribed medication from the pharmacy and takes it for three days. He then re-visits the physician because the illness had improved. The physician performs another physical examination to confirm the improved health status.

The physician decides to discontinue the Penicillin because the illness no longer requires an antibiotic. The physician issues a Pharmaceutical Advice document to record the stopping and instructs the patient to stop the intake.

Note: The same use case can be applied to a prescribed item (which has not yet been fully dispensed), with the difference that in this case the prescribed item shall no longer be dispensed.

3.2.3 Use Case 3: Reviewing and manage a dispensed item (changing)

After getting Penicillin prescribed by a physician, the patient retrieves the prescribed medication from the pharmacy and takes it for three days. He then re-visits the physician because the illness had worsened. The physician performs another physical examination to confirm the worsened health status.

The physician decides to increase the dosage of the Penicillin from 1000mg once a day to 1000mg twice a day. The physician issues a Pharmaceutical Advice document to record the change and instructs the patient about the new dosage.

Note: The same use case can be applied to a prescribed item (which has not yet been fully dispensed), with the difference that in this case the prescribed item shall be dispensed with the changed dosage instructions.

3.2.4 Use Case 4: Reviewing and manage a dispensed item (suspend/reactivate)

After getting Penicillin prescribed by a physician, the patient retrieves the prescribed medication from the pharmacy and takes it for three days. After that, he was taken to the hospital because the illness became critical. At admission, the physician recognizes the dispense of the 1000mg of Penicillin from three days earlier and decides to change this Dispense Item to "suspended"

during the patient's hospital stay because other antibiotics will be given to the patient. The physician issues a Pharmaceutical Advice document to record the suspension.

Upon discharge of the patient, the physician decides to continue the treatment of the patient with the formerly dispensed medication and changes the Dispense Item to "active". The physician issues a Pharmaceutical Advice document to record the reactivation and the patient is instructed to continue with the medication.

Note: The same use case can be applied to a prescribed item (which has not yet been fully dispensed), with the difference that in this case the prescribed item shall not be dispensed during being suspended.

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 Pharmaceutical Advice Actors and Options

Actor	Option	Section
Content	View Option (See Note 1)	PCC TF-2: 3.1.1

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

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

3.5 Groupings

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

3.5.1 Community Pharmacy Prescription and Dispense

Actors from the Pharmacy CMPD Profile embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer may be grouped with appropriate actors from the XDS, XDM or XDR profiles to exchange the content described 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 PADV Integration Profile assumes that a minimum security and privacy environment has been established across all participants. Security policies must exist 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 PADV.

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 PADV 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.

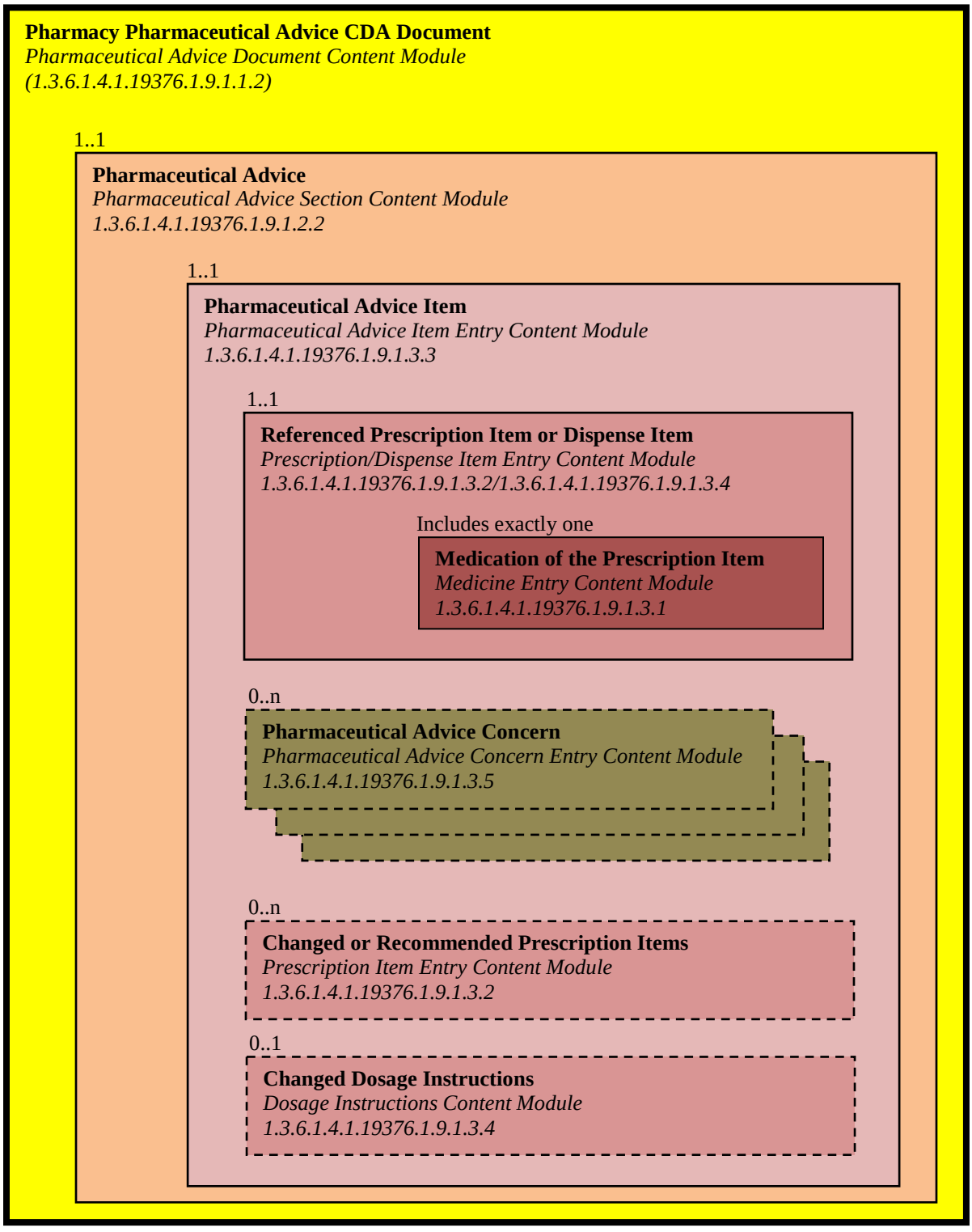
Because the information being transferred is in XML, it will be common that different Pharmacy systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and a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



Glossary

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

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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 Pharmaceutical Advice (PADV)	urn:ihe:pharm:padv:2010	text/xml	1.3.6.1.4.1.19376.1.9.1.1.2

6.0 Pharmacy Content Modules

6.3 HL7 Version 3.0 Content Modules

6.3.1 CDA Document Content Modules

Add Section 6.3.1.2

6.3.1.2 Pharmacy Pharmaceutical Advice Specification 1.3.6.1.4.1.19376.1.9.1.1.2

A Pharmaceutical Advice document is the outcome of the validation or review of one Prescription- or Dispense Item. It contains the overall result of the validation or review which affects the further processing as well as additional information such as Intolerances, Contra-indications and Allergies (ICAs) and all other information which was discovered during validation.

A Pharmaceutical Advice document is also used to manage Prescription- or Dispensation Items (e.g., change, cancel, etc.) as well as to document Medication Interaction Checking Issues and their resolutions.

Structure	Pharmacy Pharmaceutical Advice
Format Code	urn:ihe:pharm:padv:2010
LOINC Code	61356-2 (Medication Pharmaceutical Advice)
Document Template ID	1.3.6.1.4.1.19376.1.9.1.1.2
Section name / template ID	Pharmaceutical Advice 1.3.6.1.4.1.19376.1.9.1.2.2
Entry name / template ID	Pharmaceutical Advice Item 1.3.6.1.4.1.19376.1.9.1.3.3
Pharmaceutical Advice Concern Entry Module template ID	Pharmaceutical Advice Concern 1.3.6.1.4.1.19376.1.9.1.3.5

6.3.1.2.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:pharm:padv:2010**.

6.3.1.2.2 Parent Template

This document is an instance of the Medical Document template.

6.3.1.2.3 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

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6.3.1.2.4 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
HCP Organization Telecom	author/assignedAuthor/representedOrganization/telecom
~~**Service Event**~~[3]	~~documentationOf/serviceEvent~~
~~Date of Service Event~~	~~documentationOf/serviceEvent/effectiveTime~~
~~Service Event Code~~	~~documentationOf/serviceEvent/code~~
Encounter in the healthcare institution[4]	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
Pharmaceutical Advice	MEDICATION PHARMACEUTICAL ADVICE.BRIEF

[3] Service Event shall not be present in a Pharmaceutical Advice.

[4] Encounter is optional and shall contain encounter information if applicable.

6.3.1.2.5 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 HCP Organization Information Name Address Organization Identifier Contact Information	R	1.3.6.1.4.1.19376.1.5.3.1.1.1
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
Pharmaceutical Advice	R	1.3.6.1.4.1.19376.1.9.1.2.2

6.3.1.2.6 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='1.3.6.1.4.1.19376.1.9.1.1.2'/>
  <id root=' ' extension=' '/>
  <code code='61356-2' displayName='Medication Pharmaceutical Advice'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Pharmacy Pharmaceutical Advice</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 6.3.3.2

6.3.3.2 Pharmaceutical Advice Section Content Module (1.3.6.1.4.1.19376.1.9.1.2.2)

Template ID	1.3.6.1.4.1.19376.1.9.1.2.2	
Parent Template	None	
General Description	The Pharmaceutical Advice section contains a pharmaceutical advice to a medication prescribed or dispensed for the patient. It shall include exactly one Pharmaceutical Advice entry as described in the Pharmaceutical Advice Item Entry Content Module.	
LOINC Code	**Opt**	**Description**
61357-0	R	MEDICATION PHARMACEUTICAL ADVICE.BRIEF
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.9.1.3.3	R	Pharmaceutical Advice Item Entry Content Module

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.2.2'/>
    <!-- The section ID is the Pharmaceutical Advice ID -->
    <id root=' ' extension=' '/>
    <code code='61357-0' displayName='MEDICATION PHARMACEUTICAL ADVICE.BRIEF'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Pharmaceutical Advice</title>
    <text>
      Text as described above
    </text>
    <author>
      :
    </author>
    <!-- Pharmaceutical Advice -->
    <entry>
         :
        <!-- Required element indicating the Pharmaceutical Advice entry content module -->
        <observation>
            <templateId root='1.3.6.1.4.1.19376.1.9.1.3.3'/>
              :
        </observation>
    </entry>
  </section>
</component>
```

6.3.3.2.1 Parent Templates

This section content module has no parent structure.

6.3.3.2.2 Pharmaceutical Advice ID

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

A Pharmaceutical Advice 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 Pharmaceutical Advice document, this identifier shall be set equal to the document ID (ClinicalDocument/id).

6.3.3.2.3 Pharmaceutical Adviser

<author>…</author>

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

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

6.3.4 CDA Entry Content Modules

Add Section 6.3.4.3

6.3.4.3 Pharmaceutical Advice Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.3)

A Pharmaceutical Advice Item belongs to one Pharmaceutical Advice and represents the validation outcome or management command regarding the referenced Prescription- or Dispense Item (e.g., change, cancel, etc.). It may also carry Medication Interaction Checking Issue information regarding the referenced item.

6.3.4.3.1 Standards

This part describes the general structure for a Pharmaceutical Advice 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)

455 **6.3.4.3.2 Parent Template**

This entry content module has no parent structure.

6.3.4.3.3 Specification

```
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.9.1.3.3'/>
      <id root='' extension=''/>
      <!-- Outcome of the validation / Management command -->
      <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
      <!-- Narrative comment to the result of the validation -->
      <text><reference value='#comment1'/></text>
      <statusCode code='active | completed'/>
      <effectiveTime value=' ' />
      <!--
           Author of Pharmaceutical Advice Item in case of usage elsewhere as in a PADV document
      -->
      <author>
          :
      </author>
      <!--
           referenced Prescription- or Dispense Item to which this Pharmaceutical Advice
           is related to
      -->
      <entryRelationship typeCode='REFR'>
        <!-- Prescription Item -->
        <substanceAdministration classCode="SBADM" moodCode="INT">
          ...
        </substanceAdministration>
        <!-- or -->
        <!-- Dispense Item -->
        <supply classCode="SPLY" moodCode="EVN">
          ...
        </supply>
      </entryRelationship>
      <!--
           One or more Pharmaceutical Advice Concern entries, representing validation issues
           with the objective Prescription- or Dispense Item
      -->
      <entryRelationship typeCode='REFR' inversionInd='false'>
        <act classCode='ACT' moodCode='EVN'>
          <templateId root='2.16.840.1.113883.10.20.1.27'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
          <templateId root='1.3.6.1.4.1.19376.1.9.1.3.5'/>
              :
        </act>
      </entryRelationship>
      <!--
           Changed or Recommended Prescription Item Organizer
             Shall only be present if the Pharmaceutical Advice references a Prescription Item
             and the status of the Pharmaceutical Advice is set to “OK” or “CHANGE”.

            If the status is set to OK, these Organizers shall be considered as “recommendations”
            If the status is set to CHANGE, these Organizers shall be considered as “changes”

            If more than one Changed or Recommended Prescription Item Organizers are given
            they indicate a “choice” of change or recommendation.
      -->
      <entryRelationship typeCode='REFR' inversionInd='false'>
        <organizer classCode='CLUSTER' moodCode='EVN'>
          <statusCode code='completed'>
          <component>
            <seperatableInd value='false'>
              <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>
          </component>
          <component>
              :
          </component>
          :
        </organizer>
      </entryRelationship>
      <!--
           Changed Dosage Instructions
             Shall only be present if the Pharmaceutical Advice references a Dispense Item
             and the status of the Pharmaceutical Advice is set to “CHANGE”.
      -->
      <entryRelationship typeCode='REFR' inversionInd='false'>
        <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>
    </observation>
```

6.3.4.3.3.1 Pharmaceutical Advice Item Entry General Specification

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

…

</observation>

The <observation> element SHALL be present and represents the actual Pharmaceutical Advice. The moodCode attribute SHALL be EVN to reflect that the Pharmaceutical Advice has already taken place.

The organizer contains the overall status code of the Pharmaceutical Advice, the reason for decision as well as every conflicting Prescription- or Dispense Item.

6.3.4.3.3.2 Pharmaceutical Advice Item Entry TemplateID

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.3'/> **<!-- PHARM -->**

6.3.4.3.3.3 Pharmaceutical Advice Item ID

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

This ID represents the Pharmaceutical Advice Item ID and SHALL be present.

6.3.4.3.3.4 Observation Code

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

The Pharmaceutical Advice Item Entry SHALL indicate the coded result of the validation or management command regarding the referenced Prescription- or Dispense Item, implying the further proceeding with it, out of the following list:

code: **see column "Code"**

codeSystem: **1.3.6.1.4.1.19376.1.9.2.1**

codeSystemName: **IHE Pharmaceutical Advice Status List**

In case this Pharmaceutical Advice **references a Prescription Item** the following statuses may be used:

Code	Description
OK	Prescription Item is active (e.g., can be dispensed, no change expected but allowed if recommended medication given).
CHANGE	Dispense with change expected
REFUSE	Refusal to dispense until further discussion with prescriber
CANCEL	Definite cancelation of the Prescription Item (item will not be dispensed)
SUSPEND	Prescription Item is temporarily set to suspended with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.). The item shall not be dispensed during set to suspended.

In case this Pharmaceutical Advice **references a Dispense Item** the following statuses may be used:

Code	Description
OK	Dispense Item is active (e.g., resumed from being suspended).
CHANGE	Change in any information element of the Dispense Item except the medication (e.g., dosage instructions, patient instructions, etc.). The original Medicine Entry Item referenced by the Dispense Item shall be unchanged.
CANCEL	Definite stopping of the dispensed medication (patient stops intake of the medication)
SUSPEND	Dispense item is temporarily set to suspended with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.). The medication shall not be taken by the patient during set to suspended.

Detailed description of statuses

The following detailed description explains the meaning of the status codes.

OK

Usage in case when this Pharmaceutical Advice references a Prescription Item:

The status code OK shall be used to set a Prescription Item to active, (e.g., can be dispensed, no change expected but allowed if recommended medication given). If additional information concerning alternative "recommended" medication is included in the document, according to the chapter 6.3.4.3.3.11 Changed or Recommended Prescription Items. The Medication Dispenser is allowed to either dispense the original prescribed item or the recommended item (or set of item).

Example: The Pharmaceutical Adviser may approve Adol 500mg Caplet as the prescribed item, but adds two alternatives, as first a genericum of Adol and as second a combination of two other medications. In this case the Medication Dispenser may either dispense the original medication, the genericum or the alternative combination of two medications other.

Usage in case when this Pharmaceutical Advice references a Dispense item:

The status code OK shall be used to set a Dispense Item to active (e.g., resumed from being suspended). A dispensed medication may be taken by the patient during set to active.

CHANGE

Usage in case when this Pharmaceutical Advice references a Prescription Item:

The status code CHANGE shall be used, if the referred Prescription Item is allowed to be dispensed with required changes stated according to the chapter 6.3.4.3.3.11 Changed or Recommended Prescription Items. The changes may concern all levels of information of the Prescription Item (the medication itself, intake pattern, patient instructions, etc.).

Example 1: The Pharmaceutical Adviser may disapprove Adol 500mg Caplet as the prescribed item and requests a change to one of two alternatives, as first a genericum of Adol and as second a combination of two other medications. In this case the Medication Dispenser may either dispense the genericum or the alternative combination of two medications other but not the original medication.

Example 2: The Pharmaceutical Adviser may disapprove just the prescribed dosage of Adol and describes another dosage. In this case the Medication Dispenser may dispense original prescribed Adol, but has to commend the other dosage to the patient.

Example 3: The Physician changes the prescription item following the intention to change the medication treatment because of some clinical reason.

Usage in case when this Pharmaceutical Advice references a Dispense Item:

The status code CHANGE shall be used to document that the dosage instructions of the referred Dispense Item has been changed according to the chapter 6.3.4.3.3.11 Change Dispense Item. The changes may concern all levels of information of the Dispense Item (intake pattern, patient instructions, etc.) except the medication itself. The medication itself shall not be different to the medication referenced in the referring Dispense Item.

Example: The Physician increases the dosage of the medication after 5 days of intake because the effectiveness is not as desired. The physician tells the patient to change the dosage of the medication accordingly.

REFUSE

This code is used only if this Pharmaceutical Advice references a Prescription Item.

The status code REFUSE shall be used, if the referred Prescription Item is not allowed to be dispensed by a Medication Dispenser and no allowed alternatives are available. The reasons leading to this statement are documented in the Pharmaceutical Advice. Subsequently the prescription has to be further discussed with the prescriber.

Example: The Pharmaceutical Adviser disapproves Paracetamol as prescribed item because there exists a contra-indication with another medication of the patient. Since no alternative can be found the therapy has to be modified by the prescriber.

CANCEL

Usage in case when this Pharmaceutical Advice references a Prescription Item:

The status code CANCEL shall be used to cancel a prescribed medication. In difference to status code “refuse” this means a total abandonment of the Prescription Item (prescribed or dispensed) without expecting it to be refined by the prescriber.

Example: A physician wants to replace a recently prescribed medication of the patient by a new one. To keep the “current medication”-information of the patient up-to-date the physician first acts as a Pharmaceutical Adviser and cancels the current prescribed Prescription Item. Then the physician tells the patient to abandon the recent medication and prescribes a new one.

Usage in case when this Pharmaceutical Advice references a Dispense Item:

The status code CANCEL shall be used to document that the intake of the referred Dispense Item is be stopped.

Example: The Physician stops the medication after 5 days of intake because of ineffectiveness and another medication shall be prescribed. The physician tells the patient to stop the intake of the medication.

SUSPEND

Usage in case when this Pharmaceutical Advice references a Prescription Item:

The status code SUSPEND shall be used to set a prescribed medication to suspended. A Prescription Item shall not be dispensed during set to suspended.

In difference to status code “cancel” (which reflects an irreversible cancelation of the Prescription Item) a suspended Prescription Item is intended to be just temporarily paused with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.).

Example: A patient gets admitted to the hospital and the admitting physician decides to set all not yet dispensed community prescriptions to suspended, because the hospital entirely takes over the medication treatment during the hospital stay and it’s not clear whether or not the prescribed medication is continued afterwards.

Usage in case when this Pharmaceutical Advice references a Dispense item:

The status code SUSPEND shall be used to set a dispensed medication to suspended. A dispensed medication shall not be taken by the patient during set to suspended.

In difference to status code “cancel” (which reflects an irreversible cancelation of the Dispense Item) a suspended Dispense item is intended to be just temporarily paused with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.).

Example: A patient, who has a long-term medication for high blood pressure, gets admitted to the hospital and the admitting physician decides to set this long-term medication to suspended, because the hospital will take care about this during the hospital stay. It’s intended that the patient continues the long-term medication after discharge.

6.3.4.3.3.5 Narrative Text

<text><reference value='#comment1'/></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 result of the validation or management command regarding the referenced Prescription- or Dispense Item (e.g., OK, CANCEL, …), implying the further proceeding with it, and other information related to it (e.g., the reason for the decision, etc.).

The narrative comment MAY contain “Human readable dosage instructions” in narrative form.

6.3.4.3.3.6 Status Code

<statusCode code='active | completed'/>

The status code of a Pharmaceutical Advice SHALL be set to either “active” or “completed”, indicating whether the Pharmaceutical Advice is just a pre-release (active) or the final result (completed).

code	Meaning
active	This Pharmaceutical Advice is a provisional result. It is considered as a pre-release advice (e.g., assembled by an automated ICA check function), intended to be a foundation for the final decision taken by another Pharmaceutical Adviser. The results stated in this Pharmaceutical Advice do NOT affect the further workflow.
completed	This Pharmaceutical Advice is a final result. The results stated in this Pharmaceutical Advice will possibly affect the further workflow.

6.3.4.3.3.7 Effective Time (Date of becoming effective)

<effectiveTime value=' ' />

An <effectiveTime> element MAY be present to document a point of time the Pharmaceutical Advice becomes effective. It SHALL contain a value attribute representing the date the observation code provided (e.g., OK, CANCEL, etc.) becomes effective.

If this element is not present, the observation code becomes effective at the creation date of the document.

Examples for observation codes becoming effective at a later point of time:

- A patient is instructed to take the medication dispensed for another 3 days, but then abort this medication treatment and stop taking it.
  - In this case the Pharmaceutical Advice would be reference the according Dispense Item and the <effectiveTime> element would be set to 3 days later than the creation date of the document.
- A Prescription Item is approved to be dispensed, but not sooner than in 2 days.
  - In this case the Pharmaceutical Advice would be reference the according Prescription Item and the <effectiveTime> element would be set to 2 days later than the creation date of the document.

6.3.4.3.3.8 Pharmaceutical Adviser

<author>…</author>

In the case that the Pharmaceutical Advice Item is used within a Pharmaceutical Advice document according to the “Pharmaceutical Advice” (PADV) 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 issuer of the Pharmaceutical Advice Item. It SHALL contain the author and the timestamp of the Pharmaceutical Advice document in which the Pharmaceutical Advice Item was described.

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

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6.3.4.4.3.3.9 Reference to Prescription Item

… Prescription Item Id only …

```
<entryRelationship typeCode='REFR'>
  <substanceAdministration classCode='SBADM' moodCode='INT'>
725     <id root=' ' extension=' '/>       <!-- Prescription Item Id -->
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial nullFlavor='NA'/>
      </manufacturedProduct>
730   </consumable>
  </substanceAdministration>
</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 Pharmaceutical Advice was performed SHALL be present, containing a Prescription Item Entry described in the Pharmacy Prescription (PRE) Content Profile. The reference SHALL NOT be present, if this Pharmaceutical Advice was performed by a Dispense Item.

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 Pharmaceutical Advice was performed, with the following exception:

In case the Prescription Item by which this Pharmaceutical Advice was performed contains a "reason for the use of the medication"[5], 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 would result in a broken link to the internal information referenced, because such information is not allowed in the Pharmaceutical Advice document. In this case the complete copy shall be modified and all reason(s) set to nullFlavor=MSK ("masked": masked, confidential, not published).

nullFlavor 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="MSK|NA"/>
  </act>
</entryRelationship>
```

6.3.4.3.3.10 Reference to Dispense Item

… Dispense Item Id only …

<entryRelationship typeCode='REFR'>

[5] see chapter "Reason" of the Pharmacy Prescription (PRE) Profile


```
<supply classCode='SPLY' moodCode='EVN'>
  <id root=' ' extension=' '/>        <!-- Dispense Item Id -->
     :
</supply>
</entryRelationship>
```

… or complete copy of Dispense Item …

```
<entryRelationship typeCode='REFR'>
  <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'/>
     :
  </supply>
</entryRelationship>
```

The reference to the Dispense Item by which this Pharmaceutical Advice was performed SHALL be present, containing a Dispense Item Entry described in the Pharmacy Dispense (DIS) Content Profile. The reference SHALL NOT be present, if this Pharmaceutical Advice was performed by a Prescription Item.

The Pharmaceutical Advice Item Entry SHALL contain at least the Dispense Item Id (<id> element) and SHOULD be a complete copy (including the <id> element) of the element referenced to.

6.3.4.3.3.11 Reference to Pharmaceutical Advice Concerns

```
<entryRelationship typeCode='REFR' inversionInd='false'>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
    <templateId root='1.3.6.1.4.1.19376.1.9.1.3.5'/>
     :
  </act>
</entryRelationship>
```

One or more Pharmaceutical Advice Concern entries MAY be present in case of validation issues with the objective Prescription- or Dispense Item. They SHALL conform to the Pharmaceutical Advice Concern Entry Content Module template (1.3.6.1.4.1.19376.1.9.1.3.5).

A Pharmaceutical Advice Concern records one or more problems related to the concern. If the concern was caused by another Prescription- or Dispense Item a reference to that item may be present.

6.3.4.3.3.12 Changed or Recommended Prescription Items

```
<entryRelationship typeCode='REFR' inversionInd='false'>
  <organizer classCode='CLUSTER' moodCode='EVN'>
    <statusCode code='completed'>
    <component>
      <seperatableInd value='false'>
        <!-- First Prescription Item -->
        <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>
    </component>
    <component>
        <!-- Second Prescription Item -->
        :
    </component>
      :

  </organizer>
</entryRelationship>
```

(1) One or more elements SHALL be present, if the status of the Pharmaceutical Advice (<code> Element) is set to "**CHANGE**" and a reference to a Prescription Item is given.

In this case it shall indicate the changed Prescription Item(s), which are allowed to be dispensed instead of the original prescribed item. The changed Prescription Item(s) shall be documented as complete Prescription Item Entry(s).

More than one Prescription Items within the organizer indicate that the original Prescription Item has to be changed with the combination of Prescription Items as a whole.

(2) One or more elements MAY be present, if the status of the Pharmaceutical Advice (<code> Element) is set to "**OK**" and a reference to a Prescription Item is given.

In this case it may recommend an alternative (drug, dosage, form, etc.) to the original Prescription Item.

More than one Prescription Items within the organizer indicate that the original Prescription Item can be changed with the combination of Prescription Items as a whole.

(3) In all other cases this element SHALL NOT be present.

All Prescription Items shall be given "as a whole" according to the specification of the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2).

If more than one Changed or Recommended Prescription Item elements are given they indicate a "choice" of change or recommendation.

6.3.4.3.3.13 Changed Dosage Instructions

```
<entryRelationship typeCode='REFR' inversionInd='false'>
  <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 Changed Dosage Instructions are provided in a <substanceAdministration> element containing the dosage instructions data elements.

(1) This element SHALL be present, if all of the following conditions are met:

- The status of the Pharmaceutical Advice (<code> Element) is set to "CHANGE"
- A reference to a Dispense Item is given
- No Narrative Dosage Instructions are provided in the Narrative Text element.

(2) This element MAY be present, if all of the following conditions are met:

- The status of the Pharmaceutical Advice (<code> Element) is set to “CHANGE”
- A reference to a Dispense Item is given
- Narrative Dosage Instructions are provided in the Narrative Text element.

(3) In all other cases this element SHALL NOT be present.

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

6.3.4.4 Pharmaceutical Advice Concern Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.5)

A Pharmaceutical Advice Concern Item belongs to one Pharmaceutical Advice Item and represents the information to concerns (e.g., problems, allergies, etc.) which the Prescription- or Dispense Item referenced by the underlying Pharmaceutical Advice Item causes.

6.3.4.4.1 Standards

This part describes the general structure for a Pharmaceutical Advice Item. It is based on the following standards:

HL7V3 NE2009	HL7 V3 2009 Normative Edition

CDAR2	HL7 CDA Release 2.0
CCD	ASTM/HL7 Continuity of Care Document
IHE PCC	Concern Entry (1.3.6.1.4.1.19376.1.5.3.1.4.5.1)

6.3.4.4.2 Parent Template

This entry content module inherits the structure of the Concern Entry Content Module, 1.3.6.1.4.1.19376.1.5.3.1.4.5.1.

6.3.4.4.3 Specification

This section makes use of the concern entry content modules.

> This specification relies on the PCC Concern Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification and only describes additional constraints.

The chapters 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.

```
<act classCode='ACT' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.27'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
  <templateId root='1.3.6.1.4.1.19376.1.9.1.3.5'/>
  <id root='' extension=''/>
  <code nullFlavor='NA'/>
  <!-- Narrative description of the problems -->
  <text><reference value='#description1'/></text>
  <statusCode code='active'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!--
       One or more entry relationships identifying each problem or allergy determined
  -->
  <entryRelationship typeCode='SUBJ' inversionInd='false'>
     :
  </entryRelationship>
  <!--
       Exactly one referenced Prescription- or Dispense Item
       which causes the concern
  -->
  <entryRelationship typeCode='REFR'>
    <substanceAdministration classCode='SBADM' moodCode='INT'>
      :
    </substanceAdministration>
    <!-- or -->
    <supply classCode='SPLY' moodCode='EVN'>
      :
    </supply>
  </entryRelationship>
  <!-- Optional severity of the concern -->
  <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.55'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
      :
  </entryRelationship>
</act>
```

6.3.4.4.3.1 Pharmaceutical Advice Concern Entry General Specification

<act classCode='ACT' moodCode='EVN'>

…

</act>

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.2 Pharmaceutical Advice Concern Entry TemplateID

<templateId root='2.16.840.1.113883.10.20.1.27'/> **<!-- CCD -->**

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> **<!-- PCC -->**

<templateId root='1.3.6.1.4.1.19376.1.9.1.3.5'/> **<!-- PHARM -->**

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.3 Pharmaceutical Advice Concern ID

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

This ID represents the Pharmaceutical Advice Concern ID and SHALL be present.

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.4 Code

<code nullFlavor='NA'/>

The code is not applicable to a concern act, and so shall be recorded as shown above.

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.5 Narrative description of the concern

<text><reference value='#comment1'/></text>

An optional narrative description of the concern MAY be referenced in the <text> element.

6.3.4.4.3.6 Status Code

<statusCode code='active'/>

The status of the <act> element SHALL be present and must be set to "active". The concern is still being tracked.

6.3.4.4.3.7 Effective Time

<effectiveTime>

<low value=''/>

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

</effectiveTime>

The <effectiveTime> element records the starting and ending times during which the concern was active.

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.8 Problems determined

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

:

</entryRelationship>

One or more entry relationships SHALL be present identifying each problem or allergy determined. These entries SHALL conform to the specification of the IHE PCC Problem Entry or Allergies and Intolerances.

See PCC TF2, Concern Entry Module (1.3.6.1.4.1.19376.1.5.3.1.4.5.1) specification.

6.3.4.4.3.9 External Prescription- or Dispense Item triggering the concern

```
<entryRelationship typeCode='REFR'>
  <!-- Prescription Item -->
  <substanceAdministration classCode='SBADM' moodCode='INT'>
   :
  </substanceAdministration>
  <!-- or -->
  <!-- Dispense Item -->
  <supply classCode='SPLY' moodCode='EVN'>
   :
  </supply>
</entryRelationship>
```

Exactly one entry relationship MAY be present identifying the external Prescription- or Dispense Item, which triggers the concern (in conjunction with the Prescription- or Dispense Item the parent Pharmaceutical Advice Item is related to). This entry SHALL conform to either the Prescription Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.2) or the Dispense Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.4) template.

These Prescription- or Dispense Item Entries SHALL contain at least the Prescription- or Dispense Item Id (<id> element) and SHOULD be a complete copy (including the <id> element) of the one referenced to, with the following exception:

In case the referenced item is a Prescription Item and the referenced Prescription Item contains a "reason for the use of the medication"[6] 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 would result in a broken link to the internal information referenced, because such information is not allowed in the Pharmaceutical Advice document. In this case the complete copy shall be modified and all reason(s) set 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"/>
```

[6] see chapter "Reason" of the Pharmacy Prescription (PRE) Profile


```
        <id nullFlavor="MSK"/>
        <code nullFlavor="MSK|NA"/>
    </act>
</entryRelationship>
```

6.3.4.4.3.10 Severity of the concern

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.55'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
        :
    </observation>
</entryRelationship>
```

Exactly one Severity Observation MAY be present. This element SHALL conform to the IHE PCC Severity Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.4.1) specification.

6.5 PHARM Value Sets

Add Section 6.5.1

6.5.1 IHE Pharmaceutical Advice Status List

The Pharmaceutical Advice Status List is used in the Pharmaceutical Advice Item Entry Content Module (1.3.6.1.4.1.19376.1.9.1.3.3) for coding the overall outcome of the validation process or management command regarding the referenced Prescription- or Dispense Item, implying the further proceeding with it.

code: **see column "Code"**

codeSystem: **1.3.6.1.4.1.19376.1.9.2.1**

codeSystemName: **IHE Pharmaceutical Advice Status List**

Code	Description
OK	Usage in case when this Pharmaceutical Advice references a Prescription Item: Prescription Item is active (e.g., can be dispensed, no change expected but allowed if recommended medication given). Usage in case when this Pharmaceutical Advice references a Dispense item: Dispense Item is active (e.g., resumed from being suspended).
CHANGE	Usage in case when this Pharmaceutical Advice references a Prescription Item: Dispense with change expected Usage in case when this Pharmaceutical Advice references a Dispense item: Change in any information element of the Dispense Item except the medication (e.g., dosage instructions, patient instructions, etc.). The original Medicine Entry Item referenced by the Dispense Item shall be unchanged.
REFUSE	Refusal to dispense until further discussion with prescriber
CANCEL	Usage in case when this Pharmaceutical Advice references a Prescription Item: Definite cancelation of the Prescription Item (item will not be dispensed) Usage in case when this Pharmaceutical Advice references a Dispense item: Definite stopping of the dispensed medication (patient stops intake of the medication)
SUSPEND	Usage in case when this Pharmaceutical Advice references a Prescription Item: Prescription Item is temporarily set to suspended with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.). The item shall not be dispensed during set to suspended. Usage in case when this Pharmaceutical Advice references a Dispense item: Dispense item is temporarily set to suspended with the decision on how to continue postponed to a later point of time (e.g., release it again by setting it to OK, finally cancel it by setting to CANCEL, etc.). The medication shall not be taken by the patient during set to suspended.

Appendices

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