**­Integrating the Healthcare Enterprise**



**IHE Pharmacy**

**Technical Framework Supplement**

**Mobile Medication Administration**

**(mMA)**

**FHIR ® STU3**

Using Resources at FMM Level 5

**Draft in preparation for Public Comment**

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**Foreword**

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

*<For Public Comment:>* This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and may be submitted at <http://www.ihe.net/pharmacy/pharmacycomments.cfm>. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

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: [www.ihe.net](http://www.ihe.net).

Information about the IHE Pharmacy domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

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/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE <Domain name>Technical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

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# Introduction to this Supplement

FHIR is under development by HL7, and the resources and transactions in this Supplement may continue to be revised.

Release 3 of FHIR is used in the MMA profile. HL7 has designated this release as an STU (Standard for Trial Use), and appropriate for non-production use. See <http://hl7.org/fhir>.

Non-normative FHIR resources are given a FHIR Maturity Model (FMM) level 0 (draft) through 5 (normative ballot ready).

The FHIR STU3-defined resources used in this profile and their FMM levels are:

|  |  |
| --- | --- |
| **FHIR Resource Name** | **FMM Level** |
| MedicationRequest | FMM 3 |
| MedicationAdministration | FMM 2 |

The IHE Mobile and Distributed Medication Administration supplement introduces a new generation of interoperability mechanisms to be used in distributed and mobile medication workflows, namely in the requesting and registering of administration of medication, in mobile systems or otherwise distributed systems.

The use of this profile supports the administration of medication with a standard way to:

* (optionally) transmit the instructions for administration
* register and exchange information about the administration of medication

The Mobile Medication Administration profile is intended to be compatible with hospital settings, but also community settings on a mobile environment, or where CDA documents are not used. For CDA documents, refer to the IHE CMA profile.

The content of this profile is functionally compatible with the CMA profile: it is the goal of IHE Pharmacy to provide one consistent interoperability framework, which can be implemented using different technical mechanisms.

The MMA Profile enables mobile and lightweight web applications to register the planned and actual administration of medication.

The uses for MMA are:

* An application for a home care nurse, that receives the requests and informs the nurse about the medications that each patient is scheduled to take in a given period.
* An application (or the same as above) for a Nurse, where the nurse can register the planned (as above) or unplanned administration of medication
* An application for patients to receive updated medication instructions on their mobile device and / or register the use of medication, e.g. by scanning the barcodes.

Further ahead, the IHE Pharmacy Technical Framework will be extended to the entire medication circuit, and the MMA profile is not expected to change during that extension. In other words, while the MMA profile may incorporate changes due to maintenance or changes in the underlying standards, it is not expected to be redesigned when the entire medication circuit is implemented.

This supplement is intended to be fully compliant with the HL7 FHIR specification, providing only use-case driven constraints to aid with interoperability, deterministic results, and compatibility with existing Profiles.

Currently the HL7® FHIR® standard is in “Standard for Test Use” (STU) and may experience a large amount of change during this phase. Readers are advised that, while the profiled components in this supplement may not accurately reflect the most recent version of the FHIR standard, implementations of MMA will be tested as specified in this supplement. Changes to the FHIR STU will be integrated into this supplement via the formal IHE Change Proposal (CP) process.

. To include compatibility with existing IHE actors, this profile extends or adds the following actors:

**Medication Administration Performer** – checks for and receives instructions for administration of medications to patients, performs the necessary checks before administering.

**Medication Administration Informer** – sends the reports of the administration actions performed.

**Medication Administration Request Placer** – provides the instance orders of medication administrations to the medication Administration Performer.

**Medication Administration Consumer** – receives the reports of administration of medications.

The structure of this profile allows different systems to concur in the administration of medications for several patients – whether they are remote systems, mobile applications for professionals, or patient apps.

## Open Issues and Questions

1. Are we going for a push-model or pull-model? A: we need both.
2. How to handle the sending of prescription changes? Sending only the changes or the whole prescription? Suggest to do risk review on either option, but only later when we address mobile prescription.
3. How to handle workflow management by the actors? A separate actor like CMPD? Or at the actors?
   1. Maybe a hybrid model?

## 

## Closed Issues

* MMA\_001 medicationAdministration or medicationStatement
* MMA\_002 Differentiate requests from prescriptions
* MMA\_003 Can’t search on date
* MMA\_004 Can’t search on performer
* MMA\_005 medicationAdministration or medicationStatement

<Note: The sections following this Introduction will eventually be added as Final Text to Volumes 1 – 4 of the Technical Framework. The material above this note (the Introduction, and Open and Closed Issues section) will be deleted when this Supplement is moved to Final Text.>

# General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of Actors:

<Add any actor definitions for new actors defined specifically for this profile. These will be added to the IHE TF General Introduction list of Actors namespace.>

|  |  |
| --- | --- |
| Actor | Definition |
| Medication Administration Performer | *Receives instructions for administration of medications to patients, to perform the necessary checks and display it to the user (patient or heathcare professional)* |
| Medication Administration Informer | Sends the reports of the administration actions performed. |
| Medication Administration request Placer | *Submits the instance orders of medication administrations to the medication Administration Performer.* |
| Medication Administration Consumer | *Receives the reports of administration of medications* |
| Medication Administration Verifier | ????? |

Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

<Add any transaction definitions for new transactions defined specifically for this profile. These will be added to the IHE TF General Introduction list of Transactions namespace.>

|  |  |
| --- | --- |
| Transaction | Definition |
| Query Administration Request | Request for individual administration actions to be performed |
| Report Administration Results | Report on the outcome of a single administration event |

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

<Any glossary additions associated with the profile draft go here.>

|  |  |
| --- | --- |
| Glossary Term | Definition |
| Administration Request |  |
| Administration Report |  |

Volume 1 – Profiles

## <*Copyright Licenses>*

<General copyright licenses and permissions are listed in the IHE Technical Frameworks General Introduction. Add information on any standards referenced in the profile that are not already addressed in the permission section.>

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

The HL7® FHIR® standard License can be found at <http://hl7.org/fhir/STU3/license.html>.

## <*Domain-specific additions>*

<Some domains have specific sections, added as subsections to Sections 1 or 2, in their Technical Frameworks. These types of additions are allowed as long as they do not adjust the overall numbering scheme which needs to remain consistent across domains. If there are such additions, they should be included here.>

Add to Section …

<Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter “X” with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>

# Mobile Medication Administration (MMA) Profile

# The Mobile Medication Administration Profile provides integration between systems or actors that are in charge of medication administration and systems or actors that are upstream (e.g. prescription or dispensing systems) or downstream (e.g. EHRs or others).

The MMA profile supports the data exchange for the following actors and cases:

1. A Medication Administration Request Placer contains the planned individual medication administration actions. The Medication Administration Performer retrieves these scheduled actions from the Medication Administration Request Placer, in order to perform them.
   1. Note: For not scheduled (emergency or not prescribed) medications, the individual Administration Requests do not exist, neither a prescription.
   2. Note: For “As needed” orders, the individual Administration Requests do not exist, although a prescription may exist.
2. The Medication Administration Informer informs a Medication Administration Consumer about the performing of the administration activity (or its reported absence).
   1. Is this a push or a pull? The server should not be on the mobile side.

HERE section about continuous administrations.

## 3.1 MMA Actors, Transactions, and Content Modules

This section defines the actors, transactions, and content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at <http://www.ihe.net/Technical_Framework/index.cfm>.

Figure 3.1-1 shows the actors directly involved in the MADM Profile and the relevant transactions between them.

↑ Query Administration   
Requests  
[PHARM-2]

↓ Transaction 2 [2]

Medication Administration Request Placer

Actor A

Medication Administration Consumer

Actor B

Medication Administration Performer

Actor D

Medication Administration Informer

↑ Report Administration Result   
[PHARM-3]

↓ Transaction 2 [2]

Figure X.1-1: MADM Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the MMA Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

Table X.1-1: MMA Profile - Actors and Transactions

| Actors | Transactions | Optionality | Reference |
| --- | --- | --- | --- |
| Administration Request Placer | Query Administration Requests | O | PHARM-M1 TF-2: 3.Y1 |
| Administration Performer | Query Administration Requests | O | PHARM-M1 TF-2: 3.Y1 |
| Administration Request Placer | Send Administration Request | O | PHARM-M1 TF-2: 3.Y2 |
| Administration Performer | Send Administration Request | O | PHARM-M1 TF-2: 3.Y2 |
| Administration Informer | Administration Report | R | PHARM-M2 TF-2: 3.Y3 |
| Administration Consumer | Administration Report | R | PHARM-M2 TF-2: 3.Y3 |
|  |  |  |  |

Note 1: The Administration Performer must be able to get the list of planned administrations, either by querying (Pull) or receiving (Push). Therefore, either Transaction Y1 or Transaction Y2 (or both) shall be implemented for Administration Request Placer / Administration Performer.

### X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2). This section documents any additional requirements on profile’s actors.

In a typical implementation, after the Medication is prescribed, the administrations are scheduled and administration events (instance orders) are defined, for example in an EHR in a hospital. Such systems implement the Medication Administration Order Placer.

The medication orders are then consulted in a nurse’s or a patient’s mobile application, for the purpose of performing these administrations. This system thus implements the Medication Administration Performer actor.

After administration, the same system informs about the status of administrations – This system thus implements the Medication Administration Informer actor. The administration is for example received by the EHR, which then also implements the Administration Consumer actor.

#### X.1.1.1 Medication Administration Order Placer

The Medication Administration Order Placer contains the instance orders for each planned medication administration. It responds to a FHIR search request from the Medication Administration Performer.

#### X.1.1.2 Medication Administration Performer

The Medication Administration Performer invokes a FHIR search for the planned administrations that are relevant for the context of the Medication Administration Performer. This context can be a combination of any of the following:

* A specific nurse that is planned to perform the administrations (in case for example of a mobile app for a nurse);
* A specific care team that is planned to perform the administrations (in case for example of a mobile app for a care team in a hospital ward);
* The patient for which the administration is planned;
* The time of administration (e.g. only the administrations for a given day, or a given shift).
* …

#### X.1.1.3 Medication Administration Informer

The Medication Administration Informer provides, by pushing a FHIR resource, a report of the outcome of a planned administration: whether the administration was effectively performed, and the actual time of administration, the performer, any additional information, etc.

It also publishes a report of unplanned administrations if such unplanned administrations occur

#### X.1.1.4 Medication Administration Consumer

The Medication Administration Consumer receives the information about the Medication Administration.

#### X.2 MMA Actor Options

<Modify the following Table listing the actors in this profile, the options available for each, and references to sections that state requirements for compliance to each Option. For actors with no options, state “No options defined” in the Options column.>

<Note: Options are directly carried over to the Integration Statements which are published by vendors for review by buyers. Too many options can be confusing for readers.>

< Try to **minimize** options for Actors and only use if necessary.>

<Several options for Content Consumers are defined in PCC TF-2 section 3.1.1-3.1.4. It is recommended that these options are reused for content module definitions, but read the option definitions thoroughly to be certain that they apply. If they do apply in their entirety, you will need to define a corresponding option in this profile. The recommended naming convention for a similar, but different, option is, for example, “View Option - <profile acronym>, etc., “View Option – CIRC”.>

Options that may be selected for each actor in this profile, if any, are listed in the table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: Mobile Medication Administration - Actors and Options

| Actor | Option Name | Reference  *<either reference TF-3 or the applicable X.2.x subsection below table>* |
| --- | --- | --- |
| Administration Request Placer / Administration Performer | PULL requests |  |
| PUSH requests |  |
| Administration Informer | No options defined | -- |
| Administration Consumer | No options defined | -- |

Note: *<Conditional or required options must be described in this SHORT note, for longer notes use section X.2.1.>,*

### X.2.1 PULL requests

The PULL option is used when the administration performer (e.g. the nurse’s mobile app) triggers the request for medication orders. This is typically the case when the context information (e.g. which medications to pull, for which period, for which patient) is defined at the Medication Administration Informer.

### X.2.1 PUSH requests

The PSH option is used when the Administration Request Placer (e.g. the EHR) sends a set of medication requests to the Administration Performer. This is typically the case when the context information (e.g. which medications to pull, for which period, for which patient) is defined at the Administration Request Placer, like a central scheduling system that assigns patients to care teams, and there is an interest and ability to centrally control the distribution of medication requests – for example to ensure that each care team only gets their own requests and cannot query beyond that.

## X.3 MMA Required Actor Groupings

An Actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to*** all of the transactions required for the grouped actor (Column 2).

Table X.3-1: <Profile Name> - Required Actor Groupings

| <this Profile Acronym> Actor | Actor to be grouped with | Reference | Content Bindings Reference |
| --- | --- | --- | --- |
| Administration Request Placer | None |  |  |
| Administration Performer | None |  |  |
| Administration Informer | None |  |  |
| Administration Consumer | None |  |  |

## X.4 MMA Overview

The MMA profile gives the mechanisms to inform about the planned and actual administration of medications.

### X.4.1 Concepts

The use cases in MMA are kept to a small set, focused on the clear functionality profiled: getting medication administration requests, and informing about the administration.

The use of FHIR is a precursor for distributed applications, to enhanced data exchange using a reliable, common and lightweight technical approach. The approach described here may be used in a range of contexts – hospitals, communities, national or regional data exchange – but the starting focus of this profile are:

* Mobile applications used by nurses, where they check the schedule and inform the administration of medication
* Patient mobile devices such as smartphones
* Other devices reporting administration of drugs, such as ambulatory drug infusion devices, or others.
* Other cases

This profile starts with two use cases that will benefit especially from the use of REST interfaces.

### X.4.2 Use Cases

#### X.4.2.1 Use Case #1: Home Nursing Scenario

This use case describes the situation in which a nurse receives a list of medications to give to patients in an ambulatory setting, and uses a mobile device to plan and check the appropriateness of the administration, using also the same device to record the execution of the administration.

##### X.4.2.1.1 Home Nursing Scenario Use Case Description

In this use case, nurses are responsible for medication administration of elderly patients in an ambulatory environment. The patients reside at home or in a wide spread nursing homes where internet is not always available.

The nurses are responsible for the care of a group of patients, and each nurse receives a working list of the patients she has to visit on that particular day. Each patient could have multiple medications.

The assignments could involve several tasks like measuring temperature, blood pressure or taking blood samples, but this document concentrates on the medication administration.

The logistical supply of the medication is articulated with this profile but defined elsewhere and is not part of the scope of this profile. See the IHE Pharmacy Technical Framework for relevant profiles on dispense, resupply, inventory management and consumption. For this document, the patient could have the medication available at home or the nurse could take a medication strip along her, with the medication dispensed for the specific patients, or medication in bulk that she then splits as needed.

It is assumed that the nursing application has a “list” or “catalog” of the medications available, so that when the nurse scans a barcode, this barcode can be matched to a prescribed product or even an “over the counter” product, such as pain relievers.

This matter of “Catalog” / “Formulary” is also not addressed in this document, although this document provides a clear requirement for such “Catalog” or “Formulary”.

##### X.4.2.1.2 Home Nursing Scenario Process Flow

**Pre-conditions:**

1. It is assumed that the medication administrations are planned (i.e. each planned administration is scheduled and assigned to a nurse or care team).
2. There is a system (e.g. EHR) that contains this information.

**Main Flow:**

1. Each nurse logs in to her tablet.
2. **The tablet (which implements the Medication Administration Performer actor) queries the EHR for the medication that is relevant for the nurse to administer: For example, the medications for all the patients that are scheduled to be visited that same day.**
3. **The EHR responds with a list of the relevant medication administration instructions.**
4. The nurse checks her tablet and compares visually the names of the patients and the amount of medication lines with the EHR to verify if the download has been successful. If not successful she tries a second attempt to download the instructions once more.
5. The app on the tablet tells the nurse the optimal routing with the names and addresses of the patients she has to visit.
6. At each address, the nurse looks on the tablet for the medication and the dosage for the appropriate patient.
7. The nurse searches for the medication for the patient among the Baxter strips and scans the barcodes on the strip with the camera in her tablet. The app generates a warning if the medication and the patient do not match.
8. She sees to it that the medication is being swallowed.
9. For unplanned medication administrations (unplanned, or conditional medications), the nurse can also scan the barcode of the package or enters a code manually into the app.
10. If medications were scheduled but were not administered after the time has elapsed, the nurse can also register that this medication has not been consumed (including the reason).
11. Before she leaves she can enter remarks about the state of the patient.
12. If the nurse does not document all the scheduled administrations, the tablet issues a warning to the nurse.
13. After her round of patients, the nurse returns to her institution and connects with her EHR.
14. **The results of the medication administration round are reported back to the EHR. This could be initiated from the EHR from where the data from the app is uploaded to the EHR.**

**Post conditions:**

1. The medication management profile of the patients are updated with the feedback of the substance administration.

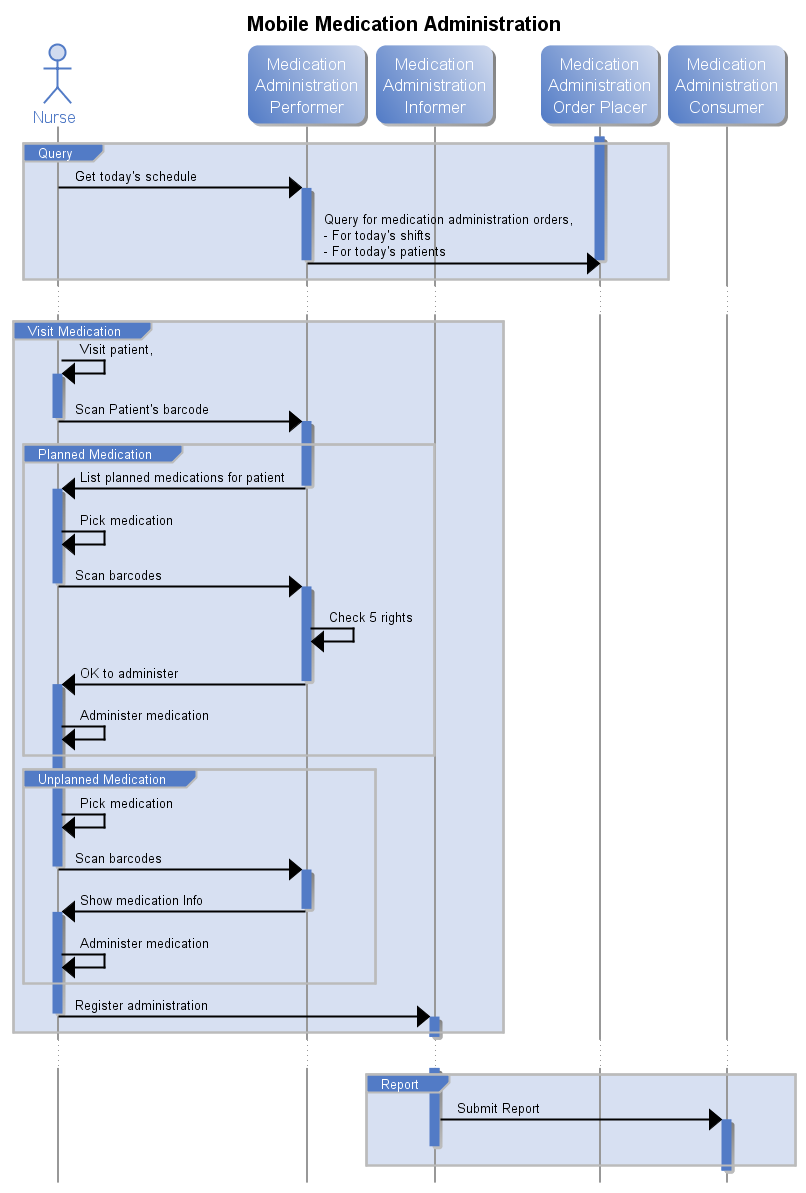


Figure X.4.2.2-1: Scheduled Administration Process Flow in MMA Profile

#### X.4.2.1 Use Case #2: Home Chemotherapy Administration

This use case describes the situation in which a patient receives instructions for the daily dosage and confirms the usage of the medication.

##### X.4.2.1.1 Home Chemotherapy Administration Use Case Description

In several countries, Chemotherapy treatments can be administered at home for improving the quality of life of the patient: The patient does not need to reside in a hospital, but can remain in his own familiar setting and follow the instructions on the app of a mobile device. These dosage instructions are complex schemas which have to prescribed by specialized oncologists. The app should be able to perform independently even if no internet connection is available.

##### X.4.2.1.2 Home Chemotherapy Administration Process Flow

Pre-conditions

1. Patient Adam Everyman has a malignant tumor in his throat. It has been treated with radiation, but Adam has to complete the therapy with a chemotherapy for 4 weeks.
2. The therapy has to be followed strictly, in dosage as well as in timing.
3. The oncologist sets up Adam for a close monitoring of the treatment administration, which means that the oncologist issues an administration order every day (i.e. there is no pre-scheduled administration orders), and Adam has to follow the instructions on his phone app every day to take the medication.
4. The oncologist enters the medication request instructions in the EHR of the hospital on a daily basis following a protocol, but this protocol is always adjusted with the outcome of the patient’s well-being.

Main Flow:

1. **The phone app downloads the medication request instructions and stores it locally in the memory of the phone. The app can function on its own, even if no internet is available.**
2. The app issues a signal every time Adam has to take his medication.
3. Adam has to take a combination of 3 drugs, each with different dosage and timing. Adam confirms the medication which he has taken or not taken. Sometimes the side effects are so strong that Adam vomits all his food and medication. He can use the same app to report that event.
4. The app provides the ability to register additional medication that Adam uses to soothe the nausea or soften pain.
5. **When Adam is back at home he synchronizes his app through internet with the hospital EHR and the results are reported back to the hospital.**

Post conditions:

1. With an updated information about the patient’s administration and its effects, the oncologist and the pharmacist evaluate Adam’s therapy and adjust the medication schema for the following day.

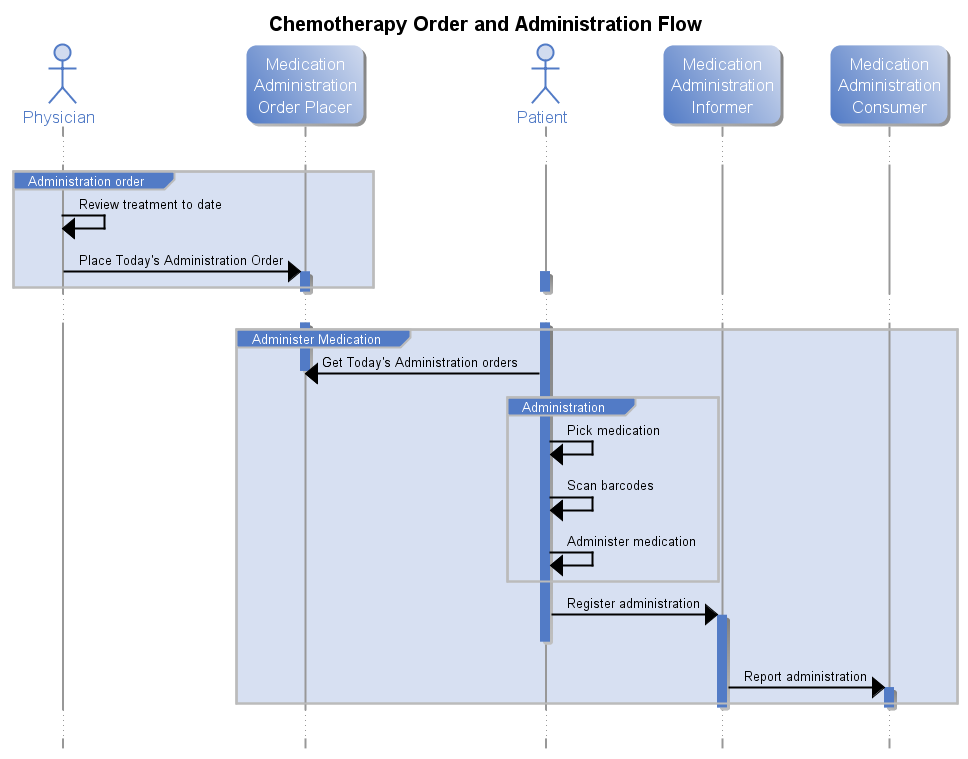


Figure X.4.2.2-1: Home Chemotherapy Administration Process Flow

## X.5 MMA Security Considerations

See IHE ITI-TF Appendix Z.8 “Mobile Security Considerations”

## 

## X.6 MMA Cross Profile Considerations

Not currently applicable.

When the Catalog transaction is available, it may be grouped with this actor, to support the case when a nurse enters a not-prescribed medication, and the system should query to get the characteristics of the medication.

Appendices

<Add Appendices to this Profile here. Examples of an appendix include HITSP mapping to IHE Use Cases or long use case definitions.>

<Volume 1 Appendices are informational only. No “SHALL” language is allowed in a Volume 1 appendix.>

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 2 – Transactions

Add section 3.Y

## 3.Y Medication Administration Request Query

### 3.Y.1 Scope

This transaction is used to retrieve the planned administrations for a given context.

### 3.Y.2 Actor Roles

<Optional: if desired, in addition to the table, add a diagram as shown below to illustrate the actors included in this transaction, or delete the diagram altogether.>

Medication Administration Performer

Actor DEF

Medication Administration Request Placer

Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | Medication Administration Request Placer |
| **Role:** | Provide the list of planned administrations |
| **Actor:** | Medication Administration Performer |
| **Role:** | Search for the planned administrations for a given context |
| **Actor:** | Medication Administration Informer |
| **Role:** | Provide the report of administration events (or non-administrations) |
| **Actor:** | Medication Administration Consumer |
| **Role:** | Obtain the report of administration events (or non-administration) |

### 3.Y.3 Referenced Standards

|  |  |
| --- | --- |
| HL7 FHIR | Fast Healthcare Interoperability Resources DSTU3 <http://hl7.org/fhir/DSTU3/index.html> |
| IETF RFC 2616 | Hypertext Transfer Protocol – HTTP/1.1 |
| IETF RFC 7540 | Hypertext Transfer Protocol – HTTP/2 |
| IETF RFC 3986 | Uniform Resource Identifier (URI): Generic Syntax |
| IETF RFC 4627 | The application/json Media Type for JavaScript Object Notation (JSON) |
| IETF RFC 6585 | Additional HTTP Status Codes |

### 3.Y.4 Interaction Diagram

Query Administration rerRequest Query (PHARM TF-2: 3.Y.4.1):   
HTTP GET /MedicationRequest

Query Administration Request Response (PHARM TF-2:3.Y.4.2):   
Bundle (MedicationRequest)

Medication Administration Order Placer

Medication Administration Performer

Actor B/ Actor C

#### 3.Y.4.1 Query Medication Administration Requests

This message represents an HTTP GET parameterized query from the Medication Administration Performer to the Medication Administration Order Placer.

##### 3.Y.4.1.1 Trigger Events

When the nurse requests the list of medications planned for a given context – a specific patient, or a specific schedule, for a specific nurse.

##### 3.Y.4.1.2 Message Semantics

The Medication Administration Order Request is conducted by the Medication Administration Performer by executing an HTTP GET against the Medication Administration Order Placer’s MedicationRequest Resource URL.

The search target follows the FHIR http specification, addressing the MedicationRequest Resource type (see <http://hl7.org/fhir/STU3>)

GET [base]/[type]{?[parameters]{&\_format=[mime-type]}}

This URL is configurable by the Medication Administration Performer and is subject to the following constraints.

The [parameters] represents a series of encoded name-value pairs representing the filter for the query specified in Section 3.Y.4.1.2.1, as well as control parameters to modify the behavior of the Medication Administration Order Placer such as response format, or pagination.

###### 3.Y.4.1.2.1 Query Search Parameters

The Medication Administration Performer may supply and the Medication Administration Order Placer shall be capable of processing all query parameters listed below. See <http://hl7.org/implement/standards/fhir/http.html#mime-type> for details on encoding.

Medication Administration Order Placers may choose to support additional query parameters beyond the subset listed below. Such parameters are considered out of scope for this document.

Table 3.Y.4.1 shows the values

| Attribute | type | repeat | Meaning |
| --- | --- | --- | --- |
| type | Fixed Value: MedicationRequest |  | … |
| identifier |  | Y |  |
| (date/time) from | Datetime  yyyy-mm-dd hh:mm:ss | N | The time start that the medication is planned to be administered |
| (date/time) to | Datetime  yyyy-mm-dd hh:mm:ss | N | The time end that the medication is planned to be administered |
| (patient) |  | N | The patient for which the medication is planned |
| status | string | N | The status of the medication request. Typically this is “active” |
| Performer |  | N | The intended performer |
| Order type | Fixed value: “instance-order” | N | The type of Medication Request. Administration Requests are of type “**instance-order**” |

**\_id**

This parameter of type string*,* when supplied, represents the resource identifier to be retrieved

Note: A search using \_id is always an exact match search.

**identifier Search Parameter**

This repeating parameter of type token*,* when supplied, specifies an identifier associated with the Medication Administration Order instance whose information is being queried (e.g., a local identifier, account identifier, etc.).

If multiple instances of this parameter are provided in the query, the query represents a logical AND condition (i.e., all of the associated identifiers must match).

**Date and time of planned administration**

These parameters of type ???????

See FHIR specs for search based on boundaries and approximate searches…

**Patient Identification**

To get the medication administrations planned for a specific patient

Note that according to FHIR specification, only one patient ID can be searched in each query.

If multiple instances of this parameter are provided in the query, the query represents a logical AND condition (i.e., all of the associated identifiers must match).

**Status**

This parameter of type ???????????????

**Intended Administration Performer**

**Medication Order Type**

This parameter of type string must have a fixed value of “instance-order”.

###### 3.78.4.1.2.5 Populating Expected Response Format

The FHIR standard provides encodings for responses as either XML or JSON. Medication Administration Order Placer Actors shall support both message encodings, whilst Medication Administration Performer Actors shall support one and may support both.

The formats are json or xml.

##### 3.Y.4.1.3 Expected Actions

In response to the request, the Medication Administration Order Placer shall return a bundle of medicationRequest resources. The response is synchronous (i.e., on the same connection as was used to initiate the request), and shall include the records (medicationRequest resources) that match all of the search criteria provided by the Medication Administration Performer.

The mechanics of the planning and scheduling requests, and how these requests are populated, are outside the scope of this framework.

If the Medication Administration Performer supplied a query parameter, or used a query parameter modifier which the Medication Administration Order Placer is not capable of utilizing, then the Medication Administration Order Placer shall respond with an **HTTP 400** (Bad request) status code and an OperationOutcome resource indicating the parameters in error.

The Medication Administration Order Placer shall respond to the query request as described by the following cases with a Medication Administration Order Response message described in Section 3.Y.4.2, and shall behave according to the cases listed below:

**Case 1:** The Medication Administration Order Placer finds in its information source, at least one patient record matching the criteria sent as HTTP query parameters.

**HTTP 200** (OK) is returned as the HTTP status code.

A resource bundle is returned representing the result set. The Medication Administration Order Placer populates the total property of the bundle with the total number of matching results. One entry is returned from the Medication Administration Order Placer for each MedicationRequest Resource found.

**Case 2:** The Medication Administration Order Placer fails to find in its information source, any patient record matching the criteria sent as HTTP query parameters.

**HTTP 200** (OK) is returned as the HTTP status code.

A resource bundle is returned representing the zero result set. The Medication Administration Order Placer populates the total with a value of 0 indicating no results were found. No entry attributes are provided in the result.

**Case 5:** The Medication Administration Order Placer is not capable of producing a response in the requested format specified by \_format parameter (specified in Section 3.Y.4.1.2.5).

**HTTP 406** (Not Acceptable) is returned as the HTTP status code.

An OperationOutcome Resource is returned indicating that the requested response format is not supported in an issue having:

| Attribute | Value |
| --- | --- |
| severity | error |
| code | {http://hl7.org/fhir/issue-type.html, ,not-supported} |

The Medication Administration Order Placer may be capable of servicing requests for response formats not listed in Section 3.78.4.1.2.5, but shall, at minimum, be capable of producing XML and JSON encodings.

The Medication Administration Order Placer may return other HTTP status codes to represent specific error conditions. When HTTP error status codes are returned by the Medication Administration Order Placer, they shall conform to the HTTP standard RFC 2616. Their use is not further constrained or specified by this transaction.

Change from PDQ to MMA:

#### 3.78.4.2 Query Patient Resource Response message

##### 3.78.4.2.1 Trigger Events

The Patient Demographics Supplier found patient demographics matching the query parameters specified by the Patient Demographics Consumer as a result of a Query Patient Resource Request.

##### 3.78.4.2.2 Message Semantics

The Query Patient Resource Response is sent from the Patient Demographics Supplier to the Patient Demographics Consumer as a Bundle of Patient Resources. The “content-type” of the response will depend upon the requested response format indicated by the Patient Demographics Consumer.

###### 3.78.4.2.2.1 (X) Resource Definition in the Context of (transaction)

The components of the Patient Resource with cardinality greater than 0 (as shown below) are required, and the detailed description of the message is provided here. All other attributes of the response are optional.   
The Patient Resource contained within the Query Patient Resource Response message is described at <http://hl7.org/fhir/STU3/patient.html>, and is not further constrained by this transaction.

###### 3.78.4.2.2.3 Resource Bundling

Please see ITI TF-2x: Appendix Z.1 for details on the IHE guidelines for implementing FHIR bundles.

###### 3.78.4.2.2.4 Incremental Response Processing - Paging of Resource Bundle

The Patient Demographics Supplier shall represent these incremental responses as specified FHIR Paging <http://hl7.org/fhir/STU3/http.html#paging>

###### 3.78.4.2.2.5 Quality of Match

The Patient Demographics Supplier may convey the quality of each match based on strength of the particular result to the supplied query parameters. The mechanism for determining the confidence of match is considered a product specific feature, and is not specified in this transaction.

If the Patient Demographics Supplier wishes to convey the quality of match, it shall represent the confidence of a particular match within the bundle as a score attribute. See FHIR Relevance section <http://hl7.org/fhir/STU3/search.html#score>

##### 3.78.4.2.3 Expected Actions

The constraints specified in Section 3.78.4.2.2 represent the minimum set of demographics information that must be implemented by a Patient Demographics Supplier. This does not prevent the Patient Demographics Supplier from sending additional FHIR attributes in a response; such as extensions, text, etc. The Patient Demographics Consumer shall ignore additional attributes and extensions if not understood.

The consumer shall process the response in some manner specific to its application function (for example: displaying on a user interface). This application behavior is not specified by IHE.

##### 3.78.4.2.5 Conformance Resource

Patient Demographics Suppliers implementing [ITI-78] should provide a Conformance Resource as described in ITI TF-2x: Appendix Z.4 indicating the query operation for the Patient Resource has been implemented and shall include all query parameters implemented for the Patient Resource.

The table below presents the optionality and cardinality for each medicationRequest that is in the response:

Add section 3.Z

## 3.Z Medication Administration Report

### 3.Z.1 Scope

This transaction is used to …

### 3.Z.2 Actor Roles

Medication Administration Performer

Actor DEF

Medication Administration Request Placer

Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

|  |  |
| --- | --- |
| **Actor:** | Medication Administration Informer |
| **Role:** | Provide the report of administration events (or non-administrations) |
| **Actor:** | Medication Administration Consumer |
| **Role:** | Receive the report of administration events (or non-administration) |

### 3.Z.3 Referenced Standards

|  |  |
| --- | --- |
| HL7 FHIR | Fast Healthcare Interoperability Resources DSTU3 <http://hl7.org/fhir/DSTU3/index.html> |
| IETF RFC 2616 | Hypertext Transfer Protocol – HTTP/1.1 |
| IETF RFC 7540 | Hypertext Transfer Protocol – HTTP/2 |
| IETF RFC 3986 | Uniform Resource Identifier (URI): Generic Syntax |
| IETF RFC 4627 | The application/json Media Type for JavaScript Object Notation (JSON) |
| IETF RFC 6585 | Additional HTTP Status Codes |

### 3.Z.4 Interaction Diagram

Administration Report (PHARM TF-2: 3.Y.4.1):   
HTTP PUT/POST /MedicationRequest

Administration Report Response (PHARM TF-2:3.Y.4.2):   
Bundle (MedicationRequest)

Medication Administration Order Placer

Medication Administration Performer

Actor B/ Actor C

#### 3.Z.4.1 Medication Administration Reports

This message represents an HTTP POST of a bundle of medication administration reports.

The bundle is necessary to contain several administration reports, since typically the nurse will upload the results when there is connectivity.

##### 3.Z.4.1.1 Trigger Events

When the nurse synchronizes the mobile application with the server or in some cases when the nurse device is online and it is possible to send an update after each administration.

Note that given the time between an administration and the reporting, expressed in section XXXX, the trigger for submitting an administration will typiclally be some time after.

##### 3.Z.4.1.2 Message Semantics

###### 3.Z.4.1.2.1 Query Search Parameters

The Medication Administration Performer may supply and the Medication Administration Order Placer shall be capable of processing all query parameters listed below. See <http://hl7.org/implement/standards/fhir/http.html#mime-type> for details on encoding.

Medication Administration Order Placers may choose to support additional query parameters beyond the subset listed below. Such parameters are considered out of scope for this document.

Table 3.Y.4.1 shows the values

| Attribute | type | repeat | Meaning |
| --- | --- | --- | --- |
| type | Fixed Value: MedicationRequest |  | … |
| identifier |  | Y |  |
| (date/time) from | Datetime  yyyy-mm-dd hh:mm:ss | N | The time start that the medication is planned to be administered |
| (date/time) to | Datetime  yyyy-mm-dd hh:mm:ss | N | The time end that the medication is planned to be administered |
| (patient) |  | N | The patient for which the medication is planned |
| status | string | N | The status of the medication request. Typically this is “active” |
| Performer |  | N | The intended performer |
| Order type | Fixed value: “instance-order” | N | The type of Medication Request. Administration Requests are of type “**instance-order**” |

**\_id**

This parameter of type string*,* when supplied, represents the resource identifier to be retrieved

Note: A search using \_id is always an exact match search.

**identifier Search Parameter**

This repeating parameter of type token*,* when supplied, specifies an identifier associated with the Medication Administration Order instance whose information is being queried (e.g., a local identifier, account identifier, etc.).

If multiple instances of this parameter are provided in the query, the query represents a logical AND condition (i.e., all of the associated identifiers must match).

**Date and time of planned administration**

These parameters of type ???????

See FHIR specs for search based on boundaries and approximate searches…

**Patient Identification**

To get the medication administrations planned for a specific patient

Note that only one patient ID can be searched in each query

If multiple instances of this parameter are provided in the query, the query represents a logical AND condition (i.e., all of the associated identifiers must match).

**Status**

This parameter of type ???????????????

**Intended Administration Performer**

**Medication Order Type**

This parameter of type string must have a fixed value of “instance-order”.

###### 3.78.4.1.2.5 Populating Expected Response Format

The FHIR standard provides encodings for responses as either XML or JSON. Medication Administration Order Placer Actors shall support both message encodings, whilst Medication Administration Performer Actors shall support one and may support both.

The formats are json or xml.

##### 3.Y.4.1.3 Response

In response to the request, the Medication Administration Order Placer shall return a bundle of medicationRequest resources. The response is synchronous (i.e., on the same connection as was used to initiate the request), and shall include the records (medicationRequest resources) that match all of the search criteria provided by the Medication Administration Performer.

The mechanics of the planning and scheduling requests, and how these requests are populated, are outside the scope of this framework.

If the Medication Administration Performer supplied a query parameter, or used a query parameter modifier which the Medication Administration Order Placer is not capable of utilizing, then the Medication Administration Order Placer shall respond with an **HTTP 400** (Bad request) status code and an OperationOutcome resource indicating the parameters in error.

The Medication Administration Order Placer shall respond to the query request as described by the following cases with a Medication Administration Order Response message described in Section 3.Y.4.2, and shall behave according to the cases listed below:

**Case 1:** The Medication Administration Order Placer finds in its information source, at least one patient record matching the criteria sent as HTTP query parameters.

**HTTP 200** (OK) is returned as the HTTP status code.

A resource bundle is returned representing the result set. The Medication Administration Order Placer populates the total property of the bundle with the total number of matching results. One entry is returned from the Medication Administration Order Placer for each MedicationRequest Resource found.

**Case 2:** The Medication Administration Order Placer fails to find in its information source, any patient record matching the criteria sent as HTTP query parameters.

**HTTP 200** (OK) is returned as the HTTP status code.

A resource bundle is returned representing the zero result set. The Medication Administration Order Placer populates the total with a value of 0 indicating no results were found. No entry attributes are provided in the result.

**Case 5:** The Medication Administration Order Placer is not capable of producing a response in the requested format specified by \_format parameter (specified in Section 3.Y.4.1.2.5).

**HTTP 406** (Not Acceptable) is returned as the HTTP status code.

An OperationOutcome Resource is returned indicating that the requested response format is not supported in an issue having:

| Attribute | Value |
| --- | --- |
| Severity | error |
| Code | {http://hl7.org/fhir/issue-type.html, ,not-supported} |

The Medication Administration Order Placer may be capable of servicing requests for response formats not listed in Section 3.78.4.1.2.5, but shall, at minimum, be capable of producing XML and JSON encodings.

The Medication Administration Order Placer may return other HTTP status codes to represent specific error conditions. When HTTP error status codes are returned by the Medication Administration Order Placer, they shall conform to the HTTP standard RFC 2616. Their use is not further constrained or specified by this transaction.

TASKS??

Management of workflows:

When updating an administration, this has an impact on the workflows.

If there is a task associated with the medicationAdministration, that task should be updated.

Management of “administration complete” must be done at the main administration task.

The table below presents the optionality and cardinality for each medicationAdministration:

|  |  |  |
| --- | --- | --- |
| Patient |  | 1..1 |
| Encounter |  | 0..1 |
| Performer |  |  |
| Medication |  | 1..?? |

Note: If any of the characteristics change from the presumed or stated in the request (e.g route is not the “official” route, or dosage differs from the prescribed dosage) then the actual elements shall be reported - they become mandatory and they convey not what was intended or default, but the actual outcome.

These are the fields from HMW which should now be ported to MMA as needed:

|  |  |
| --- | --- |
|  |  |
| Patient | (link to patient resource, or embedded patient. If embedded, following attributes…) |
| Patient Name | Name |
| Personal Identification | Identifier |
| Administrative Sex : Gender | Gender |
| Date of Birth : Birthdate |  |
| Address : Address |  |
| Contact Information : telecom |  |
| Guardian : contact |  |
| contact information |  |
| Guardian Name |  |
| Guardian Relationship |  |
| Marital Status : MaritalStatus |  |
| Race : stdExt |  |
| Ethnicity : stdExt |  |
| Religious Affiliation stdExt |  |
| Patient Contact Information : ???? |  |
| Payers : |  |
| Coded Vital Signs |  |
| Allergies and Drug Sensitivities |  |
| Active Problems |  |
| Resolved Problems |  |
| Immunizations |  |
| Pregnancy History |  |
| Encounter |  |
|  |  |
| EncounterID :context |  |
| Patient Location |  |
| Organization |  |
| Name |  |
| Address |  |
| Organization Identifier |  |
| Contact Information |  |
|  |  |
| Prescription | prescription |
| PrescriptionID |  |
|  |  |
| Ward\_Staff | Performer |
| Name |  |
| Address |  |
| HCP Identification |  |
| Department |  |
| Administered\_Item medicationX | Reference or content? |
| Effective start of administration date/time | Effective |
| Effective end of administration date/time | Effective |
| Administration | Location |
| Expiration date medication | Medication?? What if reference? |
| Batch number medication | Medication?? What if reference? |
| Quantity administered | Dosage |
| Code | Medication |
| Name | Medication |
| Units | Medication |
| Form | Medication |
| Administration comments | Note |
| Reason for non-administration | ReasonNotGiven |
| Reaction | Note |
| Route of administration | Route |
| Administration Status | Status |
| Barcode |  |

##### 3.Y.4.2.3 Expected Actions

The medication Administration Consumer is expected to add the information about the administration to the clinical and operational records existing. This can mean several things. Some examples:

* Update the clinical systems to indicate that the treatment triggered by the prescription is “started” or “in progress” (or any other status. If the planned medication administration was the last one in a treatment sequence, it is possible that the system will assign the status “complete”).
* If the management of workflow involved tasks, these tasks should also be updated accordingly (e.g. noting the progress, updating status of the task and adjacent resources).
* Any other conclusions

### 3.Y.5 Security Considerations

The Medication Administration Order Placer and the Administration Performer shall be grouped with a Secure Node actor.

Systems implementing the Medication Administration Order Placer and the Administration Performer shall implement the Secure Application actor in ATNA.

#### 3.Y.5.1 Security Audit Considerations

The event to be supported is :

Order-record-event, health-service-event, or only medication?

##### 3.Y.5.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an Actor by Actor basis.>

Appendices

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2x. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.>

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 3 – Content Modules

<The current version of the supplement template only addresses HL7 v3 CDA Content Modules. All CDA Content Modules will go in Section 6 of Volume 3 of each domain’s Technical Framework document. In the future, this supplement template may have additional sections for DICOM Content Modules (section 7 of Volume 3) and other types of Content Modules (section 8, etc., of Volume 3).

<Please note that prior to the release of the new template set, some domains may have defined CDA Content Modules in Volume 2 (e.g., PCC); however, going forward CDA Content Modules will be defined in Volume 3.>

# 5. Namespaces and Vocabularies

Add to section 5 Namespaces and Vocabularies

<Note that the code systems already defined in the Technical Framework of this domain may (but not required) be replicated here just to aid in the supplement review as a standalone document. Also note that the Section 5 table numbers and names are already defined in the TF Volume 3.>

| codeSystem | codeSystemName | Description |
| --- | --- | --- |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |
| <oid or uid> | <code system name> | <short description or pointer to more detailed description> |

Add to section 5.1.1 IHE Format Codes

| Profile | Format Code | Media Type | Template ID |
| --- | --- | --- | --- |
| <Profile name (profile acronym)> | <urn:ihe: > |  | <oids> |
|  |  |  |  |
|  |  |  |  |

Add to section 5.1.2 IHE ActCode Vocabulary

|  |  |
| --- | --- |
| Code | Description |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |
| <Code name> | <short one sentence description or reference to longer description (not preferred)> |

Add to section 5.1.3 IHE RoleCode Vocabulary

| Code | Description |
| --- | --- |
| <name of role> | <Short, one sentence description of role or reference to more info.> |
| <name of role> | <Short, one sentence description of role or reference to more info.> |
| <name of role> | <Short, one sentence description of role or reference to more info.> |

# 6. Content Modules

<Authors’ notes: This section of the supplement template is only for HL7 v3 CDA Content Module definitions. Please delete the entire section 6.3.1 if the Content Module is based on DICOM or another standard.

Please note that the template for DICOM or other types of content modules (other than CDA) has not yet been defined, although DICOM modules will eventually go into Volume 3 Section 7; yet another type of content module will go into Volume 3 Section 8, etc.>

## 6.3.1 CDA Document Content Modules

<Authors’ instructions: The understanding of content module grouping, options, and bindings are critical to CDA content modules. It is strongly recommended that the author review the IHE Technical Frameworks General Introduction section 10.3 and the Patient Care Coordination (PCC) Technical Framework Volume 2 sections 3 and 4 (PCC TF-2:3 and 4) prior to continuing. A critical understanding of CDA definitions for cardinality, optionality, coded terminology values, and CDA content module structure, as well as IHE CDA formatting conventions is also necessary. It is strongly recommended that the author is also conversant with the IHE Technical Frameworks General Introduction Appendix E “Conventions”.>

<This CDA Content Module template is divided into four parts:

D – Document –“D” will be replaced with a sub-section number when added to the Technical Framework

H – Header - “H” will be replaced with a sub-section number when added to the Technical Framework

S – Section - “S” will be replaced with a sub-section number when added to the Technical Framework

E – Entry - “E” will be replaced with a sub-section number when added to the Technical Framework

It is expected that the author will replicate each of these four parts as necessary within a supplement.>

All examples should be deleted after the example has been read and understood.>

Add to section 6.3.1.D Document Content Modules

<Authors’ note: replicate section 6.3.1.D for every CDA Document defined in this profile.>

#### 6.3.1.D <Content Module Name (Acronym)> Document Content Module

##### 6.3.1.D.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:xxx:xxx:year** <*e.g., urn:ihe:card:imaging:2011>*

##### 6.3.1.D.2 Parent Template

<The following text is common, so it is left here for consistency. If it is not relevant, then change the text to the accurate information, but retain the formatting convention. Be sure to include all parent templates.>

<e.g., This document is a specialization of the IHE PCC Medical Document template (OID = 1.3.6.1.4.1.19376.1.5.3.1.1.1).>

<e.g., Note: The Medical Document includes requirements for various header elements; name, addr and telecom elements for identified persons and organizations; and basic participations record target, author, and legal authenticator.>

<e.g., This document is a specialization of the HL7 Procedure Note template (OID = 2.16.840.1.113883.10.20.18.1).>

<e.g., Note: This document is not a specialization of the HL7 Basic Diagnostic Imaging Report template due to conflicts with two Procedure Note requirements (format of serviceEvent/effectiveTime, and title on DICOM Catalogue section). When and if these are resolved, an instance may also comply to the Diagnostic Imaging Report.>

##### 6.3.1.D.3 Referenced Standards

<Identify ALL standards referenced by THIS content module.>

All standards which are reference in this document are listed below with their common abbreviation, full title, and link to the standard.

Table 6.3.1.D.3-1: <Document Name> - Referenced Standards

| Abbreviation | Title | URL |
| --- | --- | --- |
| <abbreviated name of standard> | <full name of standard> | <link to standard> |
| <abbreviated name of standard> | <full name of standard> | <link to standard> |
| <e.g., CDA-PN> | <e.g., HL7 Implementation Guide for CDA Release 2: Procedure Note (Universal Realm) (DSTU)> | <e.g., http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2\_IG\_PROCNOTE\_DSTU\_R1\_2010JUL.zip> |

##### 6.3.1.D.4 Data Element Requirement Mappings to CDA

This section identifies the mapping of data between referenced standards into the CDA implementation guide.

<Any required data mappings should be listed in this section (mark NA if not needed). Delete SAMPLE table before publishing.>

*<To complete Table 6.3.1.D.4-1, the author should add the referenced standards abbreviations in the first row/title bar. Add or delete columns and sub-rows as necessary. If this table is more than 8 to 10 rows long, consider putting this table into an appendix of this supplement. A brief sample follows.>*

SAMPLE

| ACC Key Data Element (KDECI) | CDA-DIR |
| --- | --- |
|  | DICOM Object Catalog (5) |
| Administrative  Facility (5)  Data Source (1)  Priority (1)  Accreditation (2)  Insurance (1) | CDA Header  General (10)  Document (19)  Participants (20)  Order (1)  Service Event (12)  Encounter (10) |
| Study Referral Data (2) | Request |
| History and Risk Factors  Vital Signs (4)  Labs (2)  Problems (14)  Chest Pain (5)  Family History (1)  Tobacco Use (1)  Risk Estimates (6) | History |

*>*

Table 6.3.1.D.4-1: < Document Name Acronym> - Data Element Requirement Mappings to CDA

| Clinical Data Element <source> | < this document acronym> |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

<**Very important note:** From this point forward, the author may select one of two formats to represent the same data. The first format is a tabular format as was implemented in the Cardiology CIRC profile. The advantages to this format include that large amounts of data may be represented more concisely and that it is sometimes visually easier to determine if any information is missing. The second format is more similar to the current Consolidated CDA (C-CDA format). This format may be more verbose but may also be more recognizable to implementers familiar with other HL7 CDA Implementation Guides and may be easier for implementers to design and test with discrete conformance assertions.

The format that you select must be consistent through this supplement (do not mix and match formats). The format changes are identified by ###Begin Tabular format ###End CDA Tabular format and ###Begin Discrete Conformance format ###End Discrete Conformance format. Delete all references to the format which was not selected between the hash marks. Also, a domain may decide on a single format for all new supplements within that domain.>

##### 6.3.1.D.5 <Content Module Name (Acronym, if applicable)> Document Content Module Specification

This section specifies the header, section, and entry content modules which comprise the <Content Module Name (Acronym)> Document Content Module, using the Template ID as the key identifier.

Sections that are used according to the definitions in other specifications are identified with the relevant specification document. Additional constraints on vocabulary value sets, not specifically constrained within the section template, are also identified.

<Authors’ note: A critical understanding of CDA definitions for cardinality, optionality, coded terminology values, and CDA content module structure, as well as IHE CDA formatting conventions is necessary. It is strongly recommended that the author is also conversant with the IHE Technical Frameworks General Introduction Appendix E “Conventions”. >

###Begin Tabular format - Document

**Table 6.3.1.D.5-1 <Content Module Name (Acronym)> Document Content Module Specification**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Template Name | | <Template Name (Acronym, if applicable)> | | | |
| Template ID | | <oid/uid> | | | |
| Parent Template | | <Parent Template Name oid/uid [Domain Reference]>  <Parent Template Name oid/uid [Domain Reference]> <delete 2nd/additional parent templates if not applicable> | | | |
| General Description | | <short textual description> | | | |
| Document Code | | <MAY or SHALL> be < code/oid/uid, Code System, “Value Set name”> | | | |
| Opt and Card | Condition | Header Element or Section Name | Template ID | Specification Document | Vocabulary Constraint |
| **Header Elements** | | | | | |
| x [?..?] |  | <Header Element name> | <oid> | <reference to section of TF or supplement document for details> | <reference to section of TF or supplement document for explanation, if applicable> |
| <e.g., R [0..1] |  | Order | 1.3.6.1.4.1.19376.1.4.1.3.2 | CARD TF-3 6.3.2.H> |  |
| <e.g., M [1..1] |  | Patient Demographics | 1.3.6.1.4.1.19376.1.4.1.3.3 | CARD TF-3 6.3.2.H | CARD TF-3 6.3.1.D.5.1> |
| Sections | | | | | |
| x [?..?] |  | <Section name> | <oid> | <reference to section of TF or supplement document for details> | <reference to section of TF or supplement document for explanation, if applicable> |
| <e.g., M [1..1] |  | Medications | 1.3.6.1.4.1.19376.1.5.3.1.3.19 | PCC TF-2 | CARD TF-3 6.3.1.D.5.2> |
| <e.g., R [1..1] |  | Coded Social History | 1.3.6.1.4.1.19376.1.5.3.1.3.16.1 | CARD TF-3 6.3.3.S | CARD TF-3 6.3.1.D.5.3> |
| <e.g., O [0..1] |  | Physical Examination | 2.16.840.1.113883.10.20.2.10 | CDA-PN> |  |
| <e.g., C [1..1] | CARD TF-3 6.3.1.D.5.4 | DICOM Object Catalog | 1.3.6.1.4.1.19376.1.4.1.2.15 | CDA-PN> |  |

<For each (1:1 correspondence) Vocabulary Constraint or Condition listed in the table above, create an additional section/reference below. Add the Header Element or Section Name and then select either “Vocabulary Constraint” or “Condition” and delete the other word.>

<Note that every Conditional element MUST have an explanatory paragraph referenced below.>

<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>

###### 6.3.1.D.5.1 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., The value for serviceEvent / code SHOULD be drawn from value set 1.3.6.1.4.1.19376.1.4.1.5.2 Cardiac Imaging Procedures.>

###### 6.3.1.D.5.2 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.14 Cardiac Drug Classes, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.>

###### 6.3.1.D.5.3 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Allergies and Other Adverse Reactions section the Content Creator SHALL be able to create an Allergies and Intolerances Concern Entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 [PCC TF-2]) for each of the cardiac imaging agent classes identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.10 Contrast Agents Classes for Adverse Reactions, encoding the value in observation/participant/participantRole/playingEntity/code.>

###### 6.3.1.D.5.4 <Header Element or Section Name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., A DICOM Object Catalog Section SHALL be present if other document sections contain references to DICOM SOP Instances (images, structured report measurements, or other information objects), and MAY be present otherwise.>

###End Tabular Format - Document

###Begin Discrete Conformance Format - Document

*<Delete the example information contained in the material below (from Cardiology CRC)>*

<e.g., The complete set of body constraints, including those from C-CDA section/entry definitions are:

1. **SHALL** contain exactly one [1..1] **component** (CONF:9588).
   1. A Cath Report Content SHALL have a structuredBody (CONF:9589-CRC).
      1. A Cath Report Content SHALL conform to CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). In this template (templateId 2.16.840.1.113883.10.20.22.1.6), coded entries are optional. (CONF:9590-CRC).
   2. The component/structuredBody SHALL conform to the section constraints below (CONF:9595-CRC).
      1. Each **section** SHALL have a **title** and the **title** SHALL not be empty (CONF:9937).>

<The following table shows relationships among the templates in the body of a Cath Report Content document.>

Table 6.3.1.D.5-1 <Content Module Name (Acronym)> Document Content Module Specification

| Template Title | Opt and Card | Condition | Template Type | templateId | Vocabulary  Constraints |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Delete this row and the example information in the rows below. | | | | | |
| <e.g., Cath Report Content | R[1..1] |  | document | 1.3.6.1.4.1.19376.1.4.1.1.2 | 6.3.1.D.5.1 |
| Document Summary-Cardiac Section | O[0..1] |  | section | 1.3.6.1.4.1.19376.1.4.1.2.16 |  |
| Medical History - Cardiac Section | R[1..1] |  | section | 1.3.6.1.4.1.19376.1.4.1.2.17 |  |
| Procedure Activity Observation | O[0..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.13 |  |
| Procedure Activity Procedure | O[0..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.14 |  |
| Problem Observation - Cardiac | O[0..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.4 |  |
| Age Observation | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.31 |  |
| Health Status Observation | O[0..1] | 6.3.1.D.5.2 | entry | 2.16.840.1.113883.10.20.22.4.5 |  |
| Problem Status | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.6 |  |
| Severity Observation | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.8 |  |
| Allergies Section | R[1..1] |  | section | 2.16.840.1.113883.10.20.22.2.6 |  |
| Allergy Problem Act | O[0..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.30 |  |
| Allergy Observation | R[1..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.7 |  |
| Allergy Status Observation | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.28 |  |
| Reaction Observation | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.9 |  |
| Severity Observation | O[0..1] |  | entry | 2.16.840.1.113883.10.20.22.4.8 |  |
| Family History – Cardiac Section | O[0..1] |  | section | 1.3.6.1.4.1.19376.1.4.1.2.18 |  |
| Problem Observation - Cardiac | O[0..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.4 |  |
| Social History Section | O[0..1] |  | section | 2.16.840.1.113883.10.20.22.2.17 |  |
| Physical Exam Section | R[1..1] |  | section | 2.16.840.1.113883.10.20.2.10 |  |
| Vital Signs | R[1..1] |  | section | 2.16.840.1.113883.10.20.22.2.4.1 |  |
| Vital Signs Organizer | R[1..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.26 |  |
| Vital Sign Observation | R[2..\*] |  | entry | 2.16.840.1.113883.10.20.22.4.27> |  |

<For each (1:1 correspondence) Vocabulary Constraint or Condition listed in the table above, create an additional section/reference below. Add the Header Element or Section Name and then select either “Vocabulary Constraint” or “Condition” and delete the other word.>

<Note that every Conditional element MUST have an explanatory paragraph referenced below.>

<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>

###### 6.3.1.D.5.1 <Template Title name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., The value for serviceEvent / code SHOULD be drawn from value set 1.3.6.1.4.1.19376.1.4.1.5.2 Cardiac Imaging Procedures.>

###### 6.3.1.D.5.2 <Template Title name> <Vocabulary Constraint or Condition>

<add vocabulary constraint or condition definition>

<remove example below prior to public comment:>

<e.g., Within the Medications section the Content Creator SHALL be able to create a Medications entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.7 [PCC TF-2]) for each of the cardiac relevant medications identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.14 Cardiac Drug Classes, encoding the value in substanceAdministration/consumable/ManufacturedProduct/Material/code.>

###End Discrete Conformance Format - Document

##### 6.3.1.D.6 <Document and Acronym Name> Conformance and Example

<This section is the same, independent of whether the tabular or discrete conformance formats were chosen.>

<Describe the conformance of this Document in terms of inheritance from other template(s). Use the OIDs of those templates for clarity. A complete example of this document MUST be placed on the IHE ftp server as part of the Public Comment process of a Content Module supplement. WHERE ON THE FTP SERVER? The file naming convention for these files should be <Domain Acronym>\_<Profile Acronym>\_CDA-sample\_<version number>.xml>.

CDA Release 2.0 documents that conform to the requirements of this document content module shall indicate their conformance by the inclusion of the <templateId> XML elements in the header of the document.

A CDA Document may conform to more than one template. This content module inherits from the *<template name(s) and template ID(s)>* <e.g., CDA-PN, 2.16.840.1.113883.10.20.18.1, and the PCC TF Medical Document, 1.3.6.1.4.1.19376.1.5.3.1.1.1, content modules> and so must conform to the requirements of those templates as well this document specification, *<templateName and templateID>* <e.g., Cardiac Imaging Report template, 1.3.6.1.4.1.19376.1.4.1.1.1>.

A complete example of the <Content Module Name and Acronym> Document Content Module is available on the IHE ftp server at: <indicate location here>.

Note that this is an example and is meant to be informative and not normative. This example shows the <templateId (OIDs)> elements for all of the specified templates.

Add to section 6.3.2 Header Content Modules

## 6.3.2 CDA Header Content Modules

#### 6.3.2.H <Header Element Module Name> Header Content Module

<Replicate this section/table for as many new Header Elements are added in this supplement.>

###Begin Tabular Format - Header

<Either the Parent Template OR the Header Element may constrain this Header Element, not both. One should be “N/A”.>

<The values in the column “Participations and Act Relationships” must come from the defined terms in the CDA schema. See the IHE Technical Frameworks General Introduction, Appendix E, CDA Conventions.>

**Table 6.3.2.H-1 <Content Module Name (Acronym)> Header**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Template Name | | <Template Name> | | | | |
| Template ID | | <oid> | | | | |
| Parent Template | | <Name and oid of parent template or N/A> | | | | |
| Header Element | | <CDA Header Elements participant or componentOf or N/A>  e.g., componentOf / encompassingEncounter | | | | |
| General Description | | <short textual description. Short paragraph at most.> | | | | |
| Opt and Card | Participation/ Act Relationship | Description | Template | Specification Document | Vocabulary Con-straint |
| x [?..?] | <select from defined part /act relationship terms; App E> | <Header Content description name> | <oid> | <document reference, if applicable> | <Vocab constraint, if applicable> |
|  |  |  |  |  |  |
| <e.g., R [1..1] | RESP | Responsible Party |  | CARD TF-3: 6.3.2.H.1> |  |
| <e.g., R [1..1] | LOC | Health Care Facility |  | CARD TF-3: 6.3.2.H.2> |  |
| <e.g., O [0..1] | REF | Referring Provider |  | CARD TF-3: 6.3.2.H.3> |  |
| <e.g., C [0..1] | ATND | Physician of Record | 2.16.840.1.113883.10.20.6.2.2 | CDA-DIR | CARD TF-3: 6.3.2.H.4> |

*<For each Vocabulary Constraint or Specification Document listed in the table above, create an additional section/reference below. Add the Description Name and then select either “Vocabulary Constraint” or “Spec Document” and delete the other word.>*

*<It is required to use SHALL, SHOULD, or MAY in each definition as defined in Appendix E of the Technical Frameworks General Introduction.>*

*<Also note that the Spec Document link can be a link to an outside document/reference. Do not replicate (cut and paste) sections of other documents into this document since they could become out of sync.>*

##### 6.3.2.H.1 <Description Name> <e.g., Responsible Party> <Specification Document *or* Vocabulary Constraint>

<Describe constraints or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The responsible party element represents only the party responsible for the encounter, not necessarily the entire episode of care.>

<e.g., The responsibleParty element MAY be present. If present, responsibleParty/ assignedEntity SHALL have at least one assignedPerson or representedOrganization element present.>

<e.g., Note: This is identical to CDA-DIR CONF-DIR-67>

<e.g., responsibleParty assignedEntity id SHALL be present with the responsible physician’s identifier.>

<e.g., assignedEntity code SHOULD be present with the responsible physician’s specialty.>

<e.g., assignedEntity MAY include an accreditation element from the **urn:ihe:card** namespace to provide physician accreditation status.>

<e.g., The accreditation element SHALL use the character string (ST) data type.

The accreditation element SHALL appear after the defined elements of the Role class, and before any scoper or player entity elements.>

<e.g., assignedEntity assignedPerson name SHALL be present with the responsible physician’s name.>

##### 6.3.2.H.2 <Description Name> <Specification Document OR Vocabulary Constraint>

##### 6.3.2.H.3 <Description Name> <Specification Document OR Vocabulary Constraint>

###End Tabular Format – Header

###Begin Discrete Conformance Format – Header

The header for the <*Document Name*> document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statement must be numbered, begin with SHALL/SHOULD/MAY, identify the cardinality using [n..n], the name of the element, and a subitem which describes the value or source of the information.>

<e.g.,

1. **SHALL** contain exactly one [1..1] **typeId** (CONF:5361).
   1. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3" (CONF:5250).
   2. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD\_HD000040" (CONF:5251).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:5252) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.1.2" for the Cath Report Content document template (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **id** (CONF:5363).
   1. This id SHALL be a globally unique identifier for the document (CONF:9991).
4. **SHALL** contain exactly one or two [1..2] **code** (CONF:5253-CRC).
   1. **SHALL** be selected from ValueSet ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC (CONF:8497). Either or both of the following codes should be included:

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINC Code | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/Professional Level ‘Method\_Type’ |
| 18745-0 | Study report | Heart | Cardiac catheterization |
| 34896-1 | Interventional procedure note | {Setting} | Cardiology |

1. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
   1. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).>

###End Discrete Conformance Format – Header

## 6.3.3 CDA Section Content Modules

Add to section 6.3.3.10 Section Content Modules

<Replicate this section/table for as many new Sections as are added in this supplement.>

<Authors’ notes: Section naming instructions: If a Section is a specialization of an existing Section, begin the name with the original section name. For example, if Cardiology is creating a specialization of the “Medical History Section”, the new section should be named “Medical History Section – Cardiac” and not “Cardiac Medical History Section”.>

###Begin Tabular Format - Section

<Delete examples in rows of table below prior to Public Comment.>

#### 6.3.3.10.S <Section Module Name> - Section Content Module

Table 6.3.3.10.S-1 <Section Module Name> Section

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Template Name | | <exact same Section Module name listed above> | | | |
| Template ID | | <oid> | | | |
| Parent Template | | <Parent Template Name oid/uid [Domain - Reference]> | | | |
| General Description | | <brief textual description, one paragraph> | | | |
| Section Code | | <Code, Code Scheme, “Section Code Name”> | | | |
| Author | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified. Role and entity must be specified if not inherited. > | | | |
| Informant | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified.> | | | |
| Subject | | <If inherited from encompassing content module use “current recordTarget”, unless otherwise specified.> | | | |
| Opt and Card | Condition | Data Element or  Section Name | Template ID | Specification Document | Vocabulary  Constraint |
| Subsections | | | | | |
| x [?..?] | <ref or link to cond section below, if applicable> | <name of subsection> | <oid> | <reference or link to specification document location, if applicable> | <reference or link to vocab constraint, if applicable> |
| <e.g., O [0..1] |  | Active Problems | 1.3.6.1.4.1.19376.1.5.3.1.3.6 | PCC TF-3> |  |
| <e.g., O [0..1] |  | History of Present Illness | 1.3.6.1.4.1.19376.1.5.3.1.3.4 | PCC TF-3> |  |
| <e.g., O [0..1] |  | History of Past Illness | 2.16.840.1.113883.10.20.2.9 | CDA-PN> |  |
| Entries | | | | | |
| x [?..?] | <ref or link to cond section below, if applicable> | <name of entry> | <oid> | <reference or link to specification document location, if applicable> | <reference or link to vocab constraint, if applicable> |
| <e.g., C [1..\*] | CARD TF-3 6.3.3.x.S.1 | Problem Concern Entry | 1.3.6.1.4.1.19376.1.5.3.1.4.5.2 | PCC TF-3> |  |
| <e.g., C [1..1] |  | Diabetes Problem Entry | 1.3.6.1.4.1.19376.1.4.1.4.1 | CARD TF-3 6.3.3.1> |  |
| <e.g., C [1..1] |  | Angina Problem Entry | 1.3.6.1.4.1.19376.1.4.1.4.2 | CARD TF-3 6.3.3.1> |  |
| <e.g., C [1..\*] | CARD TF-3 6.3.3.x.S.1 | Simple Observation | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | PCC TF-3 | CARD TF-3 6.3.3.x.S.2> |

##### 6.3.3.10.S.1 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

<Describe constraints; refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The Medical History Section SHALL contain at least one Problem Concern Entry or at least one Simple Observation.

Note: Problems MAY be recorded directly in the Medical History Section, or in one or more subsections such as Active Problems, History of Present Illness, or History of Past Illness.>

##### 6.3.3.10.S.2 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

<Describe constraints, refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., A Content Creator SHALL be able to include a Problem Concern Entry for each of the conditions identified in Value Set [1.3.6.1.4.1.19376.1.4.1.5.4 Cardiac Problems/Concerns](#_1.3.6.1.4.1.19376.1.4.1.5.4__Cardia), encoding the value in act/entryRelationship/observation/code.

A Problem Concern Entry for {73211009, SNOMED CT, diabetes} SHALL use the specialized Diabetes Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.1).

A Problem Concern Entry for {194828000, SNOMED CT, angina} SHALL use the specialized Angina Problem Entry (OID = 1.3.6.1.4.1.19376.1.4.1.4.2).>

##### 6.3.3.10.S.3 <Data Element or Section Name> <Condition, Specification Document, or Vocabulary Constraint>

###End Tabular Format – Section

###Begin Discrete Conformance Format – Section

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statements must be numbered, begin with SHALL/SHOULD/MAY identify the cardinality using [n..n], the name of the element, and a subitem which described the value or source of the information.>

<e.g.,

#### 6.3.3.10.S Medical History - Cardiac Section 11329-0

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.17(open)]

[section: templateId 2.16.840.1.113883.10.20.22.2.39(open)]

The Medical History section describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Entries for History of Past Illness and History of Present Illness have been consolidated into this section. Social and Family History are discussed in their own sections. For this Cath Report Content profile, this section may also contain history about specific relevant problems as problem observations.

In the event that the patient was transferred from another facility where there was a problem indication that the patient was determined to need a cath procedure, this will be noted as a problem observation in this medical history section as text in the narrative for now until there is a code representing this.

1. SHALL contain exactly two [2..2] templateId (CONF:8160) such that it
   1. SHALL contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.4.1.2.17" (CONF:10403-CRC).
   2. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.39" (CONF:10403).
2. SHALL contain exactly one [1..1] code/@code="11329-0" Medical (General) History (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:8161).
3. SHALL contain exactly one [1..1] title (CONF:8162).
4. SHALL contain exactly one [1..1] text (CONF:8163).
5. MAY contain zero or more [0..\*] entry (CONF:CRC-xxx) such that it
   1. SHALL contain exactly one [1..1] Problem Observation - Cardiac (1.3.6.1.4.1.19376.1.4.1.4.9) (CONF:CRC-xxx).
6. **MAY** contain zero or more [0..\*] **entry** (CONF:CRC-xxx) such that it
   1. **SHALL** contain exactly one [1..1] **Procedure Activity Observation** (2.16.840.1.113883.10.20.22.4.13) (CONF:CRC-xxx).
7. MAY contain zero or more [0..\*] entry (CONF:CRC-xxx) such that it
   1. SHALL contain exactly one [1..1] Procedure Activity Procedure (2.16.840.1.113883.10.20.22.4.14) (CONF:CRC-xxx).

<section>

<templateId root="1.3.6.1.4.1.19376.1.4.1.2.17"/>

<templateId root="2.16.840.1.113883.10.20.22.2.39"/>

<code code="11329-0" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="MEDICAL (GENERAL) HISTORY"/>

<title>MEDICAL (GENERAL) HISTORY</title>

<text>

<list listType="ordered">

<item>Patient has had a recent issue with chest pain that does not seem to be related to any particular cause.</item>

<item>Previous concerns of heart disease were actually related to other causes.</item>

<item>Patient had recent weight gain due to sedentary lifestyle and

new job.</item>

</list>

</text>

<entry>

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

<templateId root=”1.3.6.1.4.1.19376.1.4.1.9”/>

<id root=”xyz”/>

…

</observation>

</entry>

</entry>

<observation classCode="PROC" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.14"/>

<!-- Procedure Activity Procedure template -->

...

</observation>

</entry>

</entry>

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

<templateId root="2.16.840.1.113883.10.20.22.4.13"/>

<!-- Procedure Activity Observation template -->

...

</observation>

</entry>

</section>

Figure Example: Example Section example>

###End Discrete Conformance Format - Section

## 6.3.4 CDA Entry Content Modules

Add to section 6.3.4.E Entry Content Modules

#### 6.3.4.E <Entry Content Module Name> Entry Content Module

<Replicate the Entry Content Module as many times as needed for this supplement.>

<If this entry has subsidiary/child entries, these entries are referenced in the table below. Create one row for each subsidiary/child entry.>

### Begin Tabular Format - Entry

Table 6.3.4.E-1 <Entry Module Name> Entry

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Template Name | | | | <Template name> | | | | | | |
| Template ID | | | | <oid> | | | | | | |
| Parent Template | | | | <Parent Template Name oid/uid [Domain - Reference]> | | | | | | |
| General Description | | | | <brief textual description, one paragraph> | | | | | | |
| Class/Mood | | Code | | | | Data Type | Value | | | |
| <use one of defined Class/Mood see General Intro App E> | | <Code, code system, code meaning e.g., 18118-0, LOINC, “LV Wall Motion Segmental Findings”> | | | | <Applies only if the Class/ Mood is OBS/EVN. Enumerated in HL7 V3 Data Types R1.> | <If the Class/Mood is OBS/EVN, then this Value field is the constraint on Observation Value. Otherwise, this field should be “N/A”.> | | | |
| Opt and Card | entryRelationship | | Description | | Template ID | | | Specification Document | Vocabulary Constraint |
| <e.g., x [?..?]> |  | | Simple Observation | | oid | | | reference to document e.g., PCC-TF-3 | <reference/link to definition of constraint, often in next paragraph/ subsection e.g., CARD TF-3 6.3.3.4.9.10> |
| <e.g., C [1..\*] | COMP | | Simple Observation | | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | | | PCC TF-2 | CARD TF-3 6.3.4.E.1 (Wall morphology)> |
| <e.g., O [0..1] | COMP | | Simple Observation | | 1.3.6.1.4.1.19376.1.5.3.1.4.13 | | | PCC TF-2 | CARD TF-3 6.3.4.E.2 (Viability)> |
| <e.g., O [0..1] | COMP | | observationMedia Entry | | 1.3.6.1.4.1.19376.1.4.1.4.7 | | | CARD TF-3 6.3.1.6> |  |

##### 6.3.4.E.1 Simple Observation (wall motion) Vocabulary Constraints

<Describe constraints, refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Can be in a tabular format or textual description.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The conditional entries specified in this table SHALL be present based on the exam type as specified in the CDA Header in the documentationOf / serviceEvent / code element.>

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Opt and Card | Condition | observation/code | Data Type | Unit of Measure | Value Set |
| <e.g., C [1..\*] | <Identifies the predicate and the if the predicate evaluates as true, then indicate whether mandatory, required or optional  e.g., Required if “exam type” is “LVG” (left ventriculogram)>  R: LVG | 60797005, SNOMED CT, “Cardiac Wall Motion”  <”+” = May be post-coordinated with priorityCode, methodCode, targetSiteCode . See HL7 V3. Include a value directly or include a link to a value set, if applicable.>  e.g., + targetSiteCode from 1.2.840.10008.6.1.219 DICOM CID 3718 Myocardial Wall Segments in Projection | CD | n/a unless the Data Type is PQ or IVL<PQ> | <include link to value set, e.g., 1.3.6.1.4.1.19376.1.4.1.5.20 Wall motion  OR, include value directly as e.g.,  <The Observation Value may also have a post-coordinated interpretation such as:>  +interpretationCode  +negationInd > |
| <e.g., C [1..\*] | R: SPECT, TTE, TEE, CMR  O:CCTA | 60797005, SNOMED CT, “Cardiac Wall Motion”  + targetSiteCode from 1.2.840.10008.6.1.218 DICOM CID 3717 Myocardial Wall Segments | CD | n/a | 1.3.6.1.4.1.19376.1.4.1.5.20 Wall motion > |

##### 6.3.4.E.2 Simple Observation (wall morphology) Constraints

<Describe constraints; refer to other Specification Document, condition, or other info. This specification may include more information on conditions or cardinality, additions elements, data mappings, or data types, or other information.>

<Can be in a tabular format or textual description.>

<Delete the example below prior to publishing for Public Comment.>

<e.g., The conditional entries specified in this table SHALL be present based on the exam type as specified in the CDA Header in the documentationOf / serviceEvent / code element.>

| Opt and Card | Condition | observation/code | Data Type | Unit of Measure | Value Set |
| --- | --- | --- | --- | --- | --- |
| <e.g., C [1..\*] | R: Cath with LVG | 72724002, SNOMED CT, “Morphology findings”  + targetSiteCode from 1.2.840.10008.6.1.219 DICOM CID 3718 Myocardial Wall Segments in Projection | CD | n/a | 1.3.6.1.4.1.19376.1.4.1.5.19 Myocardium Assessments> |
| <e.g., C [1..\*] | R: SPECT, echo, CMR  O:CCTA | 72724002, SNOMED CT, “Morphology findings”  + targetSiteCode from 1.2.840.10008.6.1.218 DICOM CID 3717 Myocardial Wall Segments | CD | n/a | 1.3.6.1.4.1.19376.1.4.1.5.19 Myocardium Assessments> |

<e.g., The observation/value MAY be a null flavor.>

<e.g., morphological assessment observation MAY have a subsidiary Severity observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.1 [PCC TF-2]).>

### End Tabular Format - Entry

### Begin Discrete Conformance Format – Entry

<An example is provided to demonstrate the desired consistent use and format. Delete this example prior to publication for Public Comment. The statements must be numbered, begin with SHALL/SHOULD/MAY identify the cardinality using [n..n], the name of the element, and a subitem which described the value or source of the information.>

##### <e.g.,6.3.4.E Result Observation - Cardiac

[observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.16 (open)]

A result observation is a clinical statement that a clinician has noted during the Cath Lab procedure. This entry is used to describe the specific procedure findings that were observed during the specific Cath Lab procedure.

The specific result observations are defined in 1.3.6.1.4.1.19376.1.4.1.5.38 Procedure Findings Constraints/ValueSet.

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7130).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7131).
3. SHALL contain exactly one [1..1] templateId (CONF:7136) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.2" (CONF:9138).
4. SHALL contain at least one [1..\*] id (CONF:7137).
   1. The first id represents this specific globally unique result observation.
   2. The second id represents the lesion ID which should be an assigned numeric code that identifies lesions within a specific targetSiteCode.This lesion ID is used to link lesion specific data in this Result Observation – Cardiac with Procedure Activity Procedure - Cardiac.
5. SHALL contain exactly one [1..1] code (CONF:7133).
   1. SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (Value Set: 1.3.6.1.4.1.19376.1.4.1.5.38) (CONF:7166-CRC).
6. SHOULD contain zero or one [0..1] text (CONF:7138).
   1. The text, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:7139).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:9119).
7. SHALL contain exactly one [1..1] statusCode="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:7134).
8. SHALL contain exactly one [1..1] effectiveTime (CONF:7140).
   1. represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards) (CONF:7141).
9. SHALL contain exactly one [1..1] value with @xsi:type="ANY" (CONF:7143).
10. SHOULD contain zero or more [0..\*] interpretationCode (CONF:7147).
11. MAY contain zero or one [0..1] methodCode (CONF:7148).
12. MAY contain zero or one [0..1] targetSiteCode (CONF:7153).
    1. The targetSiteCode, if present, SHALL contain exactly one [1..1] code where the @code SHALL be selected from ValueSet Body Site 1.3.6.1.4.1.19376.1.4.1.5.32 STATIC (CONF:CRC).
13. MAY contain zero or one [0..1] author (CONF:7149).
14. SHOULD contain zero or more [0..\*] referenceRange (CONF:7150).
    1. The referenceRange, if present, SHALL contain exactly one [1..1] observationRange (CONF:7151).
       1. This observationRange SHALL NOT contain [0..0] code (CONF:7152).
15. SHOULD contain zero or one [0..1] entryRelationship (CONF:CRC-xxx) such that it
    1. SHALL contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    2. SHALL contain exactly one [1..1] @inversionInd="true" TRUE (CONF:CRC-xxx).
    3. SHALL contain exactly one [1..1] Severity Observation (2.16.840.1.113883.10.20.22.4.8) (CONF:CRC-xxx).

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

<templateId root="1.3.6.1.4.1.19376.1.4.1.4.16"/>

<!-- Result Observation template -->

<id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>

<!-- This second ID represents the lesion ID -->

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66" extension="1"/>

<code code="233970002"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Post procedure stenosis"/>

<text><reference value="1"/></text>

<statusCode code="completed"/>

<effectiveTime value="19991114"/>

<targetSiteCode code="41879009" codeSystem="1.3.6.1.4.1.19376.1.4.1.5.32"

displayName="Distal RCA"/>

<value xsi:type="PQ" value="0" unit="%"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>

</observation>

e.g., Figure 6.3.4.E-1: Result observation example >

### End Discrete Conformance Format - Entry

Add to sections 6.4 and 6.5 Value Sets

## Section not applicable

This heading is not currently used in a CDA document.

## <Domain Acronym> Value Sets

<Replicate the Value Set 6.5.x section as many times as needed for this supplement.>

<It is preferable to use tabular format. Add notes as needed. Be aware of potential national licensing issues of coding schemes.>

### 6.5.x <Value Set Name> <oid>

<Add description or clarifications here if necessary.>

|  |  |
| --- | --- |
| Coding Scheme  Concept | <Coding Scheme Name> |
|  |  |
|  |  |
|  |  |
|  |  |

Note: <as necessary, applicable>

<Delete the example below prior to publication for Public Comment.>

### <e.g.,6.5.1 Drug Classes Used in Cardiac Procedure 1.3.6.1.4.1.19376.1.4.1.5.15

|  |  |  |
| --- | --- | --- |
| Coding Scheme  Concept | SNOMED CT | NDF-RT |
| Calcium channel blockers | 48698004 | N0000029119 |
| Beta-blockers | 33252009 | N0000029118 |
| Nitrates | 31970009 | N0000007647 |
| Aminophylline | 55867006 | N0000146397 |

Note: As described in Section 6.1.2.4, the selection of the appropriate coding system for use may be based on local policy or national regulation.>

Appendices

*<Add any applicable appendices below; NA if none.>*

Appendix A – <Appendix A Title>

Appendix A text goes here.

* 1. <Add Title>

Appendix A.1 text goes here

Appendix B – <Appendix B Title>

Appendix B text goes here.

* 1. <Add Title>

Appendix B.1 text goes here.

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

<Please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These will be added to the IHE TF General Introduction namespace appendix when it becomes available. These items should be collected from the sections above by the author, and listed here as additions when this document is published for Trial Implementation. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

4.I National Extensions for <Country Name or IHE Organization>

<A template for Volume 4 is included in this document for completeness; however, National Extensions are typically developed after a profile has been published for Trial Implementation. If you are developing a new profile for Public Comment, it is recommended that this section be marked “Not Applicable”.>

<Avoid using this section if you can, this is “only if absolutely necessary”. Differences add cost to implementation and testing and can reduce interoperability. Review carefully to determine if the national use case truly requires a difference in the profile mechanisms rather than just differences in system configuration.>

< National Extensions can add requirements above and beyond IHE, but NOT relax requirements. This would prevent Connectathon results based on national testing being recognized elsewhere. For more information, see <http://wiki.ihe.net/index.php?title=National_Extensions_Process>.>

The format of this section is not strongly specified due to the varying nature of national extensions. For an example of National Extensions, see Radiology TF Volume 4.>

4.I.1 Comment Submission

This national extension document was authored under the sponsorship and supervision of <sponsor name>, who welcome comments on this document and the IHE <country> initiative. Comments should be directed to:

<Name, organization, title, email address>

4.I.2 <Profile Name> <(Profile Acronym)>

<Add info or tables>

#### 4.I.2.1<Profile Acronym> <Type of Change>

<Add info or tables>

#### 4.I.2.2<Profile Acronym> <Type of Change>

<Add info or tables>

# 4.I+1.1 National Extensions for <Country Name or IHE Organization>

*<Repeat (and increment) the section above as needed for additional National Extensions>*

Content profiles

Names?

mPRE

mPLAN

mDIS

mADM

mLIST

mPLAN and mPRE or a single mPRE = mORDER?

Is there a need to have an mPLAN? What are the differences except workflow?

mADPlan