Integrating the Healthcare Enterprise

IHE Pharmacy
Technical Framework Supplement

Mobile Medication Administration
(MMA)

HL7® FHIR® STU 3

Using Resources at FMM Level 2-5

Rev. 1.0 – Draft for Public Comment

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Foreword

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

This supplement is published on October 19, 2017 for public comment. Comments are invited and can be submitted at http://www.ihe.net/Pharmacy_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by November 18, 2017.

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 **<u>bold underline</u>**. 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.

Information about the IHE Pharmacy domain can be found at http://www.ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://www.ihe.net/IHE_Process and http://www.ihe.net/Profiles.

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

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Introduction to this Supplement

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE committee determines that an emerging standard offers significant benefits for the use cases it is attempting to address and has a high likelihood of industry adoption, it may develop IHE profiles and related specifications based on such a standard.

The IHE committee will take care to update and republish the IHE profile in question as the underlying standard evolves. Updates to the profile or its underlying standards may necessitate changes to product implementations and site deployments in order for them to remain interoperable and conformant with the profile in question.

This MMA Profile uses the emerging HL7[1] FHIR[2] specification. The FHIR release profiled in this supplement is STU 3. HL7 describes the STU (Standard for Trial Use) standardization state at https://www.hl7.org/fhir/versions.html.

In addition, HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through 5 (normative ballot ready). The FHIR Maturity Model is described at http://hl7.org/fhir/versions.html#maturity.

Key FHIR STU 3 content, such as Resources or ValueSets, used in this profile, and their FMM levels are:

FHIR Resource Name	FMM Level
MedicationRequest	FMM 3
MedicationAdministration	FMM 2
Patient	FMM 5
Practitioner	FMM 3
Bundle	FMM 5
OperationOutcome	FMM 5

160 The IHE Mobile and Distributed Medication Administration Profile introduces a new generation of interoperability mechanisms which can be used in traditional environments as well as distributed / mobile medication workflows.

General remark on Distributed Medication Management

IHE Pharmacy realizes that the interoperability of systems can be either:

- Point-to-point – like in a typical messaging environment

165 - Broadcast – like in a document or a web services environment

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[1] HL7 is the registered trademark of Health Level Seven International.

[2] FHIR is the registered trademark of Health Level Seven International.

To support the expected diversity of workflows, this IHE profile (and subsequent) are expected to be closer to a broadcasting approach, in the following aspects:

1. The implementation of a transaction should not depend on the implementation of any actors that are not directly involved (mandatory) in the transaction.

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2. All actors can freely couple with any other actor.

3. The workflow management is to be done not by the message state or by the receiver. For example, a medication administration report can be either directed at a prescribing actor, or at a dispenser, or any other actor. For example, a medication administration report informs that the administration is "complete" but does not imply the whole treatment is

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complete, or if there are subsequent actions needed.

This new supplement implements these aspects and addresses 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 do one or both of the following:

180

- transmit the instructions for administration of medication

- register and exchange information about the administration of medication

Implementers can opt for supporting the medication administration requests (like in a patient smartphone app that serves the purpose of reminding the patient to take the medication) or the administration report (like a nurse tablet app that registers medication and submits that

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information to the hospital). Of course, implementers can opt for supporting both the administration request and the administration report.

The Mobile Medication Administration

The Mobile Medication Administration Profile is intended to be compatible with hospital settings, but the emphasis is on community settings in a mobile environment, or where CDA®[3]

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documents are not used. For CDA documents, users are advised to consult the Pharmacy CMA Profile.

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

Some uses for MMA are:

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- 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 and submit that information to the hospital EHR.

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- 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.

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[3] CDA is the registered trademark of Health Level Seven International.

The transactions for decoding barcodes and retrieving additional information about the medicinal product are described in a dedicated IHE Pharmacy technical supplement called UBP – Uniform Barcode Processing.

205 Besides mobile applications, more conventional uses are also supported, for example:

- Recording the administration of drugs in a hospital setting

- Recording the administration of drugs by an infusion device (pump)

- Recording the administration of immunization

Generally, this profile supports the request or report of any administration of medication.

210 Further ahead, the IHE Pharmacy Technical Framework will be extended to the entire medication circuit, and the MMA Profile will be part of that entire interoperability framework. In other words, the MMA Profile is a part of a broader interoperability framework for the medication circuit, and implementers can safely start implementing MMA while the remainder of the IHE medication profiles based on FHIR emerge.

215 This supplement is intended to be fully compliant with the HL7 FHIR specification, providing only use-case driven constraints to aid with interoperability 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
220 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 and profiles, this profile extends or adds the
225 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.

230 **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.

Annex A describes how these can be actors can be implemented in some scenario examples.

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

Open Issues and Questions

OperationOutcome in case of errors:

Should we not specify the possible outcome, i.e., the content of the operationOutcome?
240 Perhaps mention this is currently not in scope, but should be addressed in next version. Or

perhaps mention the user should rectify the errors directly on the Medication Administration Consumer side. I.e., the EHR-system.

Administration Report:

245   Are we able to distinguish the Medication Administration reports when they are resending an interrupted transfer of the information and the use case of chemotherapy where the user is reporting each administration the patient is consuming (i.e., the patient is confirming each administration, which is taking place each hour during the day and reported at the end of the day.)? Perhaps this is too much for now and should be deferred to the public comment period.

250   Closed Issues

The following issues have been closed, some in collaboration with HL7.

- MMA_001 MedicationAdministration or MedicationStatement

    - MedicationAdministration is the resource to be used. This question required some discussion and clarification around the FHIR documentation which has meanwhile
255   been updated and confirms the approach used in this profile and the IHE Pharmacy TF.

- MMA_002 Differentiate administration requests from prescriptions

    - A new attribute has meanwhile been requested and added – MedicationRequest.intent. An administration request is differentiated by having intent = "instance-order".

260 - MMA_003 Can't search on date

    - This has been resolved in the FHIR standard.

- MMA_004 Can't search on performer

    - This has been resolved in the FHIR standard – the intended performer has been added to the resource and to the search criteria for STU4. This profile pre-adopts that
265   change.

- MMA_005 link to prescription or order

- MMA_006 Medication (instance) as a contained resource

- MMA_007 How to represent a MedicationRequest for a composite administration?

    - MedicationRequest.dosageInstruction

270 - MMA_008: Do we favor a push-model or pull-model?

    - A: we leave that to the communication approach taken by the implementers. The common cases are those where the mobile device is the initiator (PULL requests and PUSH administration reports)

- MMA_009: When a resource is created at the beginning of the interval and then updated,
275   implementers should post both versions, so that both versions are kept in the server if the server supports versioning.

- MMA_010: PUT vs POST?

- o A: We do need to update resources. The preferred approach is that Medication Administration Informer will use POST for a creation and from then do updates, so Medication Administration Informers must support PUT, and depending on their option, implement POST as well.

- MMA_012: How to handle "Take as Needed" / PRN medication?

  - o The medication to Take as Needed May be subject to a prescription (out of scope of this profile) but will not be subject of an Administration Request but should be subject of an Administration Report.

  - o The identification of that medication requires that the nurse system has a barcode-enabled product catalog, or that a product lookup transaction be available. This will be subject of another profile from IHE as soon as the base FHIR standard is available.

- MMA_013: How to handle unknown / not prescribed medication

  - o Other medication that is not prescribed should be subject to an Administration Report.

  - o The identification of that medication requires that the nurse system has a barcode-enabled product catalog, or that a product lookup transaction be available. This will be subject of another profile from IHE as soon as the base FHIR standard is available.

- MMA_014 How do we address functional acknowledgement? E.g., if medication is unknown.

  - o This is handled in dedicated sections at the end of each transaction.

- MMA_015 How to handle two medications in the same event? This is handled by medication.partOf (see Section 3.Z.5.2).

FHIR Issues and expected changes

The base standard FHIR is still in draft mode, which means that some resources can be expected to change.

Specifically, here are some changes that are expected which will affect this profile:

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- Medication resource
  - A serial number may be added as an extension or in the core standard. See Appendix D in Vol 2 for a definition of that extension.
  - The resource structure is expected to change.
    - The following profiled attributes are expected to be impacted and will have their
310 definition changed after the change:
      - Serial Number (is expected to be outside "package.batch")
- MedicationAdministration resource
  - reasonNotGiven will no longer exist and will be in an attribute called StatusReason.
    - The MMA Profile considers the two possibilities.

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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

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

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 healthcare 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

Appendix B – Transaction Summary Definitions

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

The Pharmacy Mobile and Distributed Medication Administration supplement introduces the interoperability mechanisms to be used in the requesting and registering of administration of medication, in mobile systems or otherwise distributed systems, as well as in traditional systems.

330 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

Transaction	Definition
Query Administration Requests [PHARM-2]	Request for individual administration actions to be performed
Report Administration Results [PHARM-3]	Report on the outcome of each single administration event

335 ## Glossary

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

Glossary Term	Definition
Administration Request	An instruction for a single medication administration event. For example, a request to "administer paracetamol to patient X on 1/7, at 13:00". An administration request does not expect any further action (such as dispensing), only the administration. One event can also include several units at the same time (e.g., give paracetamol to patient X - 2 tablets at 3 pm", even different medications (e.g., "give drug A and drug B mixed together to patient X – 1 each at 3 pm ")
Administration Report	The information about an actual administration event or act. For example, a report that "1 tablet of paracetamol was given to patient X at 13:45". The administration report is for one single administration act.
Single Point in time administration	An administration that happens in one single point in time, i.e., instantaneously, or that does not take a measurable amount of time. For example, giving or taking a tablet.
Continuous administration	An administration that takes a measurable amount of time, for example an infusion.
Simple interval administration	A specific case of continuous administration where the parameters of the administration remain constant (or are changes are not considered relevant) during the entire interval. For example, one administration at a fixed rate for a given amount of time.
Complex interval administration	A specific case of continuous administration where the parameters of the administration are changed and those changes are considered relevant. For example, one administration that starts at one rate and then is changed to another rate, or when there is a change in the solvent and is important to capture that change.
PRN	*Pro Re Nata* – Medication that should be administered as needed or as the situation arises. It represents an administration of prescribed medication whose timing is left to the patient, nurse or caregiver, as opposed to medication that is to be taken according to a fixed schedule. This does not imply that the patient may take as much of the medicine as desired, but rather that the medicine may be taken in the prescribed dosage if needed.

Volume 1 – Profiles

340 | *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.

| *Add Section X* |

X Mobile Medication Administration (MMA) Profile

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The Mobile Medication Administration Profile provides integration between systems or actors that handle medication administration and systems or actors that are upstream (e.g., prescription or dispensing systems that provide the Medication Administration plan) or downstream (e.g., EHRs or others that use the information about medication administration for any purpose).

350 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.

355
   a. Note: The Medication Administration Request, as per the definition above, is for one single planned event. A request to take a medication with a given frequency is not a medication administration request because it represents more than one single event. Such a prescription is expected to be "decomposed" in several medication administration requests by a scheduler or planner system.

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   b. Note: For not scheduled (emergency or not prescribed) medications, the individual Administration Requests do not exist, neither a prescription.

   c. Note: For "As needed"/PRN orders, the individual Administration Requests do not exist, although a prescription may exist. Therefore, querying for administration requests will not return this medication. A mechanism to retrieve prescriptions is
365   needed, and will be addressed by a future IHE Pharmacy profile for prescriptions.

2. The Medication Administration Informer informs a Medication Administration Consumer about the performing of the administration activity (or its reported absence).

X.1 MMA Actors, Transactions, and Content Modules

This section defines the actors, transactions, and content modules in this profile. General
370 definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks/#GenIntro.

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

The MMA Profile consists of two reusable purpose transactions and actor sets:

375
1. The interaction for getting medication administration requests

2. The interaction for reporting medication administrations
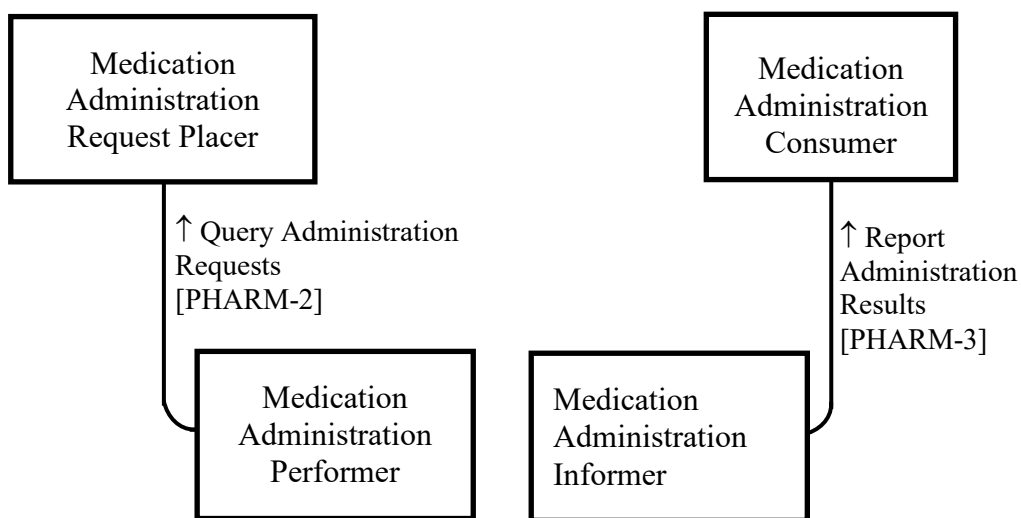
Figure X.1-1: MMA Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the MMA Profile. To claim
380   compliance with this profile, an actor shall support all required transactions (labeled "R").

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

Actors	Transactions	Optionality	Reference
Medication Administration Request Placer	Query Administration Requests [PHARM-2]	R	PHARM TF-2: 3.Y1
Medication Administration Performer	Query Administration Requests [PHARM-2]	R	PHARM TF-2: 3.Y1
Medication Administration Informer	Report Administration Results [PHARM-3]	R	PHARM TF-2: 3.Y3
Medication Administration Consumer	Report Administration Results [PHARM-3]	R	PHARM TF-2: 3.Y3

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Volume 2 Transactions. This section documents any
385   additional requirements on profile's actors.

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

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

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

X.1.1.1 Medication Administration Request Placer

The Medication Administration Request 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.

This can be implemented by systems that follow the treatment, like the prescription or medication management systems. Or it can be systems that take that information e.g., for creating medication lists.

X.2 MMA Actor Options

The MMA Profile has two independent transactions and at this moment no other optionality is required.

The optionality may be reviewed when adopting a "Push" model for sending medication requests, instead of the current pull model initiated by the medication administration performer.

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
Medication Administration Request Placer	No options defined	--
Medication Administration Performer	No options defined	--
Medications Administration Informer	No options defined	--
Medication Administration Consumer	No options defined	--

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Notes on RESTful services

This profile defines the transactions based on the common cases described, and based on a RESTful GET initiated by 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.

Other mechanisms for getting information can be Polling, Subscription and Message push. This profile does not exclude these other mechanisms, but the content of the resources should follow the same content and specifications in this profile. Further guidance in these variations in the transport mechanism shall be described in a further edition of this profile.

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).

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Table X.3-1: MMA - Required Actor Groupings

MMA Actor	Actor to be grouped with	Reference	Content Bindings Reference
Medication Administration Request Placer	None		
Medication Administration Performer	None		
Medication Administration Informer	None		
Medication Administration Consumer	None		

X.4 MMA Overview

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

450 **X.4.1 Concepts**

X.4.1.1 Basic requirements

As per the updated glossary, this profile introduces two terms:

1. Medication Administration Request (or Order): a request for a single administration;

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2. Medication Administration Report: the reports of the single administration.

455 The simplest case is the request and report of a single oral solid (tablet) medication. Taking this as a clear scenario, several variations can arise. They require guidance, in order to achieve safe interoperability. This profile contains guidance that covers several aspects that need to be safeguarded by implementers:

1. Actual administration may differ from requested / planned

460 The administration is not a simple update of status "administered as planned", but contains information whether the medication was indeed administered, when, by whom, and any other relevant information.

2. Medication administration may be one single event (a single point in time event), or a continuous action, or a relatively complex sequence, as in the case of infusions with
465 **varying rate**

   a. Furthermore, the initial request may be for a simple interval infusion, but during the execution this may change, and a complex interval may need to be captured. (See an explanation and more details in scenarios section below.)

3. The level of detail needed to capture a medication administration differs across
470 **scenarios and implementer preferences.**

   a. However, the different cases should always remain interoperable. For example, the way to capture a compound medication administration, must not differ essentially from the single medication. Another example is that a complex interval report should be understandable by systems that only handle simple intervals.

475 **4. Medication Administration Reports can be captured at the beginning of an administration or at the end**

5. A medication administration report may be updated after it is entered.

   a. If for example the patient vomits after swallowing a medication, it must be possible to express this is in a universal standard way.

480 **6. One administration event (or interval) may have one single product or several products.**

   a. In some cases, the medication that is reported is just one, with differing quantities (e.g., 2 tablets of medicinal product X)

   b. In other cases it is one "compound" product (e.g., mixture)

485   c. No code available (e.g., Tablet A and Tablet B)

All these aspects are independent, i.e., they can happen in any combination in an implementation. Some examples:

- Administration Request is for 1 tablet of 1000 mg, but Administration Report is for 2 tablets of 500 mg

490 - Administration Request is for a simple interval infusion, but the Administration Report is for a complex interval because of an unexpected change of the solvent (saline); the Medication Administration consumer (the hospital's EHR) is still expecting a simple interval reporting.

495   To ensure interoperability all the way back to the patient's EHR, implementers are expected to follow the requirements in this profile.

X.4.1.2 Types of medication administration

X.4.1.2.1 Single Point-in-time administration

500   The simplest case of administration is for the administration of one tablet at a given time. The request describes when the medication should be administered, and the report describes when it actually was administered. In some cases, the actual administration is at the requested time, in other cases there is some changes (e.g., a medication is requested for 8:00 am, but is taken at 8:10 am). The administration report does not contain information about the consequences of any divergence or incident: The administration report simply reports what happened.

505
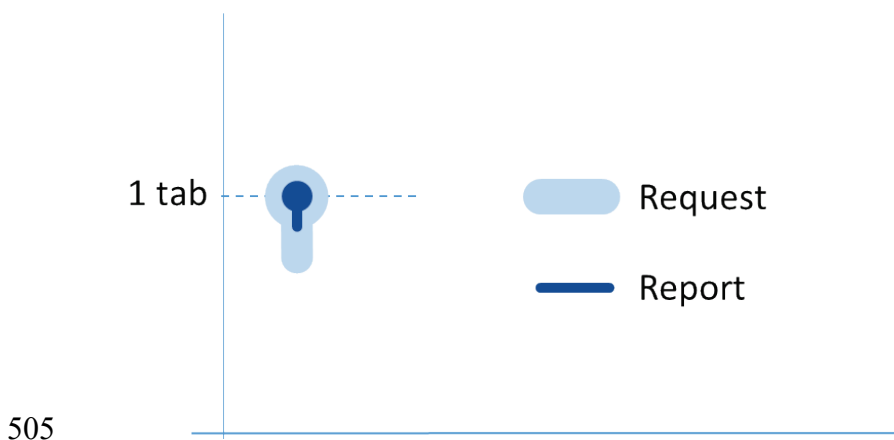
X.4.1.2.2 Simple interval administration

510   A more elaborate case is typical for infusions, where the medication is planned to be taken at a given rate, for a given interval. Also in this case, the report can coincide with the request (if the actual execution was as planned) or may diverge – e.g., started at a different time, or with a slightly different duration. In the picture below, the medication is supposed to be given at a rate of 30 ml/min for 20 minutes (in light blue). This makes for a total administered volume of 600 ml. The report (dark blue) coincides with the request, which means that the administration was taken as planned.
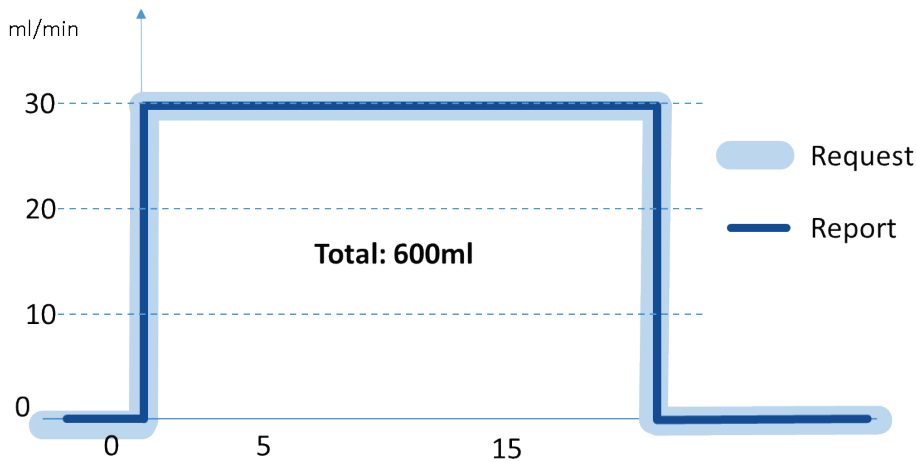
515

X.4.1.2.3 Complex administration

Finally, a more elaborate case is where the medication administration is given in one act, but that act has different phases.

520 The picture below shows a fictitious case, just to illustrate the concepts: the medication administration request (in light blue) determines that the medication is supposed to be at a rate of 20 ml/min for 5 minutes, and then for 15 minutes more at a rate of 30 ml/min.

The medication administration report (in dark blue) shows that the administration started on time and followed the planned administration for the first 5 minutes, then the rate was correctly
525 changed to 30 ml/min for 10 more minutes, and then something happened. Possibly a change in the saline bag, or an extravasation. After this deviation from the plan, the medication is again administered at the requested rate, until the total volume of 250 ml is given. The average rate (total amount infused vs total time) should be captured in the report. At the end, there will be resources for the request (what was planned to be administered, and how) and for the report (what
530 was effectively administered, and how).
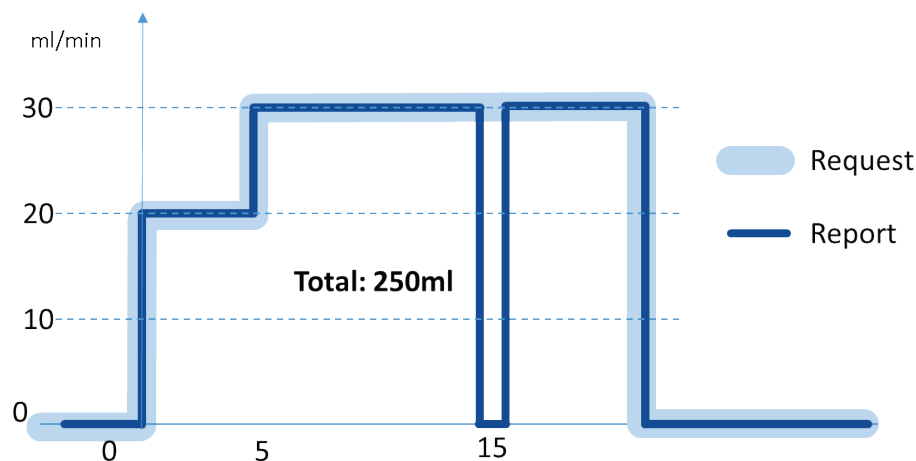
X.4.1.2.4 Handling different types of administration

Systems implementing the MMA Profile will determine whether an administration is instantaneous or if it is a continuous implementation. At runtime, this can be determined by either:

- the nature of the user actions (e.g., user simply presses a button "Done") ;

- the nature of the medication or the administration requested (oral solid forms vs continuous infusion).

To ensure interoperability, systems implementing the Medication Administration Informer must be compatible with the following logic:

- If the administration is a single point in time administration,

  - One single MedicationAdministration resource instance is issued with the details of the administration event.

  - At any time, if there is additional information (e.g., an adverse reaction), the same resource instance may be updated.

- If the administration is continuous:

  - At the beginning of the administration interval, one single MedicationAdministration resource may be issued, with status "in progress". Note that this is optional, and some systems may only send out the resource when the administration is complete. Systems that implement the Medication Administration Informer shall support this optionality.

  - At the end of the administration interval, the same MedicationAdministration resource instance is updated with status "complete". If there was no resource instance issued at the beginning of the administration, then this is the only resource instance and contains the details of the entire interval.

  - If at any time the medication administration becomes a complex administration, i.e., if there is another interval in the same administration:

    - If the MedicationAdministration resource instance for the first interval, did not have a "parent" resource instance:

      - The previous simple interval administration becomes the parent

      - A child MedicationAdministration resource instance is created, which contains the interval that just finished. This interval has status "complete" and its parent is the previous resource instance.

      - Another child MedicationAdministration resource instance is created, with status "in progress" which represents the newly started interval. The same logic applies as for the previous intervals.

  - There may be an optional "parent" MedicationAdministration resource, which is kept "in progress" for accumulating the "children" administration intervals, if there are any.

See the section "Message Semantics" for details on the constraints that support this logic.

X.4.1.3 Implementation Considerations

X.4.1.3.1 Administration Request

A simple medication request represents one medication at a given time. The simplest example is one tablet taken by a patient. This is called a **single point in time** administration.

575

> A single dose of a single medication corresponds to one single medication item in a single request.

Quantities:

580 If in a planned administration event there are two or more (or any non-integer quantity) units of the medication, this is represented by the quantity element in a single request.

Mixed drugs in one single event

585

> If two different drugs are to be administered at the same time, and if the group of these drugs does not have one unique ID, this is represented by a group of medication requests (i.e., one single request group, with two requests, each representing one medication item.
>
> An example is "Drug A 500 mg and Drug B 150 mg". Most compound products may be described this way.

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> If, however, the grouped composite medication can also be represented in an unequivocal way as a single product (even if as free text), then this can be represented as a single medication.

> Put simply, it is recommended to specify a combination of products with a unique resource that unequivocally represents that combination, if that is possible and that unique code exists.
>
> If not, then the combination needs to be described by a group of its constituents.

595

Continuous Medication administration

> In most cases, the medication administration information can be mentioned in one single planned interval (e.g., "administer 250 ml at a rate of 5 ml/min"). This is represented in one single interval.

600

> If for the same medication, there is a need to express different phases, such as complex dosing, product changes, or titration, the approach is to have different requests when needed, each representing a phase, as part of a same group.

X.4.1.3.2 Administration Report

605 A single administration report represents one event with one medication.

As in the requests, the following considerations apply:

Quantities:

> Two or more (or any non-integer quantity) units of the medication are represented by a multiplier.

610

Mixed drugs in one single event

> If two or more different drugs are administered at the same time, and if the group of these drugs does not have one unique ID, this is represented by a parent medication administration report with two child reports, each representing one medication item.
>
> 615 An example is "Drug A 500 mg and Drug B 150 mg".

> If, however, the grouped composite medication can also be represented in an unequivocal way, then this can be represented as a single medication.

> 620 Put simply, if it is possible to specify a combination with a unique code, that is recommended.
>
> If not, then the combination needs to be described by a group of its constituents.

Continuous Medication administration

> In most cases, the medication administration information can be mentioned in one single planned
> 625 interval (e.g., "administer 250 ml at a rate of 5 ml/min"). This is represented in one single interval.

> If for the same medication, there is a need to express different phases, such as any event or change – a nurse change, a change of solvent, etc., the approach is to have several medication
> 630 reports grouped under the same "parent" medication administration report, and all of these reports are pointing to the same originating Request.

Combining different products in different intervals is achieved by separating the main interval into its constituent intervals, and each interval contains the drugs. As a consequence, a drug can
635 be reported in two different intervals.

X.4.2 Five Rights of Medication Administration

The MMA Profile supports the Five rights of Medication Administration:

640
- right patient;

- right drug;

- right dose;

- right route;

- right time.

645 These are the features in MMA that enhance patient safety:

- The Medication Administration Request (as well as Prescription, to be supported in a later IHE profile) provides information of the intended drug for each patient.

- Grouping with the Patient Demographics Consumer, the Medication Administration Performer can lookup the patient from any of the available information (any identifier) and confirm the identity of the patient.

650

- With the introduction of the UBP and Product Lookup, it is possible to have a check whether the product meets the intended product for the patient. It is important to note that the product identification (barcode or RFID) is attached to the medication, preferably in the single dose instance to prevent errors. This is usually a barcode on a single tablet.

655
- The information in the Medication Administration Request can be used to do a first check whether there is a match of patient, product, schedule, etc., before actual administration.

X.4.3 Use Cases

MMA supports the retrieving medication administration requests, and informing about the administration. The use of FHIR enables distributed applications, and enhanced data exchange
660 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;

665
- 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.

670 ### X.4.3.1 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.4.3.1.1 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 are not part of the scope of this profile. See the 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 (or not prescribed) pharmaceutical product. This "catalog" contains master data (product data) and therefore can be dynamically changed, updated, etc. 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.4.3.1.2 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:

3. Each nurse logs in to her tablet.

4. **The tablet (which implements the Medication Administration Performer) 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.**

5. **The EHR responds with a list of the relevant medication administration instructions.**

6. 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.

7. The app on the tablet can for example tell the nurse the optimal routing with the names and addresses of the patients she has to visit.

8. At each address, the nurse looks on the tablet for the medication and the dosage for the appropriate patient.

9. 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.

715

10. She sees to it that the medication is being swallowed.

11. For unplanned medication administrations (unplanned, or PRN / "As Needed" medications), the nurse can also scan the barcode of the package or enters a code manually into the app.

720

12. 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).

13. Before she leaves she can enter remarks about the state of the patient.

14. If the nurse does not document all the scheduled administrations, the tablet issues a warning to the nurse.

725

15. After (performing and) registering all the treatments for one patient, the nurse visits the next patient.

16. After her round of patients, the nurse returns to her institution and connects with her EHR.

17. 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

730

to the EHR.

Post conditions:

18. The medication management profiles of the patients are updated with the feedback of the substance administration.
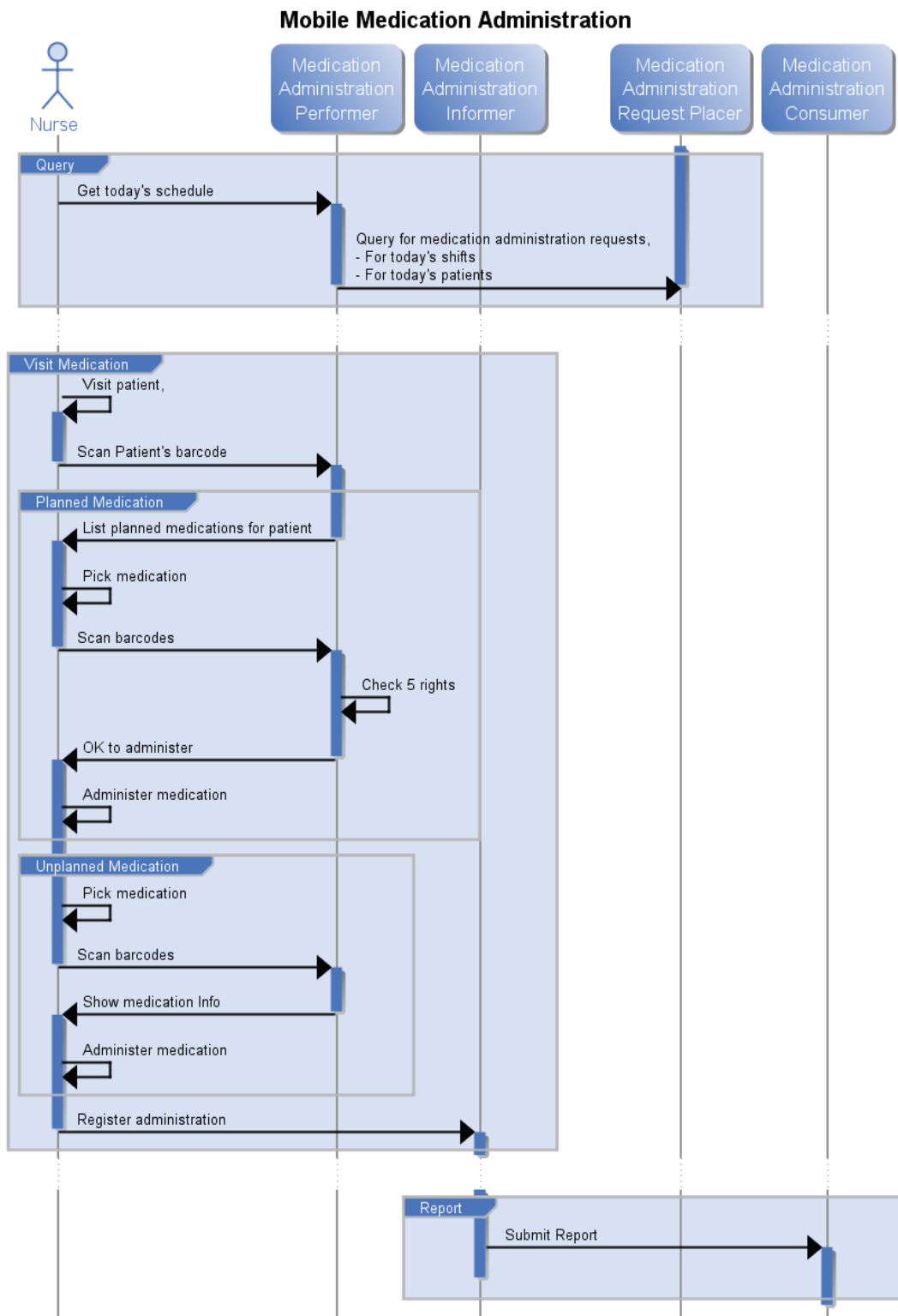
Mobile Medication Administration

Figure X.4.3.1.2-1: Scheduled Administration Process Flow in MMA Profile

_____

X.4.3.2 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.

740   **X.4.3.2.1 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 must be prescribed by specialized oncologists. The app
745   should be able to perform autonomously even if no internet connection is available.

X.4.3.2.2 Home Chemotherapy Administration Process Flow

<u>Pre-conditions</u>

1. Patient Adam Everyman is suffering from colon carcinoma. It has been treated with radiation, but Adam has to complete the treatment with a chemotherapy for 6 months.
750   2. The therapy has to be followed strictly, in dosage as well as in timing. The dosage pattern is a 3-week cycle with 2 weeks of medication followed by 1 week of rest.
3. The dosage of Capecitabine (brand name XELODA®) is 1250 mg/ m2 each 12 hours and Adam is scheduled to consume 2500 mg every 12 hours.
4. The oncologist sets up Adam for a close monitoring of the treatment administration,
755   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.
5. 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
760   the patient's well-being. In case of strong side effects, the oncologist may spread the dosage over several administrations during the day.

<u>Main Flow:</u>

6. 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.
765   7. The app issues a signal every time Adam has to take his medication.
8. Adam has to take a combination of 3 drugs, each with different dose 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.
770   9. The app provides the ability to register additional medication that Adam uses to soothe the nausea or soften pain.
10. 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.

<u>Post conditions:</u>

775   11. 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.

_____

12. If Adam has reported that he has vomited his medication, the care providers might consider increasing the dosage for the next administration.
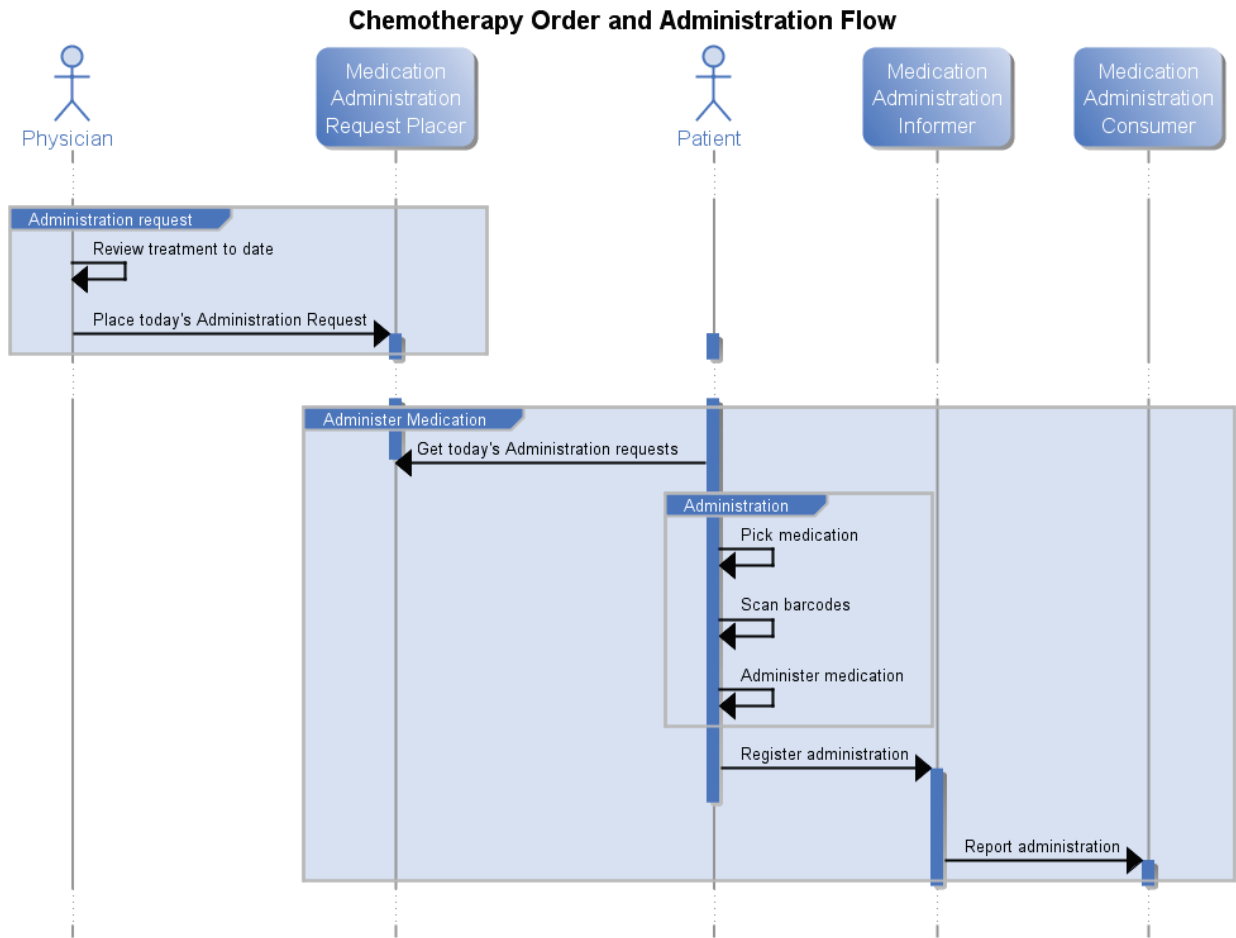
Figure X.4.3.2.2-1: Home Chemotherapy Administration Process Flow

X.5 MMA Security Considerations

See the ITI Appendix on HL7 FHIR (ITI TF-2x: Z.8 "Mobile Security Considerations") for general background on "Mobile" security considerations, and recommendations regarding security. MMA Profile provides an API for accessing Data Element level details that are identifiable to a specific Patient. Thus all the data communicated, including the query parameters, should be considered Patient Identifiable data. The grouping with IUA, or some similar User Authentication and Authorization solution, is critical to enforcing Privacy and Security. All accesses to this data should be recorded as audit log for security surveillance and Privacy 510 reporting. These topics are discussed in Appendix Z.8 with recommendations.

X.6 MMA Cross Profile Considerations

While any of the actors can be grouped with other IHE actors as needed to provide additional functionalities, security, or others, these are some highlights:

795

- For reliable, real-world implementations, transactions for Catalog / Product Lookup is can be grouped with this actor, to support the case when a nurse enters a not-prescribed medication, and the system queries the server to get the characteristics of the medication. They will be part of the Pharmacy Technical Framework in future revisions.

800

- Also "Prescription" transaction would be important, for the nurse to be able to obtain the prescription information – for context and to support "as needed"/PRN drugs. This will also be added to the Pharmacy Technical Framework. In addition, this will support that the nurse terminal (Medication Administration Performer) can take a prescription and derive all the planned administrations, without relying on the server to do so.

805

- ITI PDQm: The Medication Administration Informer can be grouped with the Patient Demographics Consumer to search for patients or obtain patient information. This can be useful for different reasons:

810

  o In systems that only implement the Medication Administration Informer but not the medication administration Performer, the patient details may not be known to the system in advance. In this case, the nurse needs to look up the patient in the server, for example using a patient wristband. This can be resolved if the system implements the Patient Demographics Consumer to look for a patient.

  o Similarly, all cases of unplanned medication administrations where the patient does not have medication administration requests, and may not be known to the system – the system may implement the Patient Demographics Consumer to look for a patient.

815

  o If the Medication Administration Request does not provide full information about the patient, for example if the MedicationRequest.Patient is a contained resource and not a link to the patient, it may be important to obtain more information about the patient.

As a general guidance, readers are advised to consult the ITI Technical Framework and, depending on the implementation requirements, other IHE materials like Patient Care

820 Coordination or Patient Care Devices.

Appendices

Appendix A – Examples of systems implementing MMA actors

A.1 Example 1: Tablet for scheduling and reporting

825

This example is depicted below and corresponds to Use Case 1. The hospital system implements the Medication Administration Request Placer – typically this is in the system that schedules the medication administrations, for example in parallel with (or after) the dispensing.

The hospital system also wishes to receive the administration reports for any intended purpose – updating the prescription system, informing how patients are using the medication, providing information for the billing, etc., so it implements the Medication Administration Consumer.

830

The nurses have a tablet with a software (or app) that can obtain the Medication Administration Requests from the hospital system, to remind or assist in the performing of the administration, so that tablet software implements the Medication Administration Performer. Finally, the tablet software can submit back to the hospital system the administration reports, so the software also implements the Medication Administration Informer.

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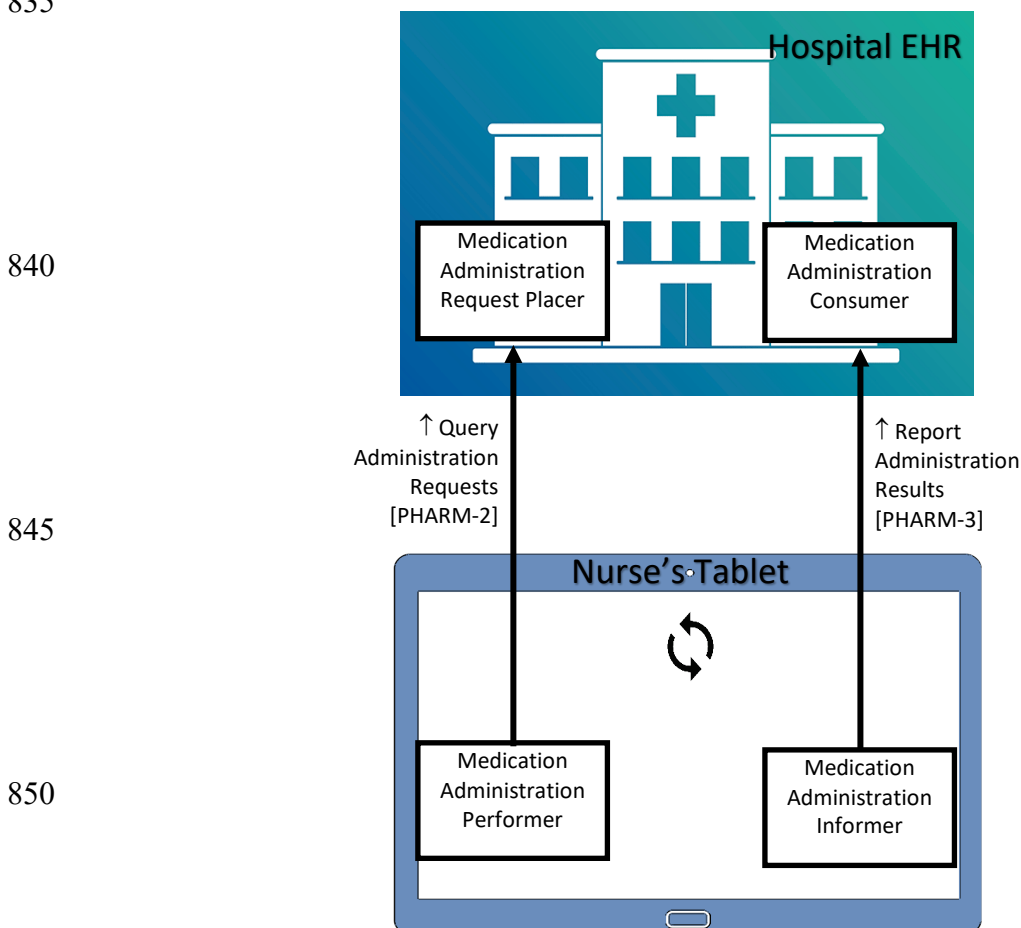
840

845

850

Figure A.1-1: MMA for assisting Nurses in homecare

855
Example 2: Patient smartphone for scheduling and reporting

This example is listed to show that the same approach in Example 1 – Tablet for Scheduling and reporting – can also be used by personal mobile devices, as in Use Case 2. The actor implementations are the same, only in a smartphone and not a tablet.

Example 3: Patient smartphone for reporting

860   In some cases, the hospital system does not provide a detailed medication administration schedule and it is up to the patient to enter that schedule. One simple reason is that the prescriber gives the patient the freedom to determine the detailed schedule, as long as the posology is respected. This is very common in the medication administration apps in the market today. The patient enters the necessary information and the smartphone app will create a schedule for the
865   patient. The smartphone app then reminds the patient and can upload the results to the patient's hospital or GP system, or to the national health system. The smartphone app informs about the administration and thus implements the Medication Administration Informer. The hospital system or GP system that receives this information implements the Medication Administration Consumer.

870
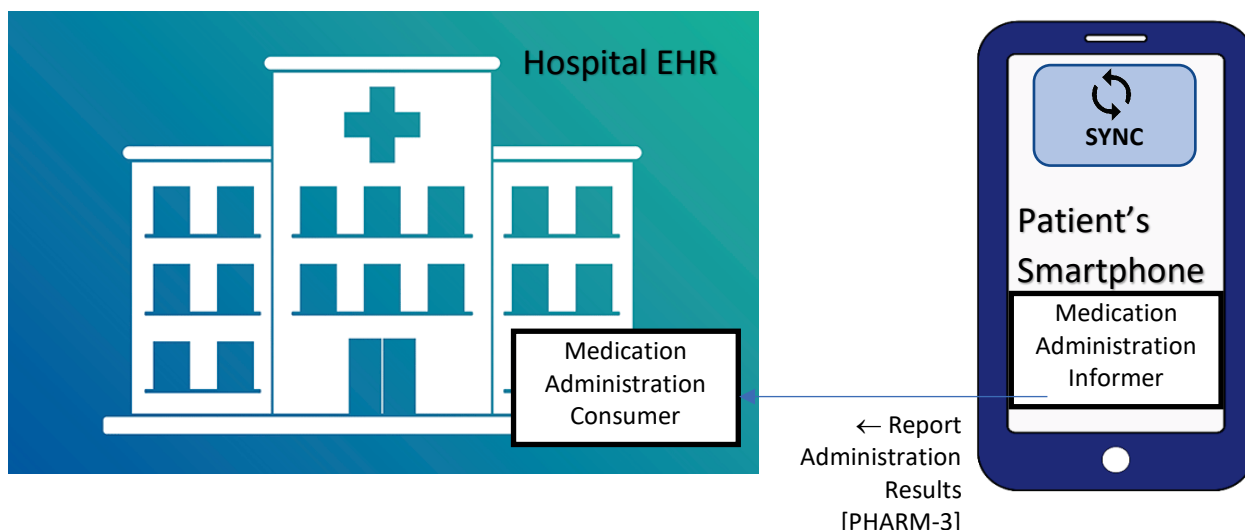
880

Figure A.1-2: MMA for Patients' reports of administration

885

Example 4: Patient smartphone for Scheduling

In some cases the patient uses the smartphone app as a reminder, and there is no interest to submit the results of the administration back to the hospital. So, the patient smartphone software consults the scheduled medication administration so that the patient can be guided for the administration (thus implementing the Medication Administration Performer). The hospital system defines the scheduled administrations and therefore implements the Medication Administration Request Placer.

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895

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905
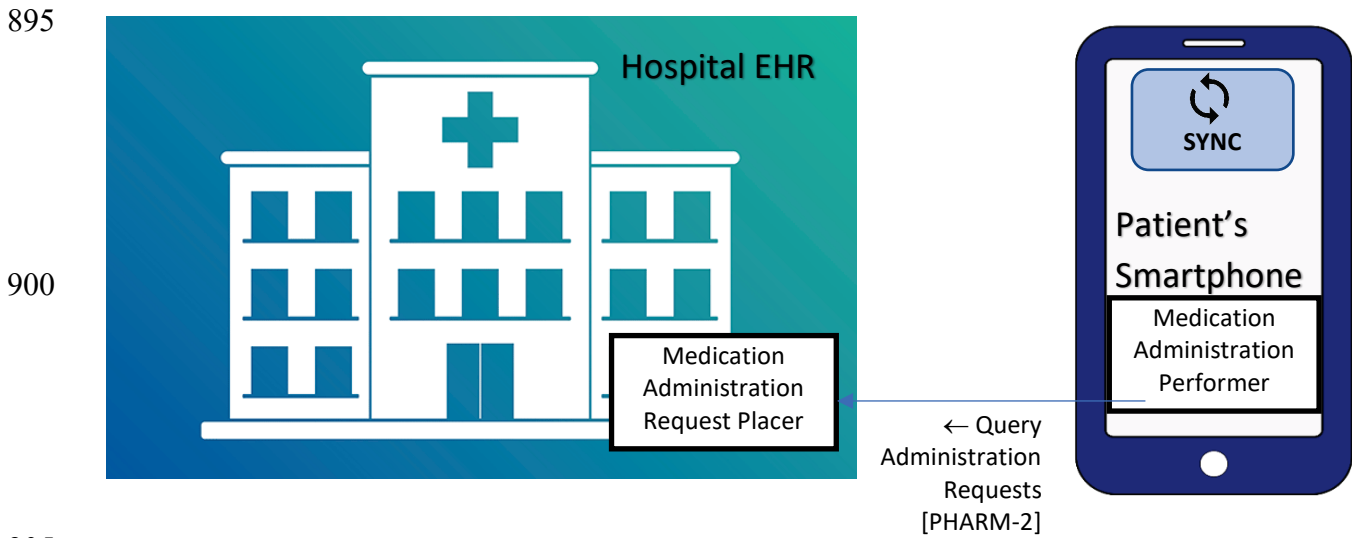
Figure A.1-3: MMA for Patients' medication schedule reminder

Example 5: Patient smartphone for Scheduling and upload to cloud

One additional example of the supported scenarios is when the patient smartphone app can get the medication administration scheduling information from the hospital, but where the smartphone app does not send the result of the administration back to the hospital but rather to another system, e.g., a Personal Healthcare Record. In this case the hospital system implements the Medication Administration Request Placer, the patient smartphone app implements the Medication Administration Performer and Medication Administration Informer Actors, and the other healthcare record implements the Medication Administration Consumer.
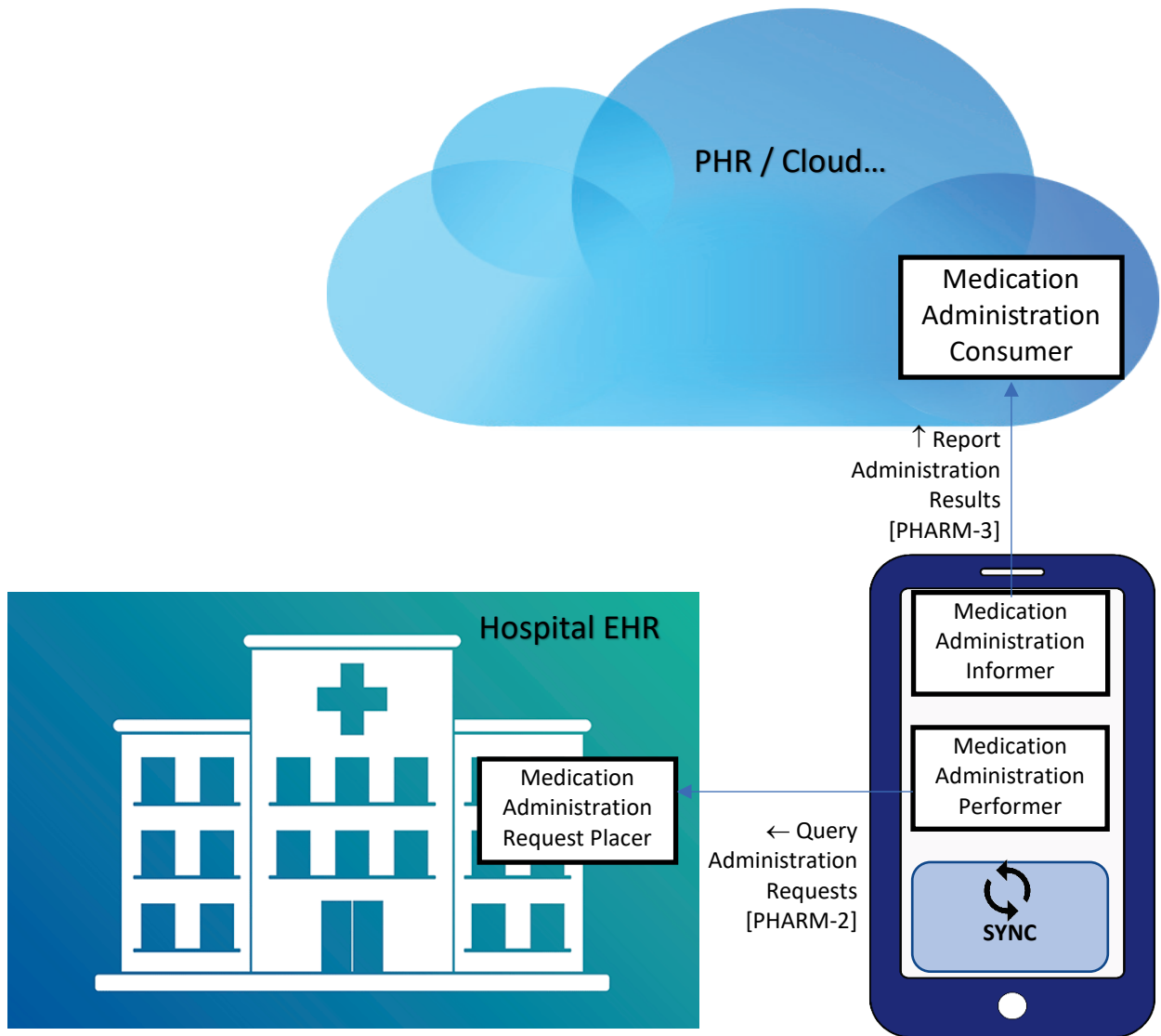
Figure A.1-4: MMA for Patients' integrated medication – schedule and reporting

Volume 2 – Transactions

940 | *Add Section 3.Y*

3.Y Query Administration Requests

3.Y.1 Scope

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

3.Y.2 Actor Roles
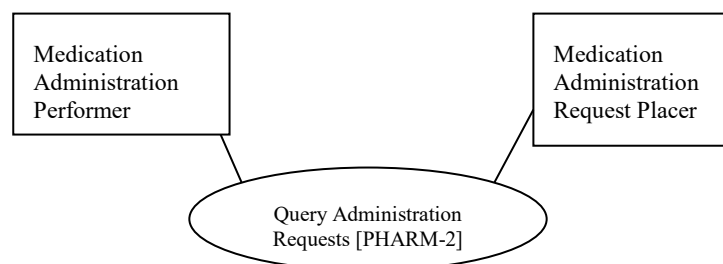
945

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

3.Y.3 Referenced Standards

950

HL7 FHIR	Fast Healthcare Interoperability Resources DSTU3 http://hl7.org/fhir/DSTU3/index.html
IETF RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

3.Y.4 Interaction Diagram
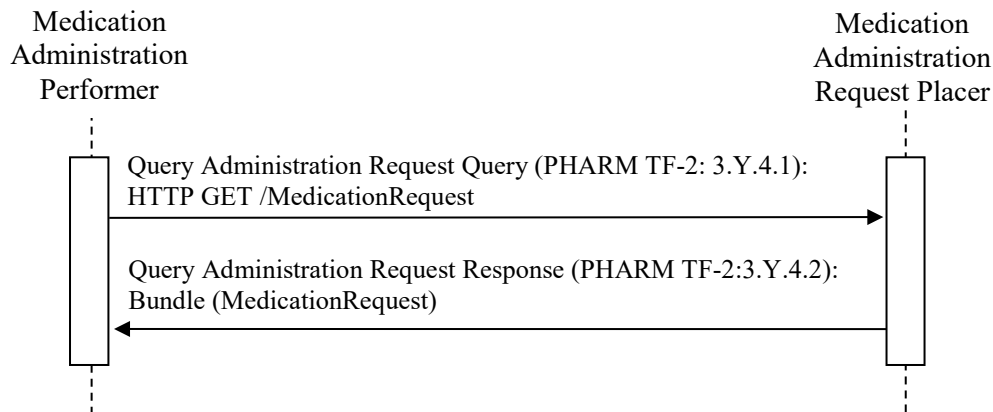
3.Y.5 Query Medication Administration Requests

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

3.Y.5.1 Query Medication Administration Requests - Query

3.Y.5.1.1 Trigger Events

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

3.Y.5.1.2 Message Semantics

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

965   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.

970   The [parameters] represents a series of encoded name-value pairs representing the filter for the query specified in Section 3.Y.5.1.2.1, as well as control parameters to modify the behavior of the Medication Administration Request Placer such as response format, or pagination.

3.Y.5.1.2.1 Query Search Parameters

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

Note that none of these query parameters are mandatory, either by FHIR specifications or by any constraints in this profile.

980 Medication Administration Request 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.5.1.2.1-1 shows the attributes that may be used in the query.

Table 3.Y.5.1.2.1-1: Parameters used for Query Medication Administration Requests

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 or performing team
Order type	Fixed value: "instance-order"	N	The type of Medication Request. Administration Requests are of type "**instance-order**"
sort	string	Y	The attributes used for sorting, prefixed by a – in case of descending order.

985 **_id**

This parameter of type string, when supplied, represents the resource identifier to be retrieved. It is intended to retrieve one specific resource instance for which the id is known. An example could be to get a specific instance for which reception is not complete or may have been updated.

990 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.).

995 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 dateTime serve to query for medication administrations planned for a given time period. For example, only a morning shift, or only a specific day.

1000   If these parameters are omitted, the server will return the medication for all time (i.e., include all past and future medication) that meets the other search criteria.

Omitting one of these parameters results in an open-ended time interval, i.e.:

Omitting the start date and providing an end date results in all the medication administration requests ("from the beginning of time") until the end date specified. An

1005   example, would be "all past medication administration requests until now".

Omitting the end date and providing a start date results in all the medication administration requests from the start date and in the future ("until the end of time"). An example, would be "all medication administration requests from now and in the entire future".

1010   See FHIR specs for search based on boundaries and approximate searches.

Patient Identification

This parameter serves to allow retrieving the medication administrations planned for a specific patient.

It is possible to search for requests for several patients in one query, by specifying several

1015   possible values for a given parameter. For example:

http://test.fhir.org/r3/MedicationRequest?subject:Patient._id=347,348,349&...

Will return the requests for 3 patients, those for which the internal resource ID is 347, 348 or 349.

Note that different attributes separated by a comma represents an OR condition, while

1020   different attributes represent an AND condition. So, for example

http://test.fhir.org/r3/MedicationRequest?subject:Patient._id=347,348,349&subject:Patient.name=peter

will return those patients for which

- the id is either 347 OR 348 OR 349

1025   AND

- the name contains "peter"

Status

This parameter of type string serves to get only medication administration requests that have one specific status. Normally, this could be only "active" medication administration

1030   requests. Other statuses are supported.

Intended Administration Performer

This parameter of type string serves to get only medication administration requests that already have an intended performer associated. This performer can be for example the care team or the specific professional.

1035 **Medication Order Type**

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

Sort Order

1040
This optional parameter determines how the results will be sorted in the received bundle. It may be important to sort the results by patient or by administration time. Implementers may use this parameter according to the needs of each use case.

See http://build.fhir.org/search.html#sort for more information about how to use sorting.

3.Y.5.1.3 Populating Expected Response Format

1045
The FHIR standard provides encodings for responses as either XML or JSON. Medication Administration Request Placer Actors shall support both message encodings, whilst Medication Administration Performer Actors shall support one and may support both.

3.Y.5.1.4 Expected Actions

In response to the request, the Medication Administration Request Placer shall return a bundle of
1050
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.

1055
If the Medication Administration Performer supplied a query parameter, or used a query parameter modifier which the Medication Administration Request Placer is not capable of utilizing, then the Medication Administration Request Placer shall respond with an **HTTP 400** (Bad request) status code and an OperationOutcome resource indicating the parameters in error.

The Medication Administration Request Placer shall respond to the query request as described by
1060
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 Request 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.

1065
A resource bundle is returned representing the result set. The Medication Administration Request Placer populates the total property of the bundle with the total number of matching results. One entry is returned from the Medication Administration Request Placer for each MedicationRequest Resource found.

Case 2: The Medication Administration Request Placer fails to find in its information source, any
1070
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 Request Placer populates the total with a value of 0 indicating no results were found. No entry attributes are provided in the result.

1075
Case 5: The Medication Administration Request 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:

1080

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

The Medication Administration Request 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.

1085   The Medication Administration Request Placer may return other HTTP status codes to represent specific error conditions. When HTTP error status codes are returned by the Medication Administration Request Placer, they shall conform to the HTTP standard RFC2616. Their use is not further constrained or specified by this transaction.

3.Y.5.2 Query Administration Requests Response

1090   **3.Y.5.2.1 Trigger Events**

The response is triggered when the Medication Administration Request placer finds administration requests matching the query parameters specified by the MedicationRequest as a result of a Query Medication Orders Request.

3.Y.5.2.2 Message Semantics

1095   The Query Medication Request Response is a bundle of MedicationRequest resources.

3.Y.5.2.2.1 MedicationRequest Resource Definition in the Context of Query Medication Request

The components of the MedicationRequest Resource with cardinality greater than 0 (as shown below) are required, and the detailed description of the content is provided here. All other
1100   attributes of the response are optional.

For all the MedicationRequest resources, the following constraints apply:

- An Administration Request for a single dose or instantaneous administration shall consist of one medication request per medication item

- If there are several medications in the same event or interval, MedicationRequest.groupId
1105   must be filled with a same unique identifier in the same group. Implementers may choose any identifier format as long as it is unique. Systems implementing the Medication Administration Performer must be able to interpret the medication.groupId.

- MedicationRequest.basedOn must be filled in with the reference to the prescription that triggered the medication Administration Request.

- MedicationRequest.intent must be "instance-order" for all medication administration requests.

- The MedicationRequest.medication is typically a resource representing a product kind, and not a physical instance, i.e., MedicationRequest.medication does not contain expiry date and lot number. As such, it will normally be a link, and not a contained resource.

  - o If the product referred is a kind, the MedicationRequest.medication should be a link to a resource, not a contained resource. This is to ensure synchronization of product information:

  - o In some cases, the medication indicated is a physical instance. This can be the case when the medication is dispensed and the batch numbers and expiry dates are known for each administration for each patient (e.g., Patient 171 will receive medication X at 1 pm, and the physical product dispensed for that event has a lot L0123 and expiry date August 2021). In these cases, the MedicationRequest.medication may be either contained or a link to a resource representing that physical instance.

- The time shall be indicated in the dosage, as a single event.

- An Administration Request for a simple interval shall consist of:

  - o One medication request per medication item.

  - o If there are different medication items at the same time, the different items to be administered shall have the groupIdentifier attribute filled in, with a unique identifier. The groupIdentifier attribute simply explains that the medication is requested together, i.e., as part of the same event.

  - o In addition, if there is a need to provide additional information about that grouping, like dependencies, conditions like "the second medication should only be given if the first one is correctly administered", a RequestGroup resource can be used and these MedicationRequest resource instances can be part of that RequestGroup resource instance. This is optional and can be done in combination with the specifications in this profile, but the details on how to use RequestGroup are not covered in this version of the profile.

  - o The time shall be indicated in the dosage, as a single event.

- An Administration Request for a complex interval:

  - o If the changes in a complex interval are dosage-related, the Administration Request shall contain the conditions for each sub-interval in the dosageInstruction repetitions.

  - o If there are changes to other parameters e.g., different medications, these changes should correspond to different sub-intervals.

3.Y.5.2.2.2 Resource Bundling

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

3.Y.5.2.2.3 Incremental Response Processing - Paging of Resource Bundle

Paging is supported: the response may be split into different pages….

The Medication Administration Request Placer shall represent these incremental responses as specified by FHIR – Paging: http://hl7.org/fhir/STU3/http.html#paging

3.Y.5.2.3 Expected Actions

The constraints specified in Section 3.Y.4.2.2 represent the minimum set of information that must be implemented by a Medication Administration Request Placer. This does not prevent the Medication Administration Request Placer from sending additional FHIR attributes in a response; such as extensions, text, etc. The Medication Administration Performer 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.Y.5.2.4 Capability Statement

Medication Administration Performer implementing [PHARM-2] should provide a CapabilityStatement as described in ITI TF-2x: Appendix Z.4 indicating the query operation for the MedicationRequest Resource has been implemented and shall include all query parameters implemented for the MedicationRequest Resource.

3.Y.6 Security Considerations

The Medication Administration Request Placer and the Administration Performer shall be grouped with a Secure Node Actor.

Systems implementing the Medication Administration Request Placer and the Administration Performer shall implement the Secure Application Actor in ATNA.

3.Y.6.1 Security Audit Considerations

The auditing considerations defined in Appendix Z apply.

3.Y.7 Error Control

When the medication administration reports are uploaded to the Medication Administration Consumer, they are stored and persisted. If the processing of the resources is without problems, then the response has http code 200, as described before.

If there is any issue in the processing of the medication administration reports, the server shall respond with an OperationOutcome resource.

Systems implementing the MMA Profile MUST be able to issue an error or warning, or take corrective action in the cases presented in this section.

3.Y.7.1 Medication Administration Performer

Upon receiving the Medication Administration Requests, the Medication Administration Performer shall:

- If the Product is unknown (which is not a situation expected to happen commonly), systems implementing the Medication Administration Performer may choose to accept the information and search for the product, or simply reject it with an error.

1185

- o If the product is not known, the Medication Administration Performer may use another transaction to consult the medication from a catalog. This transaction will be defined in another Pharmacy profile.

1190

- o If a match is not found (or if the Medication Administration Performer cannot support the Catalog Lookup), the systems that implement this actor MUST inform the user (the patient or the nurse) about such an error. This allows the nurse to acknowledge that there is medication planned, and the nurse must take measures. Otherwise, a silent error (not showing an error to the nurse and ignoring the request) could give the wrong indication that no medication is planned.

1195

- In the Patient is unknown (for example, the patient is not known in the system because it is incorrectly marked as transferred or marked as deceased, etc.

1200

- o The Medication Administration Performer can look up the patient using the transactions defined in PCC PDQm, or display a warning or error to the nurse, who then can act appropriately (e.g., entering the name manually, etc.). This affects the Medication Administration Report transaction: The Medication Administration Reports for that patient may be registered and submitted, but the receiving system (Medication Administration Consumer) may receive information for a patient that is not known, and may need to reconcile or merge that information back into the patient's record.

1205

Add Section 3.Z

3.Z Report Administration Results

3.Z.1 Scope

1210 This transaction is used to record a medication administration event (or to record a skipped medication administration).

3.Z.2 Actor Roles
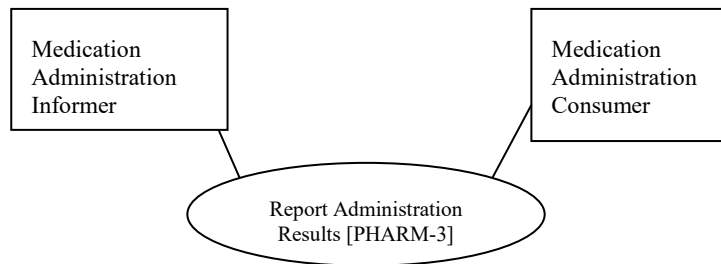
Figure 3.Z.2-1: Use Case Diagram

Table 3.Z.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)

1215

3.Z.3 Referenced Standards

HL7 FHIR	Fast Healthcare Interoperability Resources DSTU3 http://hl7.org/fhir/DSTU3/index.html
IETF RFC2616	Hypertext Transfer Protocol – HTTP/1.1
IETF RFC7540	Hypertext Transfer Protocol – HTTP/2
IETF RFC3986	Uniform Resource Identifier (URI): Generic Syntax
IETF RFC4627	The application/json Media Type for JavaScript Object Notation (JSON)
IETF RFC6585	Additional HTTP Status Codes

3.Z.4 Interaction Diagram

1220

3.Z.5 Report Administration Results
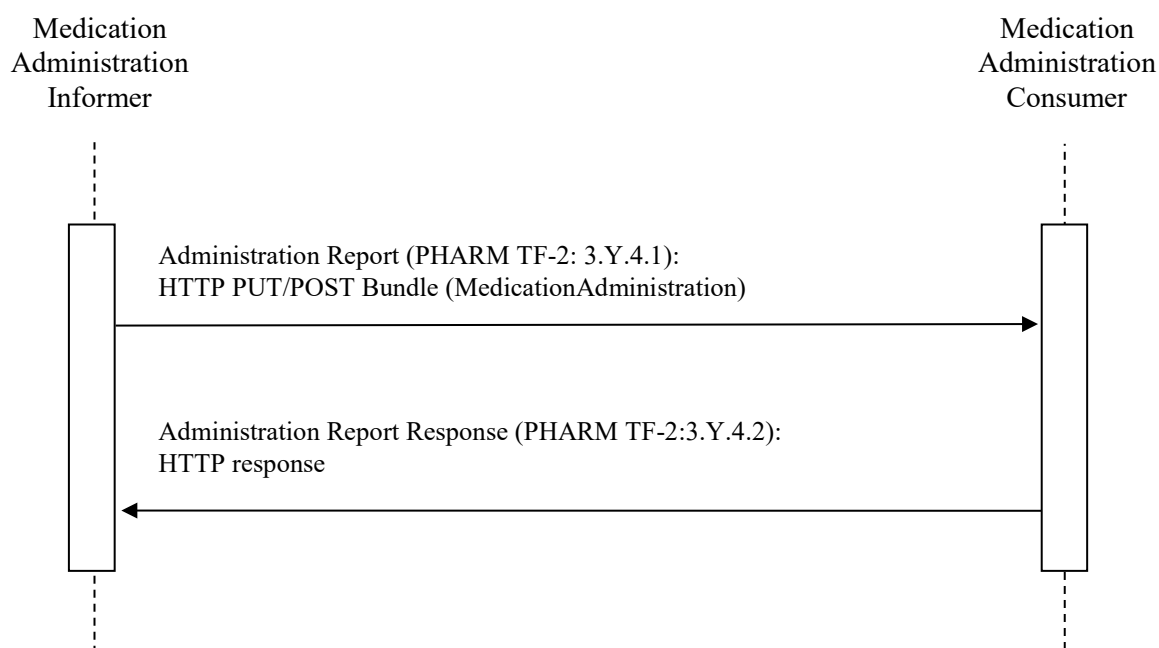
1225   This action represents an HTTP PUT or HTTP POST of a bundle of medication administration reports.

POST may be used for a first submission of a resource instance. If the Medication Administration Informer is able to generate the resource id, then it may use a PUT for a first submission.

PUT is used in further updates of a resource instance.

1230   The bundle is necessary to contain several administration reports from different patients, since typically the nurse will upload the results when there is connectivity. In some circumstances, the administration report may be sent immediately, so in that case there is only one MedicationAdministration resource in the bundle.

3.Z.5.1 Trigger Events

1235   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, the trigger for submitting an administration will typically be some time after. This is often the case but not always: For example, in some exceptional case, the patient may inform about a skipped administration even
1240   before the scheduled time.

3.Z.5.2 Message Semantics

- If the medication administration is a result of an "administration request", MedicationAdministration.request shall not be empty and must point to that "administration request" as specified in transaction [PHARM-2]

1245   o If the medication administration is a result of a prescription without a precise and single schedule, e.g., ad-hoc, "take as needed"/PRN, the MedicationAdministration.request shall point instead to the Prescription.

_____

- o If the administration has a documented reason or related information besides an explicit prescription or request, for example is consequence of an implicit order that comes a dispense or is related to a condition that justifies the use of a medication, then MedicationRequest.supportingInformation shall be filled in with that information.

- o If medication is emergency/unplanned and there are no documented requests, MedicationAdministration.request shall not be filled in. This is the case for the OTC medication which the patient acquires from the local drugstore, such as pain relievers, NSAID's, cough syrups, vitamins etc.

- If any of the characteristics change from the implicit or explicitly 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.

- If there are several different medications being administered at the same time (for example, two different tablets taken at the same time, or two medications in an infusion), then two MedicationAdministration resource instances shall be used, with the same timing values. In this case, the groupId must also be filled in with a common value for all the medications to be administered at the same time. This applies to all cases except when it is the administration of more than one units of the same medication, or when there is a medication representing the two medications, for example if there is a unique code that unambiguously represents "mixture of product A and product B diluted in solvent C", then it is correct to use the code, and in this case the mixture is considered a single medication. This consideration applies to the entirety of this document: when there is an indication that one MedicationAdministration resource instance shall be issued, it should be considered that it is one MedicationAdministration resource instance per medication.

- MedicationAdministration.subject should be linked, not a contained resource. Only exceptional circumstances should require a contained patient resource, such as an emergency administration for a patient that is not known by the systems.

- MedicationAdministration.Medication shall refer to a physical instance of a product and as such contain, whenever available, the lot or batch number, the expiry date, and serial number, as well as other identifiers.

  - o If the system does not have the capability to obtain this information by e.g., decoding the scanned barcode, the system can use the UBP Profile in one of two ways:

    - ▪ Request that the barcode be decoded before submission of the administration record

    - ▪ Pass the barcode information to an actor that will handle the submission of the administration record

  - o For this reason, MedicationAdministration.Medication would normally be a contained resource, pointing to a specific instance of a medication, unless the medication administration request already specifies a linked medication instance resource (i.e., if the medication administration request already contains a link to a physical instance, with lot number, expiry date, etc.)

- If admin is a single point in time, MedicationAdministration.effectiveDateTime is mandatory and contains the time of administration.

- If administration is continuous,

  o At the beginning, a MedicationAdministration resource instance should be issued for the entire administration interval, with

    - status = "in-progress"

    - period.starttime contains the time when the administration interval started

    - period.stoptime is empty.

    - Implementers may opt to include a "parent" administration, to support the case of a complex interval administration. This is not guaranteed or mandatory.

  o At the end of the interval, if the administration is completed with this interval:

    - If no resource was previously submitted, a new MedicationAdministration resource instance is issued.

    - If a MedicationAdministration resource instance was issued at the beginning of the interval, the same resource instance is updated.

      - status is "complete",

      - period.starttime is the same as the previous resource instance

      - period.stoptime is now filled in with the time the administration stopped.

  o If the administration is complex or when it becomes complex (i.e., a new interval is added, whether planned or not), there shall be a parent MedicationAdministration resource instance, and the previous interval and present and future intervals shall be linked to this parent. Typically, to implement this, the following logic (or similar) is followed:

    - The first step is to see if there is already a parent administration. If not:

      - The MedicationAdministration resource instance corresponding to the first interval (if it had not been created before, one shall be created at this moment) becomes the parent of the complex administration.

        o The Start time of the parent interval remains the same,

        o The Stop time is still unknown

        o The status remains "ongoing"

      - A new child MedicationAdministration resource instance shall be created for the first interval, where:

        o *part of = (resourceID of the "parent").* Note that to obtain the ID may imply either a query to the server, or, most commonly, that the resource is created with a predefined id.

        o *Starttime is the start of the first interval*

        o *Endtime is the time when the 1st interval ended*

        o *Status = "complete"*

- A new child MedicationAdministration resource instance may be created for the second interval, where:
    - part of = (resourceID of the "parent").
    - Starttime is the time of the change (i.e., typically the end time of the previous interval. If not, this could mean a pause in the administration between the two intervals)
    - Endtime is empty
    - Status is "in-progress"

1335

Later, when the second interval is finished, the resource instance is updated. Like for the simple interval, the MedicationAdministration resource instance for the second interval may only be created at the end of the interval instead, and not updated.
Each of the intervals in a complex interval administration thus follows the same rules as the simple interval administration.
The parent interval SHALL contain the aggregate information about the different intervals: the total time of administration, the total volume, the average infusion rate, etc.

1340

- When it is known that the medication has not or will not be taken (for example one medication administration is coming up and the previous is known not to have been taken), a MedicationAdministration resource instance is created
    - Time = <The time when the medication should have been administered but was not>
    - Status must have the value "NotDone"
    - StatusReason (or ReasonNotGiven) should be filled in if status is NotGiven
        - Note: ReasonNotGiven is expected to be subsumed into SatusReason.
        - Note: The reasons for status depend largely on the implementer clinical and legal environment. At this moment, IHE does not provide a mandatory value set. Appendix C shows a sample value set that can be used.

The serialNumber extension is recommended to the Medication resource. An example excerpt containing the serial number information would look like this:

```
<Medication xmlns="http://hl7.org/fhir">
 <!-- ... -->
 <package>
  <batch>
    <extension url="http://ihe.net/fhir/mma/StructureDefinition/SerialNumberExtension">
     <valueString value="1072608460521" />
    </extension>
  </batch>
 </package>
 <!-- ... -->
</Medication>
```

Appendix D, specifically Section D.1, shows the full definition of the Serial Number extension.

3.Z.5.3 Expected Actions

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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:

1375
- 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). 1380 It is beyond the scope of this profile to provide further guidance on this. The management of "administration complete" must be done at the main administration task.

- Any other conclusions

3.Z.5.3.1 Management of workflows:

When updating an administration, this has an impact on the workflows. It is beyond the scope of 1385 this profile to provide guidance on this. For example, if there is a task associated with the MedicationAdministration, that task should be updated. The management of "administration complete" must be done at the main administration task.

3.Z.5.4 Report Administration Results Response

In response to the request, the Medication Administration Consumer shall return the http result 1390 code together with the outcome of the operation. The response is synchronous (i.e., on the same connection as was used to initiate the request).

If the operation is successful, the Medication Administration Consumer shall respond with an HTTP 201 (Created) and return a bundle of MedicationAdministration resources that were created or updated.

1395 The Medication Administration Consumer may return other HTTP status codes to represent specific error conditions. When HTTP error status codes are returned by the Medication Administration Consumer, they shall conform to the HTTP standard RFC2616. Their use is not further constrained or specified by this transaction.

3.Z.5.5 CapabilityStatement Resource

1400 Systems implementing the Medication Administration Informer transaction [PHARM-3] should provide a CapabilityStatement resource as described in ITI TF-2x: Appendix Z.4 indicating the MedicationAdministration Resource.

3.Z.6 Security Considerations

The Medication Administration Request Placer and the Administration Performer shall be 1405 grouped with a Secure Node Actor.

Systems implementing the Medication Administration Request Placer and the Administration Performer shall implement the Secure Application Actor in ATNA.

3.Z.6.1 Security Audit Considerations

The auditing considerations defined in Appendix Z apply.

3.Z.7 Error Control

When the medication administration reports are uploaded to the Medication Administration Consumer, they are stored and persisted. If the processing of the resources is without problems, then the response has http code 200, as described before.

If there is any issue in the processing of the medication administration reports, the server shall respond with an OperationOutcome resource.

Systems implementing the MMA Profile MUST be able to issue an error or warning, or take corrective action in the cases presented in this section.

3.Z.7.1 Medication Administration Informer

- Upload errors
  - Systems implementing the Medication Administration Informer must be able to detect if the upload was correctly processed by the Medication Administration Consumer.
- Data Entry errors
  - Data entry errors can be resolved by updating the resource. Systems implementing the Medication Administration Informer MUST support PUTting an updated resource.
- If the Product reported to be administered is unknown (for example, foreign products being taken, or home preparations), systems implementing the Medication Administration Consumer SHOULD accept the information, and MAY try to complement the information:
  - If the product is not known, the Medication Administration Consumer may use another transaction to consult the medication from a catalog. This transaction will be defined in another Pharmacy profile.
  - If a match is not found (or if the Medication Administration Consumer cannot support the Catalog Lookup), the systems that use this actor SHOULD preserve the information so that it can be complemented later or simply shown as is whenever relevant – for example in medication lists, or any other relevant record. Otherwise, a silent error (not showing an error and ignoring the medication administration report) could give the wrong indication that no medication is administered.

3.Z.7.2 Medication Administration Consumer

Systems implementing the Medication Administration Consumer SHOULD provide the functional validation in the same transaction.

The following cases MUST be checked:

- Whether the patient is unequivocally identified
- Whether the medicinal product is unequivocally identified
  - If not, the system can look up the product from a catalog. This transaction will be described in another profile.

o   If the product is not unequivocally identified, this MUST NOT be a blocking situation, since there may be administration of medication that is no longer known, or medication that

If any of the cases described above is not correct, Systems implementing the Medication Administration Consumer MUST be able to inform the users that the errors occurred, thus avoiding silent errors.

Appendices

Appendix C – Additional code values

1455   This section shows some code values that can be used in support of the MMA Profile and intended behavior.

C.1 StatusReason code set and application

The following table gives some examples of StatusReason codes, and their possible relevance to justify a medication administration event, or a non-administration event.

1460   This table is for illustrative purposes and is not binding – implementers may choose another code set, or expand and truncate the code set shown below.

When the code "OTH" is used, a narrative explaining the reason should be added in the text.

Code	Description	Administration	Non-Administration
6	Allergy / Hypersensitivity	Y	Y
3	Difficulty in administration		Y
1	No effect or not perceivable effect		Y
2	Effect too strong		Y
4	Due to newly diagnosed disease or condition	Y	Y
5	Due to newly prescribed other medicine		Y
7	Other mode of administration chosen	Y	Y
8	Out of stock		Y
12	Problem solved or improved		Y
9	On instructions of caregiver, no known reason	Y	Y
11	According to prescription	Y	Y
OTH	Other	Y	Y

1465

Appendix D – Extensions

This is the list of extensions used in the MMA Profile

D.1 Serial Number

1470 The serial number of a medication product is required in several cases, for example in chemotherapy preparations. For other medication the serial number is not yet common but is becoming increasingly required, for example in support of the Falsified Medicines Directive in the EU. Using a serial number is not mandatory for the Pharmacy MMA Profile, but is recommended.

1475 Below is the structure definition for the extension Serial Number. This extension SHOULD be implemented by all systems implementing the MMA Medication Administration Informer and Medication Administration Consumer Actors.

```
<StructureDefinition xmlns="http://hl7.org/fhir">
 <meta>
<lastUpdated value="2017-10-07T11:09:17.767+02:00"/>
</meta>
<url value="http://ihe.net/fhir/profile/StructureDefinition/SerialNumberExtension"/>
<name value="serialNumber"/>
<status value="draft"/>
<date value="2017-10-07T11:04:28.948+02:00"/>
<fhirVersion value="3.0.1"/>
<kind value="complex-type"/>
<abstract value="false"/>
<contextType value="resource"/>
<context value="Medication"/>
<type value="Extension"/>
<baseDefinition value="http://hl7.org/fhir/StructureDefinition/Extension"/>
<derivation value="constraint"/>
 <differential>
 <element id="Extension.url">
<path value="Extension.url"/>
<fixedUri value="http://ihe.net/fhir/profile/StructureDefinition/SerialNumberExtension"
/>
</element>
 <element id="Extension.value[x]:serialNumber">
<path value="Extension.valueString"/>
<sliceName value="valueString"/>
<short value="Serial Number or identifier"/>
<definition value="Serial number of the medication instance"/>
<comment value="Text or number"/>
 <type>
<code value="string"/>
</type>
</element>
</differential>
</StructureDefinition>
```

Volume 4 – National Extensions

Add appropriate Country section

1515   4 National Extensions

None