Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine Technical Framework Supplement

Laboratory Clinical Communications (LCC)

Rev. 2.2 – Trial Implementation

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Foreword

This is a supplement to the IHE Pathology and Laboratory Medicine (PaLM) Technical Framework V11.0. 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 for trial implementation on April 8, 2024 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Pathology and Laboratory Medicine Technical Framework. Comments are invited and may be submitted at http://ihe.net/PaLM_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Pathology and Laboratory Medicine domain can be found at https://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 https://www.ihe.net/about_ihe/ihe_process and https://www.ihe.net/resources/profiles.

The current version of IHE Pathology and Laboratory Medicine Technical Framework can be found at https://profiles.ihe.net/PaLM/index.html.

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Introduction to this Supplement

The current order-result paradigm supported under HL7 V2 includes ordering, order cancellation, unsolicited replacement of issued orders by the Order Placer or Order Filler, and result reporting. It does not encompass other clinically-important interactions related to ordering and resulting laboratory tests, such as recommendations for order modification by the Order Filler, or additional work after resulting required for fulfillment of the original clinical need. The former occurs when an Order Filler such as a clinical laboratory has information indicating that one or more orders (such as an order for laboratory tests) may not meet the clinical need optimally, but does not have prior permission to replace or supplement that order without clinical input. The latter occurs when a result may need to be verified or interpreted before being acted upon.

Communications satisfying these needs are typically carried out by phone, fax, or other manual methods, which are inefficient for Order Fillers and ordering clinicians, are not amenable to automation and decision support, prevent Order Fillers from communicating through the EHR as a full member of the patient's care team, and do not create structured documentation useful in quality assurance and process improvement. The Laboratory Clinical Communication (LCC) Profile defines workflows, messages, and data elements to support automated communications between Order Filler and Order Placer/EHR systems about orders and results. It is intended to carry enough information about existing orders or results that systems can implement streamlined, convenient methods to support requesting replacement or supplementation of orders, or issuing new orders for additional work related to particular results.

The LCC Profile also enables improved Order Filler quality assurance. The communication and resolution of needs for order replacement/supplementation, result confirmation, and, if appropriate, result interpretation are integral parts of service quality that are currently managed on an *ad hoc* basis outside of information systems. Communications can be delayed or lost and summary data about ordering and resulting problems is difficult to compile. Thus, recognition and correction of the acute and/or systemic problems indicated by these communications is time consuming and error prone. This new profile will enable rapid, standardized, automated capture of and response to problems related to orders and questions about results, and will allow this information to be logged, tracked, and included in QA studies and process improvement projects.

The LCC Profile was developed from a clinical laboratory and anatomic pathology perspective and will benefit interactions in both of those specialties. The use cases cited in this document are laboratory-oriented. However, the problems the profile addresses are general to ordering and resulting workflows, and thus these communication patterns should be useful to any clinical services that respond to orders and/or create clinical information that may require further action.

Open Issues and Questions

Extension of the LCC Profile to a broader set of communications tasks should be considered for future work. The Profile in its current form is tightly tied to recommendations by the Order Filler for replacement of orders or creation of additional orders to supplement existing orders, and to creation of new orders by the Order Placer for additional work related to previous orders. There

are additional types of order-related communications that may be clinically important, for example, requests from the Order Filler for additional clinical data about an order or patient, or for information about clinical strategy. The Order Filler may also wish to provide information or advice to the Order Placer about laboratory issues that are not tied to specific orders or results. These types of communications might incorporate flexible approaches to triggers and entity relationships. Such communications could support an efficient and collaborative diagnostic or patient monitoring process, and further promote the inclusion of the laboratory as a full member of a patient's care team.

Closed Issues

- OO CR-855 (V2.10) modified the REL segment in order to describe the type of objects linked by the REL segment identified in REL-4 and REL-5 respectively by adding two new fields (REL-17 and REL-18). This approach is pre-adopted for use in [LAB-7] using the v2.9 message structure created for this use case

IHE Technical Frameworks General Introduction

The IHE Technical Frameworks General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

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IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

*Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located here.*

Appendix A – Actors

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

No new actors.

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Order Recommendation [LAB-6]	The Order Recommendation transaction is used to communicate recommendations for clinical order replacement or supplementation from the Order Filler to the Order Placer.
Request for Fulfillment [LAB-7]	The Request for Fulfillment (e.g., verification of a result) transaction is used to streamline the ability of the Order Placer/Order Result Tracker application to issue follow up orders on results that do not meet expectations, either clinically or operationally.

Appendix D – Glossary

200 *Add the following new or modified glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

No new terms.

Volume 1 – Profiles

Domain-specific additions

N/A

X LCC (Laboratory Clinical Communications) Profile

The Laboratory Clinical Communications (LCC) Profile supports information exchanges between clinicians and laboratories in the context of a set of test orders. This profile covers use cases, workflows and transactions for additional information exchange after placing an order or receiving a result. This additional clinical communication may include recommending replacement or supplemental orders when the submitted orders are not optimal or inappropriate for the type of specimen or clinical setting, or requesting follow up on a specific result that does not fully meet the clinical need or does not fit the clinical presentation of the patient.

X.1 LCC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at https://profiles.ihe.net/GeneralIntro/.

Figure X.1-1 shows the actors directly involved in the LCC Profile

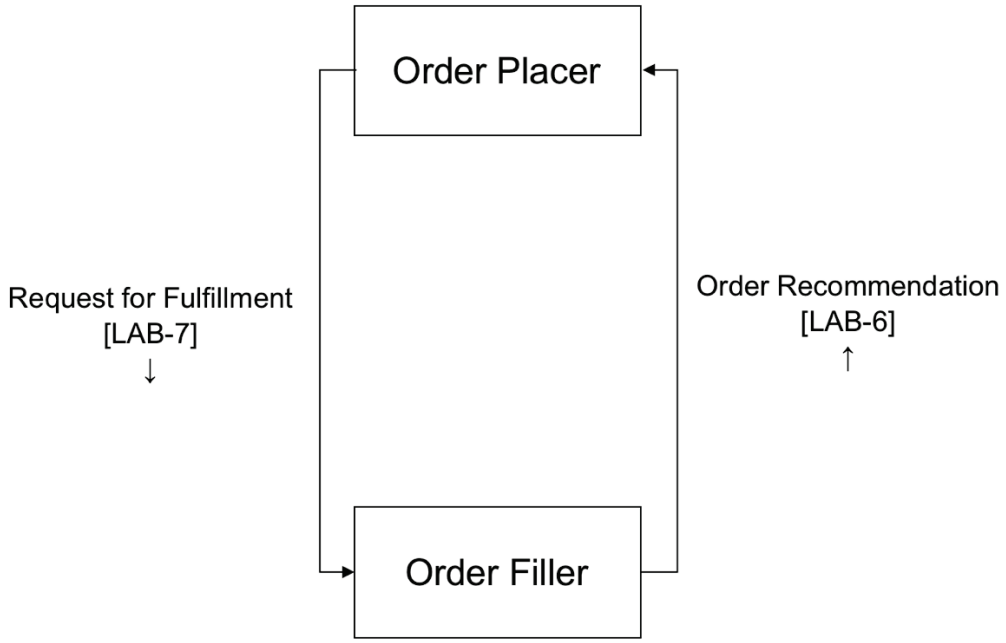


Figure X.1-1: LCC Actor Diagram

The LCC Profile defines two transactions occurring between the Order Filler representing the laboratory application, and the Order Placer representing the application used in the clinical care setting. The transactions are independent of each other and support separate sets of use cases (see Use Cases below).

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

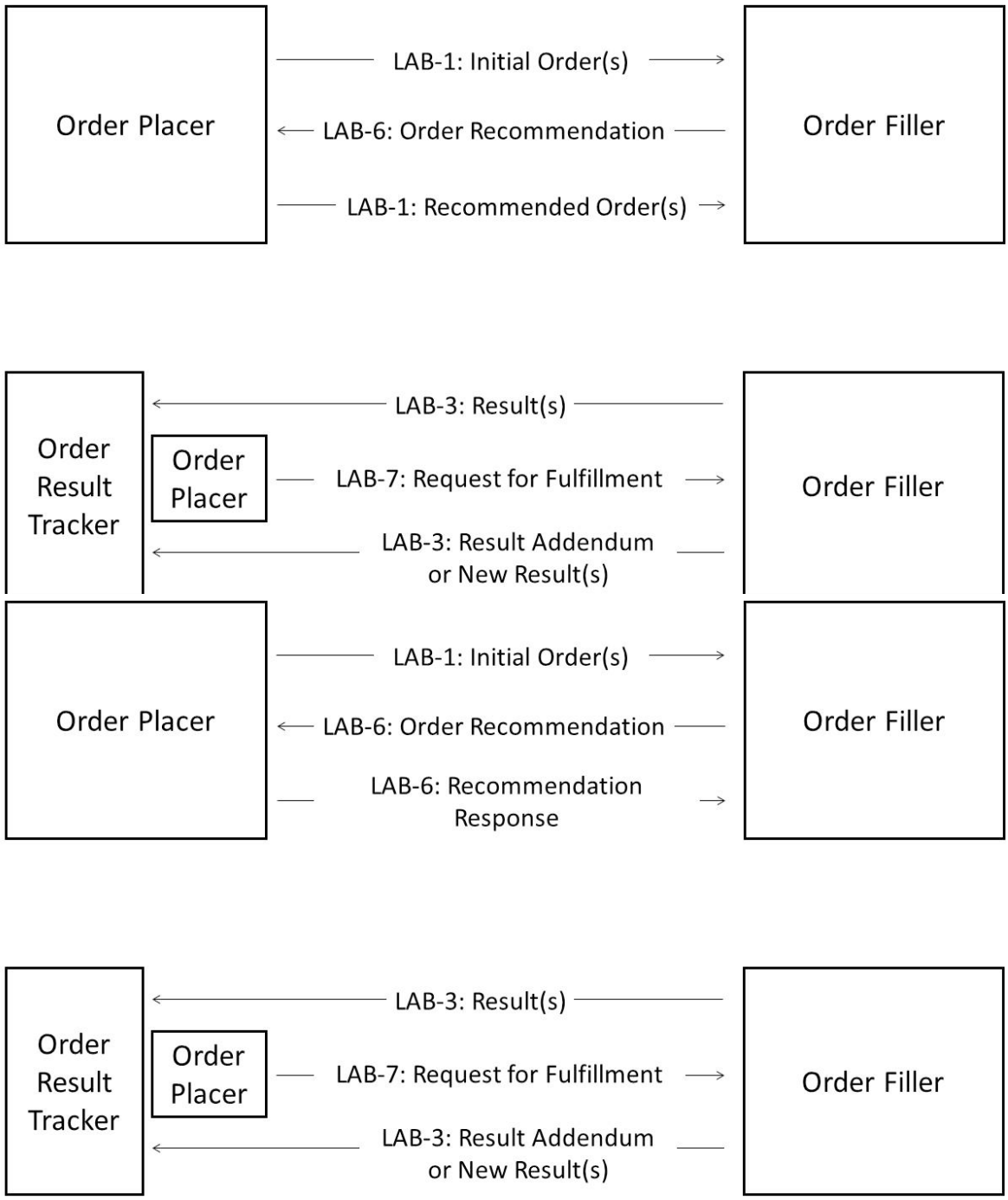
Table X.1-1: LCC Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Order Filler	Order Recommendation [LAB-6]	R	PaLM TF-2: 3.6
	Request for Fulfillment [LAB-7]	R	PaLM TF-2: 3.7
Order Placer	Order Recommendation [LAB-6]	R	PaLM TF-2: 3.6
	Request for Fulfillment [LAB-7]	R	PaLM TF-2: 3.7

X.1.1 Actor Descriptions and Actor Profile Requirements

Requirements are documented in transactions (Volume 2a). There are no additional requirements on the profile's actors imposed by LCC transactions.

Transactions Order Recommendation [LAB-6] and Request for Fulfillment [LAB-7] support independent sets of use cases and integrate into the transaction flow of the LTW Profile of the PaLM Technical Framework.



240

Figure X.1.1-1: LCC Profile transactions in relationship with other PaLM TF transactions

Note that communication between Order Placer and Order Result Tracker shown for [LAB-7] is assumed to take place outside of this profile: These two actors might be grouped in a single

application, or have information exchanges, or be used separately by two distinct applications used by the clinician.

LCC may also be used in the context of inter-laboratory workflows (for instance orders submitted by a local clinical laboratory to a reference laboratory). In such situations, the transactions of the LCC Profile are interleaved with those of the ILW Profile instead of the LTW Profile. On the figure above, for these kind of workflows, [LAB-1] would be replaced by [LAB-35] and [LAB-3] by [LAB-36].

X.2 LCC Actor Options

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: LCC - Actors and Options

Actor	Option Name	Reference
Order Filler	No options defined	--
Order Placer	No options defined	--

X.3 LCC Required Actor Groupings

Section not applicable.

X.4 LCC Overview

The LCC Profile introduces two independent feedback loops between the clinicians placing the orders and receiving the results on one side, and the laboratory performing the orders and sending the results on the other side. The first feedback loop (order recommendation) operates between the Order Placer and Order Filler systems. The second feedback loop (result fulfillment) is triggered by a result and requires coordination between the Order Result Tracker and the Order Placer systems so that a follow-up order from the Order Placer to the Order Filler may refer to the previous result. This coordination is represented by grouping the Order Placer and Order Result Tracker (Fig. X.1.1-1).

The LCC Profile works in tandem with the Laboratory Testing Workflow (LTW) Profile in support of the use cases described below.

The LTW Profile defines five transactions ([LAB-1] to [LAB-5]) that flow between four actors to support laboratory test ordering and resulting (see PaLM TF-1: 3). These transactions support standard ordering and resulting but are insufficiently flexible to support the range of communications related to orders and results that typically occur between clinicians and ancillary services such as laboratories. For example, orders that cannot or should not be carried out may be refused or cancelled directly, or the Order Filler may contact the Order Placer outside the system and ask that replacement orders be issued. Furthermore, when results do not completely fill the

clinical need there is no facility within systems to request additional work related to that order or result. The LCC Profile defines two additional transaction types ([LAB-6] and [LAB-7]) for the LTW, each with new triggers and distinct use cases, that increase the flexibility of the order-result interaction within the system and meet these needs.

Prior to the LCC Profile, Order Placers were able to send replacements for existing orders to Order Fillers as part of the [LAB-1] transaction (referred to in the PaLM Technical Framework as "order update"). Order Fillers could create new orders and send them to Order Placers for order number assignment using the [LAB-2] transaction, but this transaction does not allow association of the new orders with previous Order Placer orders as would be required to express and document order replacement. The LTW Profile "order update" concept is derived from the HL7 V2.5.1 order replacement pattern, which includes order replacement by either the Placer or the Filler, though as noted the latter is not included in the LTW Profile. The new [LAB-6] transaction expands these existing transactions and adds new order control and status codes to support an order recommendation transaction starting with the Filler that can specify replacement or supplementation of one or more specific existing orders with one or more new orders. The transaction uses the message structure of the HL7 Filler order replacement message, identifying the orders to be replaced or supplemented and defining recommended new orders. This message structure is similar to the Placer order update currently covered by the LTW Profile. It differs from these previous messages by using new control codes to indicate that a transaction is a recommendation rather than a report of a completed act. The Placer may accept, decline, or modify the recommended orders and return a message to the Filler with control codes indicating those responses.

Transaction [LAB-6] also introduces a time window during which recommendation responses from the Placer can be accepted by the Filler. This time window is represented in recommended orders by Order Status code, on hold (HD), Order Status Modifier, expires on time (EOT), and the beginning and end times for the time window in a new field, Order Status Date Range (ORC-36). This hold status and date range is also contained in the existing orders that are recommended for replacement. Orders that are recommended for supplementation are not held and do not show this hold status. Processing of replacement and supplemental orders proceeds as soon as they are received. If no responses are received by the end of the time window, order processing by the Filler proceeds as it would have without the transaction.

Orders for additional work on one or more results are carried in a new [LAB-7] transaction. This additional work may include, for example, confirmation or interpretation, follow up of a process problem, an assertion of error, or a request for annotation, from the Order Placer to the Order Filler. The order includes the patient identity and results to be interpreted or annotated, and may incorporate results from multiple tests as well as observations entered at order time. The transaction does not assume that the Order Filler system originally provided the results to be interpreted. Because the [LAB-7] order may require information from a result, a [LAB-7] implementation would be most convenient when the Order Placer and Order Results Tracker are integrated in a single system, allowing automatic incorporation of the result information into the new order. The response by the Order Filler may be in the form of an addendum or amendment to the original result and/or a report or other result associated with the [LAB-7] order. These

orders are called "fulfillment orders" because the requested additional work is required for the result to fulfill its intended clinical purpose.

Transaction [LAB-7] establishes a target relationship between the new order and a previous information instance (such as an order or result) by incorporating the REL segment into the order message with a new relationship type, Service Target (SVTGT, REL-2), and two new fields (REL-17 and REL-18) to identify the types of the source and target information instances.

In addition to communicating recommendations and orders, [LAB-6] and [LAB-7] messages allow original orders to be linked with related recommendations, or results to be linked with fulfillment orders, so that the frequency, context, and performance quality of recommendation and fulfillment activities can be monitored.

This LCC Profile incorporates and extends concepts from the HL7 V3 laboratory ordering behavioral model into HL7 V2 so that they may be available to the laboratory community prior to broad implementation of HL7 V3. The V3 behavioral modeling is ongoing and the LCC Profile will track that work as it continues. The current IHE PaLM Technical Framework and the ONC laboratory ordering and reporting initiatives are based on HL7 V2.5.1. LCC development initially focuses on repurposing existing HL7 V2.5.1 messages and data elements to carry the data that LCC transactions require. Where extension of field definitions, new fields, new codes, or new messaging patterns are required, they are proposed for the next version of the HL7 V2 in cooperation with the HL7 Orders & Observations (OO) workgroup, and approved new features are "pre-adopted" individually into the overall HL7 V2.5.1 environment of the PaLM Technical Framework.

The intent of this work is to create a communication standard for use by separate LIS and EHR/order entry systems. LCC Profile development does not modify the LTW and other profiles, except for the definition of a limited number of new codes/terms/fields and minor modifications of code and segment usage specifications affecting only LCC messages. As such it sits within the framework defined by the LTW. In addition, the workflow and use cases from this project should be beneficial to integrated LIS/EHR systems through the definition of a more comprehensive order-result workflow that addresses clinical needs.

X.4.1 Concepts

See PaLM TF-1: 3.4.

X.4.2 Use Cases

The following paragraphs describe the use cases for the LCC Profile. They can be divided into two independent sub-categories:

1. Recommendation for replacement or supplementation of existing orders, supported by the [LAB-6] transaction, see PaLM TF-2.
2. Result fulfillment and follow up after testing, supported by the [LAB-7] transaction, see PaLM TF-2.

X.4.2.1 Use Case #1: Order Recommendation

After receiving an order from a clinical practice and identifying some issues, the laboratory creates an order recommendation message and sends it to the clinician with a suggestion for replacement of some or all of the ordered tests before testing begins, or for the addition of one or more orders to supplement the existing orders.

X.4.2.1.1 Order Recommendation Description

Pre-condition:

An order group (or single order) is created by the Order Placer and sent as a “New Order” message to the Order Filler.

Initial Part:

The receiving Order Filler identifies that the test(s) should not be performed as ordered for one of the following reasons (for example):

1. **Test prioritization.** A set of laboratory tests is ordered but the patient is a difficult draw and inadequate volume is obtained to run all tests. The selection of the most useful of the ordered tests depends on the patient's clinical status. An LCC message is returned to the ordering EHR that provides notice of the volume problem and presents a suggested prioritization of tests with an option to modify the priority. Using the message display, the clinician quickly prioritizes the tests to run immediately and schedules a follow up blood draw to provide specimens for the remaining tests. The information is returned to the LIS where the initial order is amended, the follow up blood draw is scheduled as a new procedure, and the problem and its resolution are captured into a QA database.
2. **Optimizing diagnostic yield for individual patients.** A set of orders is received by the laboratory that is expected to have poor diagnostic yield for the patient based on an individualized Bayesian analysis including demographics, prior diagnoses, and prior testing results. The laboratory issues an LCC message recommending replacement of some or all of the ordered tests with tests that are expected to have a higher diagnostic yield in this context and includes explanations in the message along with the recommendations. The clinician can consider the recommendations and either accept or decline them in the returned message.
3. **Reference laboratory order modification.** Specimens are drawn by a local clinical laboratory and shipped to a reference laboratory, with a testing order transmitted via their reference laboratory interface. On arrival it is found that the specimen is inadequate (incorrect type, volume, tube type, etc.). An LCC message is returned to the local laboratory via the interface that indicates the problem, the tests that can be carried out on the available specimen, and the amount and type of additional specimen needed. If appropriate specimens are available, the local lab can elect to ship them immediately to complete the original order. Otherwise, the laboratory can pass the message back to the ordering EHR for amendment of the original order and/or additional sampling.

4. **Proactive follow-up of inconclusive testing.** A fine needle biopsy is sent to pathology but proves to be inconclusive. Rather than report an essentially negative result with a recommendation for resampling, an LCC message is sent to the clinician indicating that the sample was inadequate for diagnosis and presenting a supplemental order for repeat sampling. If the clinician chooses to repeat the test, the results of both tests are reported together with a definitive diagnosis. If no further specimen is provided, the results of the initial specimen are reported. *This potential use of the LCC with inconclusive specimens in AP allows initial and follow up specimens to be reported together rather than reporting potentially misleading negative results.*
5. **Handling future order timeout.** A physician seeing a patient for hyperlipidemia writes a future order for a lipid panel in 4 months and asks the patient to return in 6 months for follow up. When the patient has not visited the lab by 5 months, the order expires and an LCC message is returned to the physician's EMR indicating no-show expiration and allowing replacement of the original order with a new order having a longer time frame and notification to the patient, or cancellation of the order. *It often matters clinically whether a test has expired due to a no-show or has been canceled for other reasons. Current systems do not do a good job of providing this information to clinicians and queuing up their likely responses.*
6. **Proactive correction of incorrect test orders.** A laboratory receives an order for an expensive genetic test. Other test results and a check of the clinical history indicate that a different genetic test is indicated. An LCC message is returned to the clinician with the correct test presented for ordering and an explanation for the substitute order. The clinician can quickly order the replacement test. *Incorrect test orders are not uncommon and the problem is especially acute with new genetic tests according to studies in the past two years by academic centers and major reference laboratories. These errors yield unnecessary cost, delays in diagnosis, and incorrect diagnoses. Currently there is no good way to communicate this information within the order/result transactions.*
7. **Promotion of test utilization goals, payor requirements, or guideline adherence.** A laboratory receives an order for an expensive confirmatory test without a history of the appropriate screening test. An LCC message is returned to the physician that recommends replacement of the ordered test with the screening test and provides the option to order the latter or confirm the previous order. Alternatively, the laboratory receives an order for a test that is not covered by the patient’s insurance pre-authorization and an LCC message is returned recommending replacement of that order with an order for an authorized test. In either case, the physician is able to quickly order the appropriate replacement test from within the message display. *Though these are simple examples, a similar mechanism might provide decision support related to test utilization and testing guidelines. In settings where a lab supports multiple small ambulatory EHRs, maintenance of decision support rules individually in those EHRs may be difficult. Future standardization of decision support rule format will help, but certain forms of sophisticated or laboratory-specific decision support may be best managed in the LIS. The LCC will provide one mechanism for the results of LIS-based order filtering or decision support to be communicated back to the EHR and ordering physicians.*

8. **Capture or correction of data required for testing.** A test is ordered with required data that is missing or erroneous. An LCC message is returned to the ordering system indicating the omission or error and requesting replacement with a similar order that contains the required data. The message display queues up the order with a heading describing the problem and the missing or incorrect fields easily accessible for correction. The physician quickly enters the new data and submits the replacement order. *Limited rules-based processing of orders received in the lab might be used to detect errors, omissions, and other data problems that could be followed up quickly for correction.*
9. **Correction of missing orders or incomplete sets of orders.** A set of orders is received that is missing one or more orders typically associated with the set and important for correct interpretation of the results. An LCC message recommending supplementation of the order set with the missing orders is sent to the ordering system. The clinician is notified and the missing orders are queued and presented for acceptance, with an explanation of their importance. A simple example would be an order for a spot urine protein without an order for a corresponding urine creatinine. In this case the laboratory could issue a recommendation for a supplemental urine creatinine test. *Laboratory and clinician time is saved by incorporating the transaction into the laboratory and clinical workflow, and by allowing the Placer system to present the needed order(s) in a ready to use form. The frequency of missing orders along with their locations and providers can be tracked for quality improvement. Since the new orders supplement rather than replace existing orders, it may be possible to continue processing the existing orders while the supplemental orders are being considered.*
10. **Results-dependent test ordering in extended testing algorithms.** At some locations, clinician orders are required for all tests in a complex reflex algorithm, where the nature of the downstream testing is unknown at the time of the initial order. This situation may occur in AP or CP; a typical AP example might be ER/PR/HER2 testing in evaluation for breast cancer, which may extend over multiple specimens (see published ASCO/CAP guidelines). A similar situation might occur in the complete evaluation of a CSF in a complex patient. The communication process around these algorithms is currently awkward; the availability of the LCC would allow intermediate orders based on "results so far" to be queued up for the clinician, with an explanation. The official result would be optimally communicated as a single report at the end of the algorithm. *This use case can be addressed currently using pending and final results, but that approach requires the clinician or pathologist to switch to the order entry module and manually find the correct follow up order. The LCC allows supplemental orders to be queued up by the lab with all necessary details (e.g., specific tissue block to test) so that it is ready to execute in the context of the preliminary result. This supports accurate reflex ordering and compliance needs of healthcare organizations, allowing the ordering provider to approve and authorize the additional testing.*

In all these scenarios, the Order Filler creates an Order Recommendation message and sends it to the Order Placer.

Middle Part and **Final Part** follow the Use Case #1 in PaLM TF-1: 3.4.2.1.1.

X.4.2.1.2 Order Recommendation Process Flow

In the UML diagram below the [LAB-1] transactions are pre-and post-conditions respectively of the [LAB-6] transaction.

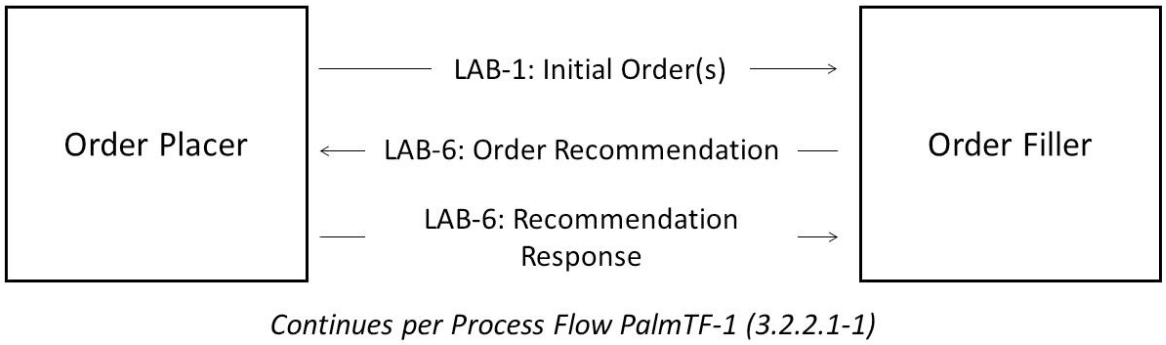


Figure X.4.2.1.2-1: Order Recommendation Process Flow

Note that for the scenario 3 described above, LCC is used in combination with the ILW Profile instead of the LTW Profile. In this particular case, [LAB-1] is replaced by [LAB-35] on the figure above.

X.4.2.2 Use Case #2: Request for Fulfillment

The clinician reviews received results against the clinical history or current presentation of the patient and needs some clarification or follow up on one or more results and sends a request for follow up to the laboratory.

X.4.2.2.1 Request for Fulfillment Description

Pre-condition:

A full cycle of order and result reporting has already occurred – see PaLM TF-1: 3.4.2.1; the Order Result Tracker has received results from the Order Filler.

Initial Part:

The clinician requests a follow up review of a specific order or result in the Order Placer application. The Order Placer creates a New Order to the Order Filler that contains reference to the respective order or result in question.

Here are several scenarios that could trigger a Request for Fulfillment:

1. **Identification and follow-up of results with unusual patterns or lack of clinical support.** A patient in the ER with substernal chest pain and a non-diagnostic EKG initially has a cardiac Troponin I (cTnI) below the level of detection but the second value

is elevated, prompting the patient's admission to the acute cardiology service. The third cTnI value is again undetectable. Confirmation of the previous elevated value and the current normal value are requested through the EHR via an LCC message, yielding a corrected result of "undetectable" for the previously elevated specimen. The patient is discharged without catheterization. Routine monitoring of confirmation requests reveal an elevated number for cTnI since a new test formulation was deployed several months previously. Reports of these results to the test vendor from multiple sites lead to reformulation of the assay with improved performance. *This scenario is derived from actual events and is representative of multiple examples of feedback to test kit vendors from practical use settings. Such test performance monitoring is currently done manually with significant effort, cost, and delay in reporting.*

2. **Interpretation of unusual or complex results.** A patient with joint pain, fever, and sudden onset deep venous thrombosis showed an elevated PT and PTT with otherwise normal coagulation tests. An interpretation was requested of the PT and PTT results from the EHR via an LCC message. The interpretation added as an addendum to the test panel indicated that the results were consistent with a lupus anticoagulant and recommended the appropriate evaluation strategy.

3. **Identification of local test performance problems.** A mechanical problem develops in an analyzer such that the next scheduled recalibration results in inappropriately low cortisol values in patients while controls and other parameters remain within defined ranges. Physicians receiving results that seem clinically inconsistent can easily request confirmation of those results directly from results review, yielding faster recognition of problems and correction of results. *This scenario is derived from actual events in which the analyzer had an unrecognized mechanical problem and all check parameters were within specifications. The discrepancy was phoned in by a single endocrinologist who was known to be a demanding client. Confirmation on a second analyzer yielded a normal cortisol and immediate service performed on the first analyzer revealed the problem. Multiple results required correction.*

4. **Identification of test performance problems across populations.** An endocrine service that performed IGF-1 testing for pituitary evaluation found occasional instances where mildly-to-moderately elevated levels of IGF-1 occurred in patients who did not have pituitary disease. This discrepancy between lab and clinical findings was reported on an ongoing basis when it occurred, with a brief LCC message that could be sent from the EHR to the LIS with only a couple of clicks to note the lack of clinical correlation. No technical problems with the test were found locally, but ongoing statistical analysis of these responses across multiple tests revealed a higher-than-expected rate for elevated IGF-1 and this was reported to the test vendor. Similar performance monitoring reports from multiple locations led the vendor to review the use of a reference range established in Scandinavian populations with US patients, and design a reference range study for the US. *This scenario is derived from actual events. A standard method to simply and easily capture clinical assessment of test performance would allow automated performance monitoring and much faster reporting and response to performance issues than is*

currently possible. Ultimately, this capability would promote performance improvement at both the local laboratory and national vendor levels.

5. **Local process improvement.** A local quality or process problem in testing, for example, the wrong test was done, the turnaround time was excessive, the interaction with the patient or ordering physician was problematic, etc., is noted as a request for follow up by the physician at results review, yielding a coded and/or free text problem flag attached to the original order and result. The outcome of quality assurance follow up can be reported as a result of this request. *This capability allows development of data sets that directly support and monitor local laboratory performance improvement. The ability to flag a result quickly for a quality issue would encourage reporting of problems, as opposed to the more typical incident reports which are handled externally and are awkward to manage within the clinical workflow, and the ability to return a result on quality assessment follow up could improve collaboration between a laboratory and its clients.*
6. **Request for storage or banking of residual specimen for future use.** Test results and clinical characteristics of a patient indicate that a particular specimen would be useful for research or quality-related work. At results review, a physician or pathologist may request that a specimen be captured for these purposes. *This mechanism may be useful to identify particular specimens for specialized follow up, e.g., heterophile antibody analysis, quality activities, e.g., creating quality control specimen pools, or research. Such specimens are often lost to follow up due to lack of ability to annotate them for capture during their residence in the lab.*
7. **Annotation of interesting test results.** An endocrinologist with a busy practice sends testing to an academic center in a nearby city, and collaborates with faculty there in clinical research studies. When a patient displays an interesting result suggesting benefit from future research follow up, or inclusion in a clinical trial, the clinician can quickly flag the result with a pre-defined code that allows it to be retrieved easily in subsequent searches. The academic center scans their results on a regular basis and takes appropriate action for flagged results (e.g., follow up under appropriate IRB oversight for inclusion in registries or trial participation). *This scenario repurposes the fulfillment mechanism to allow arbitrary annotation of results.*

   In all these scenarios the Order Placer creates a Request for Fulfillment message and sends it to the Order Filler.

Middle Part and **Final Part** follow the Use Case #1 in PaLM TF-1: 3.4.2.1.1.

X.4.2.2.2 Request for Fulfillment Process Flow

The UML diagram below the [LAB-3] transactions are Pre-and Post-condition, respectively, of the [LAB-7] transaction.

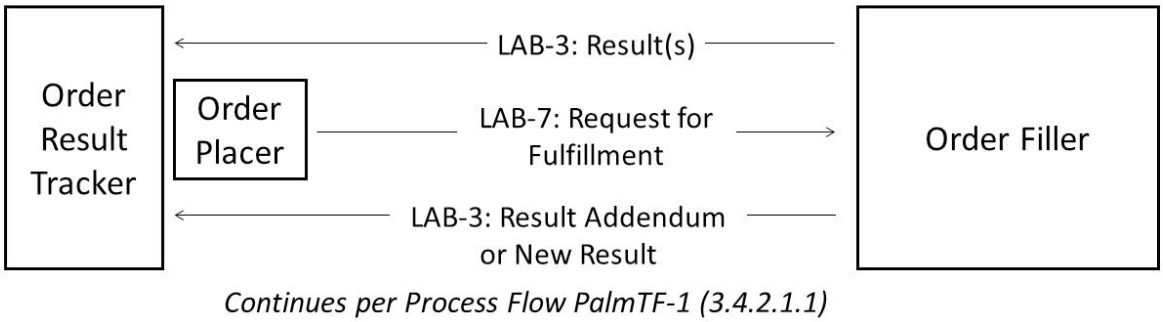


Figure X.4.2.2.2-1: Request for Fulfillment Process Flow

Note that LCC can also be used in inter-laboratory workflows, in which case it is used with the ILW Profile instead of the LTW Profile. In such cases [LAB-3] is replaced by [LAB-36].

X.5 LCC Security Considerations

The LCC message transactions take place in the context of existing LTW or ILW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW/ILW transactions. Thus the LCC messaging extensions fit within LTW security requirements. Because local software implementations may allow selection of replacement or supplementation orders or initiation of fulfillment orders in the context of results review, those implementations would need to make sure that order entry security is correctly incorporated into these streamlined order entry views.

X.6 LCC Cross Profile Considerations

N/A

Appendices

N/A

Volume 2 – Transactions

Add Section 3.6

3.6 Order Recommendation [LAB-6]

3.6.1 Scope

This transaction is used to communicate clinical order recommendations.

This transaction occurs when the Order Filler receives testing orders and has information about either the specimen or the patient indicating that one or more of the orders may be impossible to carry out or may not represent optimal care, or that additional orders are required in the context of the first order set to meet the clinical need. The purpose of the transaction is for the Filler to recommend to the Placer one or more replacement orders for one or more existing orders, or one or more supplemental orders in the context of a defined set of existing orders (see Use Cases, Order Recommendation). This situation may occur any time from immediately after the order is placed until the initiation of the technical testing workflow (replacement), or until results become available (supplementation). Recommended orders must be returned within a defined recommendation time window to be accepted. [LAB-6] differs from existing Filler order replacement in that it solicits orders from the Placer instead of canceling the Placer's orders and creating new orders without Placer input. Thus, it supports collaborative agreement between the Placer and Filler on a final order set in a variety of contexts where order selection may be challenging. Recommended orders, replaced orders, supplemental orders, accepted recommendations, and declined recommendations are denoted with specific order control codes so that they may be archived and tracked to evaluate the performance and impact of order recommendation. While [LAB-6] is intended to be consistent with and an optional addition to the LTW, some extension of HL7 V2.5.1 is required and is pre-adopted from later versions of the standard into the IHE profile, as outlined below.

3.6.2 Actor Roles

Table 3.6.2-1: Actor Roles

Actor:	Order Placer
Role:	In addition to roles defined in Palm TF-2a: 3.1.2: Receives order recommendation from the order filler Sends accept or reject transaction for one or more of the recommended orders to the order filler
Actor:	Order Filler

Role:	In addition to roles defined in PaLM TF-2a: 3.1.2: Sends order recommendation to the order placer with specified time window Receives the accept or reject transactions to one or more of the recommended orders from the order placer, or initiates default processing if the time window closes before a transaction is received.

3.6.3 Referenced Standards

- Order Recommendation [LAB-6]:
- HL7 V2.5.1, Ch. 4 Order Entry
- HL7 V2.9, Ch. 4 Order Entry
- HL7 V2.9, Ch. 2C, Code Tables (Tables 38 and 119)
- LOINC (Universal Service Identifiers for identification of replacement orders)

3.6.4 Messages

Order Recommendation [LAB-6] is shown in red within the [LAB-1] sequence diagram below, based on Figure 3.1.4-1 in the PaLM TF-2a.

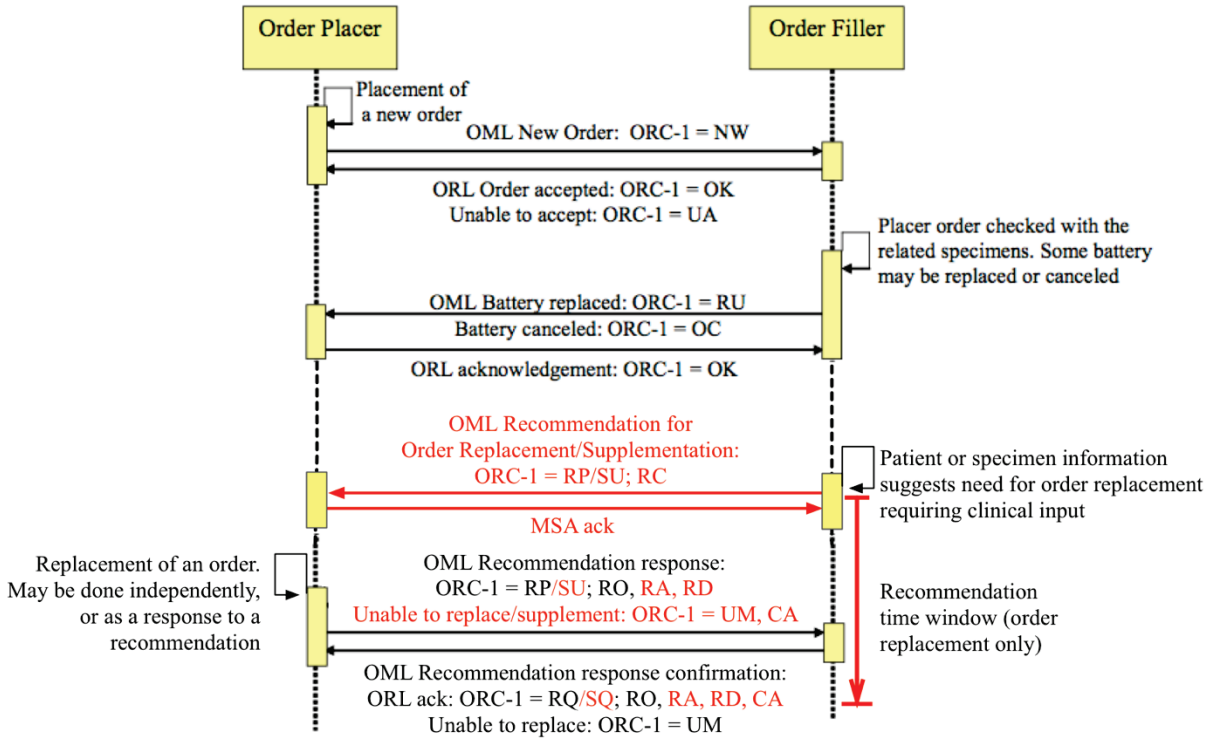


Figure 3.6.4-1: Order Recommendation transactions within the [LAB-1] ordering sequence.

Order replacement and supplementation transactions follow a similar pattern except that replacement uses the RP Order Control Code in ORC-1 for the original orders in the recommendation and response messages and RQ in the confirmation message whereas supplementation uses SU and SQ control codes in those locations, and supplementation does not use a recommendation time window.

[LAB-6] consists of 4 interactions:

1. An order recommendation sent from Filler to Placer
2. An immediate acknowledgement of the recommendation, sent from Placer to Filler
3. A later recommendation response message sent from Placer to Filler, which for order replacement must be received within the recommendation time window to be valid and which may accept, reject, or modify the recommendation, and
4. A confirmation of the recommendation response message from the Filler to the Placer.

The last two interactions are similar to the current order replacement interactions except for the addition of several order control codes (shown in red).

3.6.4.1 Order Recommendation [LAB-6] Messages

Order recommendation and response extends the previous order replacement messaging pattern to allow an Order Filler to recommend order replacement or supplementation and wait a defined period for a response from the Order Placer. Order recommendations use the previous Filler-to-Placer unsolicited replacement message except that modified and new codes for order control, order status, and order control code reasons identify the original orders, recommended new orders, and responses to the recommendations. The recommendation hold time window is specified by codes in Order Status (ORC-5) and Order Status Modifier (ORC-25), and timestamps in Order Status Date Range (ORC-36). The ORC-36 field with the associated value set and the expanded set of codes for ORC-25 field are pre-adopted from HL7 V2.10.

3.6.4.1.1 Trigger Events

[LAB-6] is triggered in the Order Filler in two ways. Order replacement is triggered after ordering but prior to initiating order fulfillment, when an order cannot or should not be carried out based on information available. It will carry information to the Order Placer on why the order cannot be completed, a recommendation for one or more replacement orders and/or order cancellation, a wait (hold) time for a response to the recommendation, and an indication that the hold status expires based on that time. Order supplementation may be triggered on order receipt, if a set of orders is recognized as incomplete, or by the results of a prior order that clarify a complex future testing pathway. Recommended supplemental orders carry a defined wait time over which the recommendation is valid, similar to replacement orders. The response to [LAB-6] is carried in the current Placer Order Management [LAB-1] unsolicited order "update" transaction defined by the LTW (essentially returning the completed message, with or without modification to the replacement orders, to the Filler).

3.6.4.1.2 Message Semantics

3.6.4.1.2.1 OML^O21 Static Definition

Table 3.6.4.1.2.1-1: OML^O21 Message Static Definition

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	RE	[0..1]	
PID	Patient Identification	R	[1..1]	3
[	--- PATIENT_VISIT begin	RE	[0..1]	
PV1	Patient Visit	R	[1..1]	3
]	--- PATIENT_VISIT end			
]	--- PATIENT end			
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[{	--- TIMING begin	RE	[0..1]	

Segment	Meaning	Usage	Card.	HL7 chapter
TQ1	Timing Quantity	R	[1..1]	4
}]	--- TIMING end			
	--- OBSERVATION REQUEST begin	R	[1..1]	
OBR	Observation Request	R	[1..1]	4
[{NTE}]	Notes and Comments	O	[0..*]	2
[{	--- OBSERVATION begin	O	[0..*]	
OBX	Observation Result	R	[1..1]	7
[{NTE}]	Comment of the result	O	[0..*]	2
}]	--- OBSERVATION end			
[{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Container	RE	[0..*]	13
}]	--- SPECIMEN end			
[SGH]	Segment Group Header**	O	[0..1]	
[{	--- PRIOR_RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER_PRIOR begin	R	[1..*]	
ORC	Common Order - previous result	R	[1..1]	4
OBR	Order Detail - previous result	R	[1..1]	4
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
{	--- OBSERVATION_PRIOR begin	R	[1..*]	
OBX	Observation/Result - previous result	R	[1..1]	7
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
}	--- OBSERVATION_PRIOR end			
}	--- ORDER_PRIOR end			
]}	--- PRIOR_RESULT end			
[SGT]	Segment Group Trailer**			
	--- OBSERVATION REQUEST end			
}	--- ORDER end			

*** Pre-adopted from HL7 V2.8*

This profile is based on the existing order replacement patterns defined in HL7 V2.7.1 Ch. 2C, Table 0119, pp. 34-37 (in HL7 V2.5.1 this material is in Ch. 4, pp. 30-32). The transaction has four components (also see the example message fragments in **Figures 3.6.4.1.2.1-1 to Figure 3.6.4.1.2.1-3** below):

1. **Order recommendation.** When the Order Filler receives orders (or identifies existing orders) from the Order Placer that it wishes replaced or supplemented, the Filler sends a recommendation message to the Placer in which the orders to be replaced or supplemented have the control code “RP” or “SU” (ORC-1), respectively, and the

recommended replacement or supplemental orders have the new control code “RC”. This replacement or supplementation request is generally similar in structure to the unsolicited and solicited replacement messages (OML^O21) that are currently supported between the Filler and Placer, with the following features:

1. As in the existing order replacement messages the ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the recommended replacement or supplemental orders. Groups of existing orders may be replaced or supplemented, but not both (i.e., the control codes of an entire group of targeted existing orders should be uniformly RP or SU). Groups of original orders also should all be issued by the same provider (ORC-12 and OBR-16) to allow correct routing of the new orders for review and signing. Multiple groups of orders may be replaced or supplemented independently, by alternating groups of existing orders to be replaced or supplemented with groups of new order recommendations that target the immediately preceding group of existing orders. If multiple groups of existing orders are used, each group may have a different ordering provider. This pattern supports 1:1, 1: many, many:1, and many:many order replacements as well as supplementation.
2. Existing orders that are to be replaced contain the RP control code in ORC-1 and the ORC-5 Order Status of the orders is set to status code HD (on hold). Orders that are to be supplemented contain the SU control code in ORC-1. Since they are not held pending recommendation acceptance, these orders reflect their current processing status in ORC-5. Existing orders should show both placer and filler order numbers (ORC-2/3 and OBR-2/3).
3. Existing orders may contain a code in ORC-16 Control Code Reason indicating the general reason for the replacement or supplementation recommendation drawn from code system HL7-0949 and extended with IHE specific codes as described under ORC-16. Additional information may be provided in an NTE segment associated with the original orders.
4. Orders that are to be replaced contain EOT, expiration on time, in ORC-25 Order Status Modifier. The start and stop times for the hold status are contained in ORC-36 Order Status Date Range (DTM^DTM). This interval represents the time window during which the Filler will wait for a response to the replacement recommendation message. Orders that are to be supplemented show their processing status in ORC-36.
5. Recommended orders (replacement or supplemental) contain RC in ORC-1 Order Control Code. All recommended orders have hold status (ORC-5 = HD) with ORC-36 Order Status Date Range (DTM^DTM) containing the start and stop times over which a response to the recommendation will be accepted. In order replacement these values will match the corresponding values for the existing orders that are on hold. In order supplementation, only the recommended orders contain the time window over which the recommendations will be accepted.
6. ORC/OBR-2 (Placer Order Number) and ORC/OBR-3 (Filler Order Number) are empty for all recommended orders. These fields are conditional and the LCC extends

this conditionality to include no content in both fields when the Order Control Code is RC. Fields that carry information about the ordering provider, timing of order placement, and ordering facility should be left empty in recommended orders so that they can be populated by the Order Filler. These fields include ORC 10-15, 17-19, and 21-24, and OBR 16-17 (all are optional). The other ORC/OBR fields should populated as needed to define the recommended order consistent with existing optionality requirements and local policy. The Order Placer system is responsible for routing recommendations to correct providers based on information in the existing orders and managing provider coverage, and it should set the ordering provider and related information correctly when the recommendations are accepted or rejected.

7. Optionally, recommended orders (control code RC) may carry the name and address of a contact person at the order filler in ORC-12 and OBR-16 (ordering provider), ORC-14 (call back phone number), and ORC-24 (ordering provider address). The identity of the order filler may be placed in ORC-21-23 (ordering facility name/address/phone). This information may be helpful in complex testing scenarios with collaborative decision-making. Any accepted recommended orders that are sent from the placer to the filler in the recommendation response (below) should not retain these values and as appropriate should populate the fields with ordering physician and facility information in the usual way.

2. **Immediate acknowledgement.** The Placer responds immediately with an acceptance acknowledgement (MSA) to indicate that the replacement or supplementation recommendation has been received.

3. **Recommendation response.** After consideration of the recommendation, the Placer issues a response with a structure similar to the replacement recommendation (OML^O21) and also to the current solicited replacement request, with the following features:

    1. The ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the recommended orders.

    2. The original orders contain control codes RP (replace), UM (do not replace), SU (supplement), or CA (cancel) depending on the Placer's desired outcome.

    3. The recommended replacement orders contain control codes RA (recommendation accepted) or RD (recommendation declined) based on the Placer's desired outcome. Orders with control code RA must contain Placer order numbers and appropriately populated fields for typical orders.

    4. Additional orders may be added by the Placer to the replacement order list. These additional replacement orders contain control code RO and Placer order numbers. They are handled as solicited replacements that are in addition to the recommended replacements. Additional orders may be issued along with supplemental orders as standard new orders (control code NW).

5. If the placer wishes to cancel the original orders without replacement or supplementation, the original orders should be returned with control code CA and the replacement or supplemental orders with control code RD.
6. Placer systems should respond to recommendations for replacement or supplemental orders only within the date range specified in ORC-36 of the recommendations.

4. **Recommendation response confirmation.** If a recommendation response is received from the Placer before the HD Order Status stop time, or if a supplementation request is received, the Filler responds with an ORL^O22 confirmation message similar in structure to the confirmation of a solicited order replacement, with the following features:
    1. The ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the accepted recommended orders. Declined orders are not included in the confirmation.
    2. The original orders contain RQ (replaced as requested) or SQ (supplemented as requested) Order Control codes, similar to the response to a solicited order replacement.
    3. Accepted replacement or supplemental orders echo their RA or RO Order Control codes, are assigned both Placer and Filler order numbers, and have an appropriate Order Status such as IP (in process).
    4. Any Placer-specified replacement orders (RO) or supplemental orders that cannot be executed are included in the replacement order list with an Order Control code UA (unable to accept).

In order replacement, if the HD Order Status Date Range stop time is passed without a replacement request from the Placer, a status update message for the existing order(s) is transmitted from the Filler to the Placer changing the HD Order Status to an appropriate value, and the recommendations are canceled.

Specimens. If specimens are available and appropriate for analysis, order recommendations (Filler to Placer) may include SPM segments referring to those specimens. If more than one order can be fulfilled by a specimen, its SPM segment must be repeated for each order to be assigned to it. It is the responsibility of the Filler to ensure that the assigned specimens are appropriate and have the capacity (e.g., volume) to support the proposed testing. OBR-11 (specimen activity code) may also be populated in recommended orders to indicate whether that recommended test can be run on a specimen in the laboratory, or whether a new specimen should be drawn by the lab or by another service. Because the use of the SPM segment as described above provides more information (it associates a specific available specimen with a specific recommendation) it takes precedence in communicating specimen availability and test assignment, and use of OBR-11 is discouraged except in cases where it is useful to communicate who should be responsible for providing a new specimen.

The replacement or supplementation request message (Placer to Filler) must return the SPM segment with each accepted or new order to confirm use of that specimen for those orders. If a proposed order does not contain an SPM segment or if the replacement request does not confirm

the SPM segment, the accepted replacement or supplemental order(s) will require a new specimen. Because order replacement is inherently an order-centric process, specimen- and container-centric ordering patterns (O33 and O35 events) are not supported by the LCC. Instead, the message should be oriented around the orders, and specimens should be assigned to them as noted above.

```
Initial message from Placer to Filler (Lab order OML^O21):
…
ORC|NW|1234|| …                                          New order with Placer order number
OBR| …
…
                          ------------Order replacement example------------
Replacement recommendation -- Filler recommends a change in this order (Filler to Placer
OML^O21):
… (1)          (5)          (16)       (25)       (36)          Field numbers
ORC|RP|1234|5678|||HD|||||||||||IY|||||||||EOT|.|.<start>^<end>|  Order to be replaced
OBR| …
NTE| …                                                   Opt. additional information
ORC|RC|||HD|||||||||||||||||||||EOT|.|.<start>^<end>|    Replacement order (no order numbers)
OBR| …
NTE| …                                                   Opt. additional information
…
SPM|1|4321| …                                            Specimen available
…

Immediate acceptance acknowledgement (Placer to Filler MSA)

If the Placer does not send an acceptance or rejection message within the required time, a
status update message is sent changing ORC-5 HD to IP and continuing processing according to
default procedures, otherwise…

Replacement request within the time window (Placer to Filler OML^O21):
… (1)                (16)       (25)       (36)          Field numbers
ORC|RP|1234|5678|||||||||||||IY|||||||||EOT|.|.<start>^<end>|  Confirm replace this order
OBR| …
ORC|RA|1504|| …                                          Accepted replacement with Placer order number
OBR| …
…
```



```
SPM|1|4321|...                                   Use proposed specimen
850
Replacement confirmation (Filler to Placer ORL^O22):
...
ORC|RQ|1234|5678|||||||||||||IY|...              Replaced as requested
OBR|...
855 ORC|RA|1504|5679||IP|...                     Replacement order now with Filler order number and
                                                 status change
OBR|...
...
SPM|1|4321|...                                   Use proposed specimen
860
                        ------------Order supplementation example------------
Supplementation recommendation -- Filler recommends adding an order (Filler to Placer
OML^O21):
... (1)                  (16)          Field numbers
865 ORC|SU|1234|5678|||||||||||||IY|...          Order to be supplemented (no time window here)
OBR|...
NTE|...                                          Opt. additional information
ORC|RC|||HD|||||||||||||||||||EOT|..|.<start>^<end>|  Supplemental order with time window
OBR|...
870 NTE|...                                      Opt. additional information
...
SPM|1|4321|...                                   Specimen available
...

875 The remainder of the supplementation interaction is similar to order replacement, with final
acceptance indicated using the SQ control code in place of RQ
```

Figure 3.6.4.1.2.1-1: Single Order Replacement or Supplementation

```
Placer sends three new orders (not shown)...

880 Filler recommends replacing the three orders with two orders (Filler to Placer OML^O21):
... (1)      (5)      (16)      (25)      (36)      Field numbers
ORC|RP|1234|5678||HD|||||||||||IY|||||||||EOT|..|.<start>^<end>|  Order to replace
OBR|...
ORC|RP|1235|5679||HD|||||||||||IY|||||||||EOT|..|.<start>^<end>|  Order to replace
```



```
OBR|…
ORC|RP|1236|5680||HD|||||||||||IY|||||||||EOT|.|.<start>^<end>|     Order to replace
OBR|…
ORC|RC|||HD|||||||||||IY|||||||||EOT|.|.<start>^<end>|              Replacement order
OBR|…
NTE|…                                                               Optional information
ORC|RC|||HD|||||||||||IY|||||||||EOT|.|.<start>^<end>|              Replacement order
OBR|…
NTE|…                                                               Optional information
…
```

No SPM segment is included indicating that a new specimen must be drawn.

Placer returns immediate acceptance acknowledgement (MSA) …

Placer returns the replacement request, accepting replacement of two of the three original orders and rejecting replacement of one of the original orders. Of the recommended orders, one is accepted, one is declined, and an additional order is added to the recommendations (Placer to Filler OML^O21):

```
… (1)                          (16)        (25)        (36)          Field numbers
ORC|RP|1234|5678|||||||||||||IY|||||||||EOT|.|.<start>^<end>|       Order to replace
OBR|…
ORC|RP|1235|5679|||||||||||||IY|||||||||EOT|.|.<start>^<end>|       Order to replace
OBR|…
ORC|UM|1236|5680|||||||||||||IY|||||||||EOT|.|.<start>^<end>|      Do not replace this order
OBR|…
ORC|RA|2236||…                          Accepted recommendation with Placer order #
OBR|…
NTE|…
ORC|RD|||…                                  Declined recommendation
OBR|…
NTE|…
ORC|RO|2238|||…                             New order added by Placer
OBR|…
NTE|…
…
```


Filler confirms replacement (Filler to Placer ORL^O22):

…

ORC|RQ|1234|5678|||||||||||IY|… *First replaced order*

OBR|…

ORC|RQ|1235|5679|||||||||||IY|… *Second replaced order*

OBR|…

ORC|RA|2236|5690||IP|… *Accepted recommendation with Filler order # and IP status*

OBR|…

NTE|…

ORC|RO|2238|6123||IP|… *New order with Filler order # and IP status*

OBR|…

NTE|…

ORC|SC|1236|5680||IP|… *Retained original order with IP status*

OBR|…

…

Figure 3.6.4.1.2.1-2: Multiple Order Replacement, Partially Declined Replacement, and Added Replacement Orders


```
Placer places the initial order (not shown)…

Filler recommends replacement of the order (Filler to Placer OML^O21):
… (1)          (5)          (16)       (25)       (36)          Field numbers
ORC|RP|1234|5678||HD|||||||||||IY|||||||||EOT|..|.<start>^<end>|  Order to replace
OBR|…
ORC|RC|||HD|||||||||||IY|||||||||EOT|..|.<start>^<end>|          Replacement order
OBR|…
NTE|…
…

Placer declines replacement, original order stays in effect (Placer to Filler OML^O21):
…
ORC|UM|1234|5678|||||||||||||IY|||||||||EOT|..|.<start>^<end>|   Do not replace
OBR|…
ORC|RD|||…                                                       Recommendation declined
OBR|…
NTE|…
…

Filler confirms return of original order to active status (Filler to Placer ORL^O22):
…
ORC|SC|1234|5678||IP|||||||||||…                                 Status change to in process
OBR|…
…
```

Figure 3.6.4.1.2.1-3: Declined Replacement

LCC uses the same segment definitions as described for [LAB-1] in PaLM TF-2a: 3.1.3.2 Constraints on OML Message Structures added by [LAB-1] transaction.

3.6.4.1.3 Expected Actions

[LAB-6] defines three new interactions, the order recommendation from Filler to Placer, the recommendation response from Placer to Filler, and the response confirmation from Filler to Placer. These transactions support new communications capabilities between the Placer and Filler, but they do not define specific implementation requirements for the Placer and Filler systems. The Actions described here are based on reasonable implementations, but others are possible.

Order Recommendation

1. The Filler system reviews incoming and pending orders automatically or manually to detect those requiring a recommendation
2. The Filler system constructs an Order Recommendation message using automated rules or a user interface supporting a laboratory expert, including a time limit for a Placer response
3. The Order Recommendation is transmitted to the Placer system.

Recommendation Response

1. The Placer system immediately sends an acknowledgement of receipt of the Order Recommendation to the Filler system.
2. The Placer system follows a locally-defined report and escalation process to notify a responsible party of the Order Recommendation within its time limit, usually the care provider responsible for the original order or a covering provider
3. The Placer system displays the order recommendations to the provider, and offers a convenient method to accept or reject the recommendations and optionally add new orders or cancel the original orders
4. The Placer system transmits the accepted, rejected, canceled, and new orders to the Filler system in a Recommendation Response

Recommendation Response Confirmation

1. The Filler system receives the Recommendation Response and transmits a Recommendation Response Confirmation message to the Placer system, updating the status of all orders to in progress, replaced, or canceled as appropriate
2. If the Placer does not send a Recommendation Response by the required time limit, the Filler sends a status update message changing the status of the existing orders to reflect the final filler action

3.6.5 Security Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus, the LCC messaging extensions fit within LTW security requirements.

3.6.5.1 Security Audit Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW auditing requirements.

3.6.5.1.(z) <Actor> Specific Security Considerations

Not applicable.

3.7 Request for Fulfillment [LAB-7]

3.7.1 Scope

This transaction is used to streamline the ability of the Order Placer/Order Result Tracker application to issue follow up orders on results that do not meet expectations, either clinically or operationally.

[LAB-7] is triggered when test results are clinically or operationally problematic. It yields a new fulfillment order that is created in the context of an existing result in the Order Result Tracker. The new order automatically includes references to that result and its order, and allows additional information to be entered by the clinician. Additional results may be included in the transaction. The message is sent from the Order Placer/Order Results Tracker to the Order Filler as an unsolicited order message. The response from the Order Filler is returned to the Order Result Tracker in the current Order Results Management [LAB-3] transaction as an addendum or amendment to the original result, and/or as a separate result of the fulfillment order.

3.7.2 Actor Roles

Table 3.7.2-1: Actor Roles

Actor:	Order Placer grouped with Order Result Tracker
Role:	In addition to roles defined in PaLM TF-2a: 3.1.2: Sends a fulfillment request to the order filler, referencing an existing result. Receives an updated result for the requested fulfillment from the order filler
Actor:	Order Filler
Role:	In addition to roles defined in PaLM TF-2a: 3.1.2: Receives the fulfillment request from the order placer After completion of the fulfillment request, sends an appended result transaction and/or a new result to the order placer

3.7.3 Referenced Standards

Results Fulfillment [LAB-7]:

- HL7 V2.9, Ch. 4 Order Entry
- HL7 V2.9, Ch. 7 Observations (OBX-21)
- HL7 V2.9, Ch. 12 Patient Care (REL segment)

- LOINC (Universal Service Identifiers for fulfillment actions like confirmation and interpretation)
- SNOMED CT (Universal Service Identifiers for fulfillment actions like quality review and specimen storage)

3.7.4 Messages

[LAB-7] interaction appears in red in the sequence of [LAB-3] reporting in the diagram below.

The [LAB-1] blue and dashed interactions appear only when Order Placer and Order Result Tracker are not grouped together.

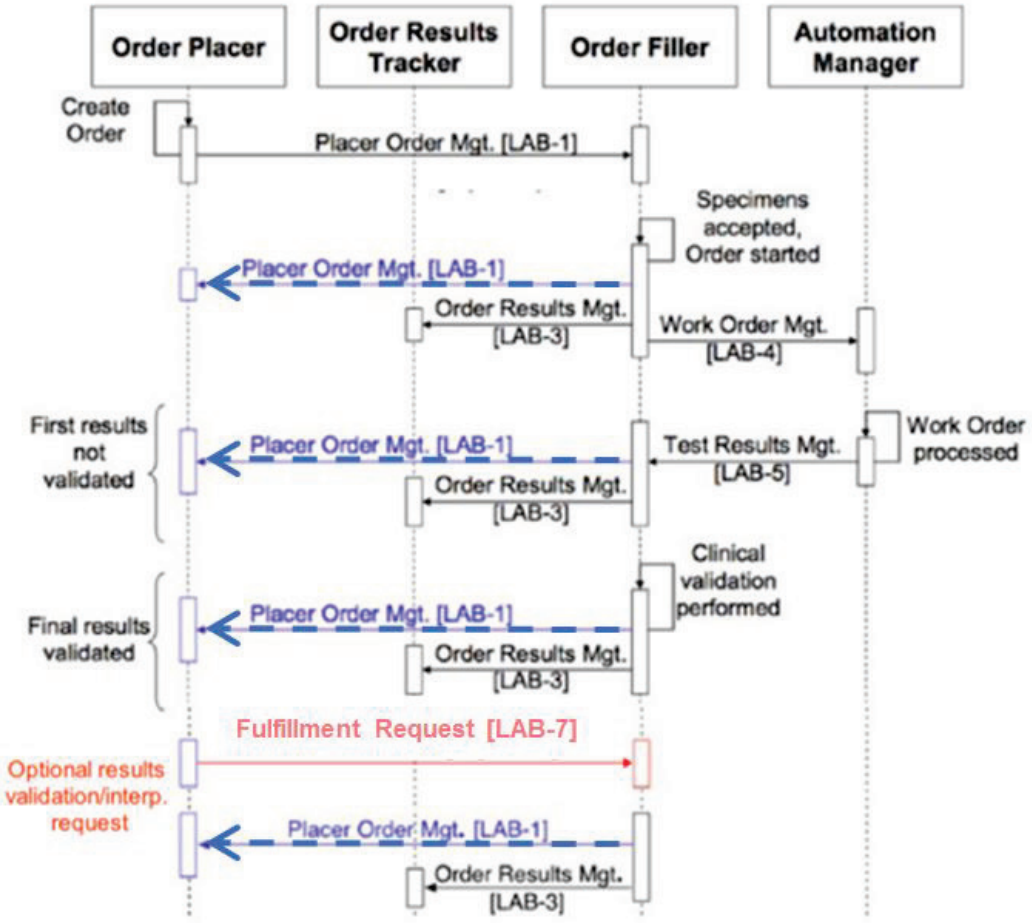


Figure 3.7.4-1: Request for Fulfillment within the [LAB-3] reporting sequence

3.7.4.1 Message Request for Fulfillment [LAB-7]

[LAB-7] supports the ability of clinicians to issue orders for further work on a result that by itself may not be understandable or fully meet the clinical need, or may appear to be in error. This workflow may be most convenient in a combined Order Placer/Order Results Tracker application in which new orders may be issued in the context of clinical results review, though other implementations are possible. In an abstract sense, [LAB-7] asks that an existing result be annotated with the outcome of additional work. That annotation may be an amendment, addendum, or correction to a previous result, or may be expressed as the result of the [LAB-7] order itself. These annotations are necessary for the result to fulfill a clinical purpose and thus the [LAB-7] order created by the Tracker application is referred to below as a *fulfillment order.*

The primary result of interest for the fulfillment order is referred to as the *target result* and the original order that produced this result is called the *target order.* [LAB-7] accommodates settings that include multiple targets such as concurrent interpretation of several results in context.

3.7.4.1.1 Trigger Events

The [LAB-7] transaction is normally triggered by the clinical staff during results review, when results do not fully meet the clinical need, are inconsistent or confusing, or indicate a process problem. [LAB-7] may also provide a general mechanism for attaching annotations to results for a variety of purposes. A primary goal of the transaction is to allow a request for additional work related to an existing order/result to be issued quickly from the results review workflow and to automatically incorporate a reference to the patient and targeted order/result. This capability avoids the current disruption in workflow required to issue orders for interpretation or results review (exit results review, open order entry, create order, describe which order/result to target, describe problem). A [LAB-7] transaction creates a fulfillment order that targets a particular result, and it may include other results for additional context. The target result may or may not have been created by the Filler of the fulfillment order. The fulfillment order may yield an addendum, amendment, correction, or annotation of the target result, and it may also yield its own result or a reference to the update of the target.

The service ID for fulfillment orders may represent concepts such as *result confirmation, result interpretation, service process problem, inconsistent with clinical findings,* or *incorrect test done,* which are applied to the target result. Since the presence of the fulfillment order itself linked to the parent result represents a form of annotation, the mechanism could be used with an Ask at Order Entry and a generic *annotate* service ID for arbitrary annotation of results from Tracker/Placer systems. In the future, LOINC will be the usual source for standard service IDs and it should be reviewed to determine whether useful service IDs for these concepts exist or whether new concepts should be submitted for coding.

The results of [LAB-7] orders yield information useful in the clinical management of patients. In addition, [LAB-7] is intended to enable aggregate queries that support process monitoring and process improvement. For example, an unexpectedly high rate of confirmation requests for a particular test result might prompt a review of that test's performance under conditions associated with the requests. To support this capability, fulfillment orders are linked to the target results and

their orders in a consistent way such that the targets can be retrieved in either the Filler or the Placer/Tracker system using structured data contained in the fulfillment order.

3.7.4.1.2 Message Semantics

3.7.4.1.2.1 OML^O59 Static Definition

We are using v2.9 for this message – in v2.7 several fields in segments dealing with persons, organizations or devices have been marked for backwards compatibility only and the Participation (PRT) segment was introduced for use instead. We are only noting PRT segments in the below message definition table, where IHE has constrained the base standard and readers using optional elements that should now use the PRT segment are encouraged to review the base standard on how to use those here.

Table 3.7.4.1.2.1-1: OML^O59 Message Static Definition*

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	RE	[0..1]	
PID	Patient Identification	R	[1..1]	3
[	--- PATIENT_VISIT begin	RE	[0..1]	
PV1	Patient Visit	R	[1..1]	3
]	--- PATIENT_VISIT end			
]	--- PATIENT end			
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
{[PRT]}	Participation (for Common Order)	R	[1..*]	
[{	--- TIMING begin	RE	[0..1]	
TQ1	Timing Quantity	R	[1..1]	4
}]	--- TIMING end			
	--- OBSERVATION REQUEST begin	R	[1..1]	
OBR	Observation Request	R	[1..1]	4
[{NTE}]	Notes and Comments	O	[0..*]	2
{[PRT]}	Participation (for Observation Request)	R	[1..*]	
[{REL}]	Relationship Segment*	R	[1..*]	12
[{	--- OBSERVATION begin	O	[0..*]	
OBX	Observation Result	R	[1..1]	7
{[PRT]}	Participation (for OBX)	RE	[0..*]	
[{NTE}]	Comment of the result	O	[0..*]	2
}]	--- OBSERVATION end			
[{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Container	RE	[0..*]	13

Segment	Meaning	Usage	Card.	HL7 chapter
}]	--- SPECIMEN end			
[SGH]	Segment Group Header	O	[0..1]	
[{	--- PRIOR_RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER_PRIOR begin	R	[1..*]	
ORC	Common Order - previous result	R	[1..1]	4
{[PRT]}	Participation	R		
OBR	Order Detail - previous result	R	[1..1]	4
{[PRT]}	Participation (for Order Prior)	R		
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
{	--- OBSERVATION_PRIOR begin	R	[1..*]	
OBX	Observation/Result - previous result	R	[1..1]	7
{[PRT]}	Participation (for Observation Prior)	RE		
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
}	--- OBSERVATION_PRIOR end			
}	--- ORDER_PRIOR end			
]}	--- PRIOR_RESULT end			
[SGT]	Segment Group Trailer**			
	--- OBSERVATION REQUEST end			
}	--- ORDER end			

** Pre-adopted from HL7 V2.9 – per OO CR-851*

The fulfillment order for the [LAB-7] transaction message is carried in a modified OML^O21 laboratory order message that includes information that makes a link to the prior order, order group or result using one or more clinical relationship segment (REL) segments (HL7 V2.7 Chapter 12) pre-adopted from HL7 V2.9 per OO CR-851. The REL segment establishes a service target relationship between the order segments in the message and the previous orders/results that are to be acted upon. The prior target order and/or target result are included in the prior results section of the order message, and other results may be included in this section for context. The acknowledgement of the fulfillment order from the Filler is a standard ORL^O22. The result of the fulfillment order may be coded or text, and the order may trigger confirmation, correction, or amendment of the previous result. If the annotation use case is supported, the fulfillment order could also result in addition of an arbitrary annotation to a previous result.

Figure 3.7.4.1.2.1-1, below, is a simplified fulfillment order. The ORC and OBR are the new fulfillment order requesting review of a previous result. The REL segment establishes a target relationship between the new order and a previous order requiring additional action such as confirmation or interpretation. The REL segment includes a variety of fields defining a clinical relationship and the identity of the asserting party. For this use, the required fields are the

Relationship Type (REL-2), the Source Identifier (REL-4), used to carry the new order number, and the Target Identifier (REL-5, used to carry the previous order group (ORC-4), order (OBR-2), or result identifier (OBX-21). When using order (OBR-2, Placer Order Number) or order group (ORC-4, Placer Group Number) identifiers as targets, the target encompasses the entire order or order group and all related results; when the target is restricted to the specific result, the result identifier (OBX-21, Observation Instance Identifier) is sent. In cases where a single order targets several orders or results, an REL segment is included for each target, and these segments are numbered sequentially beginning with "1" in REL-1 (Set ID).

```
Clinician working from order review requests review of a blood test result (OML^O21):
...
ORC|NW|1567|...                                                    New fulfillment order
OBR||1567||21026-0^Pathologist interpretation of blood tests ^LN|...   LOINC code for review
      (2)                        (17) (18)                         REL field number
REL||SVTGT|9999|1567|1234|...|PLAC|PLAC|                          Fulfillment target link
                                                                   to existing placer order nmbr
...
ORC|PR|1234|...                                                    Prior order (fulfillment target)
OBR||1234||55231-5^Electrolytes panel - Blood^LN|...               LOINC code of order to be reviewed
```

Figure 3.7.4.1.2.1-1: Example Fulfillment Order (REL segment)

Notes:

1. REL-2 contains the relationship type code drawn from Relationship Type codes system HL70948 introduced in v2.9 and REL-3 carries the EI for this relationship.
2. The REL segment uses EI datatypes for the source and target of the link, which carry a single identifier. REL-4 (Source) will carry the Placer Order Number (OBR-2) for the current order (ORC-1 of that Order group is 'NW') and REL-5 (Target) will carry either the Placer Group Number (ORC-4), Placer Order Number (OBR-2), or Observation Instance Identifier (OBX-21) for the prior order group, order, or result respectively (ORC-1 of the order group of these identifiers is valued 'PR').
3. The OML message is modified to add one or more REL segments as the last segment of each OBR group.
4. If the fulfillment message is sent to the Filler who processed the prior order, the prior order does not need to be included in the message. If the message is sent to a third party Filler, the pertinent orders and results must be included in the message as prior results with Placer group, order, or result EIs matching the EI named as the target of the relationship.

Order fulfillment action

Codes that might be used as Universal Service Identifiers (OBR-4, CWE) in [LAB-7] are listed below in Table 3.7.4.1.2.1-2. Additional codes might be identified for other types of fulfillment actions or annotations.

Table 3.7.4.1.2.1-2: Possible service codes for use with the LCC Profile [LAB-7] transaction (Universal Service Identifier, OBR-4, CWE)

Code	Code System	Description
21026-0	LOINC	Pathologist interpretation of blood tests
386344002	SNOMED CT	Laboratory data interpretation (Procedure)

Code	Code System	Description
80970002	SNOMED CT	Medical evaluation, quality of care, review of exception case (Procedure)
C93374	NCI Thesaurus/BRIDG	Defined specimen storage

Fulfillment actions and result annotations are likely to be specified by a limited number of Universal Service Identifiers as above. More information about the purpose of a fulfillment request that could be useful for identifying particular types of quality problems or specific specimen handling instructions might be communicated as structured data in OBR-31 Reason for Study, using the following proposed codes. The code system Reason for Study HL70951 supporting OBR-31 was added in HL7 v2.9.

Table 3.7.4.1.2.1-3: Reason for Study codes (OBR-31, CWE, HL70951)

Code	Context	Description
CR	Lab review	Confirm results value; requests verification of previously reported results
IN	Lab review	Interpret results, requests interpretation of previously reported results
IR	Lab review	Review clinically inconsistent results, requests comparison of previously reported results amongst themselves
SI	Lab review	Suspected interference, requests verification of previously reported results due to suspected interference
OP	Quality of care	Test ordering problem, for process improvement work this code can be used to identify orders and the respective results, where problems occurred during ordering
SP	Quality of care	Sampling problem, for process improvement work this code can be used to identify orders, where problems occurred during sample collection
TP	Quality of care	Specimen transport problem, for process improvement work this code can be used to identify orders, where problems occurred during sample transport
TT	Quality of care	Turnaround time problem, for process improvement work this code can be used to identify results with excessive reporting delay
IT	Quality of care	Incorrect test performed, for process improvement work this code can be used to identify when an incorrect test was performed for the target order
PI	Quality of care	Patient identification problem, for process improvement work this code can be used to identify when a patient identification issue has occurred on the target order
XR	Quality of care	Incorrect results, for process improvement work this code can be used to identify when incorrect result were reported for the target order
BS	Specimen storage	Bank residual specimen, requests that the specimen should be stored long term, provides instructions for specimen storage in OBR-46
TS	Specimen storage	Transfer residual specimen, requests that the specimen should be moved to a different location, provides instructions for specimen storage in OBR-46
FP	Specimen storage	Store residual specimen pending follow up, requests that the specimen should be saved for a short duration until a follow up contact, provides instructions for Specimen storage in OBR-46

3.7.4.1.3 Expected Actions

[LAB-7] defines one new transaction, the fulfillment request from Placer to Filler. This transaction supports new communication capabilities between the Placer and Filler, but they do not define specific implementation requirements for the Placer and Filler systems. The Actions described here are based on reasonable implementations, but others are possible.

Fulfillment Request

1. The Filler system reviews incoming orders automatically or manually to detect those requesting fulfillment
2. The Filler system identifies the target(s) of the fulfillment order, either in existing data or in the prior results group in the incoming message.
3. The Filler system evaluates if it can perform the request and creates an appropriate acknowledgement message and sends it to the placer.

3.7.5 Security Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW security requirements.

3.7.5.1 Security Audit Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus, the LCC messaging extensions fit within LTW auditing requirements.

3.7.5.1.z <Actor> Specific Security Considerations

Not applicable

Appendices

Appendix C – Common HL7 Message Segments

Profiling conventions, messaging details, and segments that have common definitions across the LCC transactions are discussed below.

Update the ORC segment definitions in PaLM TF-2x: C.5 as follows:

C.5 ORC – Common Order Segment

HL7 V2.5: chapter 4 (4.5.1). The ORC and OBR segments contain a number of duplicate fields. The Technical Framework is defined in such a way that fields in the OBR segment will be used in preference over their equivalents in ORC. If a field is listed as being optional in ORC, its equivalent in OBR may well be mandatory.

Table C.5-1: ORC Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	2	ID	R	[1..1]	**0119**	00215	Order Control
5	2	ID	C	[0..1]	**0038**	00219	Order Status
16	250	CE	~~O~~ **C(RE/O)** **CP: When MSH-21 is valued "LAB-6"**	[0..1]		00230	Order Control Code Reason
25	250	CWE	~~X~~ **C(RE/X)** **CP: When ORC-5 is valued "HD"**	[0..~~0~~**1**]	**0950***	01473	Order Status Modifier
32*	**8**	**DT**	**O**	**[0..1]**		**02301**	**Advanced Beneficiary Notice Date**
33*		**CX**	**O**	**[0..*]**		**03300**	**Alternate Placer Order Number**
34*	**250**	**CWE**	**O**	**[0..*]**	**0934**	**03387**	**Order Workflow Profile**
35*		**ID**	**O**	**[0..1]**	**0206**	**00816**	**Action Code**
36*		**DR**	**C(RE/X)** **CP:When ORC-5 is valued "HD"**	**[0..1]**		**TBD**	**Order Status Date Range**

**** Pre-adopted from HL7 V2.9***

ORC-1 Order Control (ID), required.

This field may be considered the "trigger event" identifier for orders. Many order control codes are defined in the *HL7 table 0119 – Order Control Codes*. The Technical Framework allows only the following subset:

Subset of HL7 table 0119 – Order Control Codes Supported by IHE

Value	Description of use
NW	"New Order". Event request in OML message sent by the Order Placer in transaction [LAB-1] or in OML message sent by the Order Filler in transaction [LAB-4].
OK	"Notification or request accepted". Event notification in OML message. Event acknowledgement in ORL message.
UA	"Unable to accept order/service". Event notification in OML message. Event acknowledgement in ORL message sent by the Order Filler in transaction [LAB-1] or in ORL message sent by the Automation Manager in transaction [LAB-4].
SC	"Status changed". Event notification in OML, ORU and OUL messages.
CA	"Cancel order/ service request". Event request in OML message sent by the Order Placer in [LAB-1], or by the Order Filler in [LAB-4].
CR	"Canceled as requested". Event acknowledgement in ORL message responding to OML (CA).
UC	"Unable to cancel". Event acknowledgement in ORL message responding to OML (CA).
OC	"Order service canceled". Event notification in OML message sent by the Order Filler in transactions [LAB-1] and [LAB-3].
SN	"Send order/service number". Event request in OML message sent by the Order Filler in transaction [LAB-2].
NA	"Number assigned". Event acknowledgement in ORL message sent by the Order Placer in [LAB-2], responding to OML (SN).
RP	"Order/service replace request". Event request in OML message sent by the Order Placer in transaction LAB-1 or in OML message sent by the Order Filler in transaction [LAB-4]. **Orders to be replaced in Replacement Recommendation and Replacement Request messages.**
RQ	"Replaced as requested". Event acknowledgement in ORL message responding to OML (R~~Q~~**P**) **Replacement confirmation message indicating that an order was replaced as requested.**
UM	"Unable to replace". Event acknowledgement in ORL message responding to OML (R~~Q~~**P**). **Replacement Request messages for orders that should not be modified (declined replacement)**
RU	"Replaced unsolicited". Event notification in OML message [LAB-1] and OUL message [LAB-3] sent by the Order Filler.
XO	"Change order/service request". Used by the Order Placer in [LAB-1].
XR	"Changed as requested". Used by the Order Filler in [LAB-1] in response to XO.
UX	"Unable to change" Used by the Order Filler in [LAB-1] in response to XO.
PR	"Previous results with new order/service". Used in [LAB-1], [LAB-4], [LAB-21] and [LAB-22] to provide some previous results with the order or work order or wok order step that is requested by the sender.
RC*	**"Recommended change". Identifies that this OBR represents a recommended order; used in the Replacement and Supplementation Recommendation message sent from the Filler to the Placer. When the control code is RC, both the Order Placer Number and Order Filler Number (ORC-2/3 and OBR-2/3) should be empty.**
RA*	**"Recommendation accepted". Identifies that this previously recommended replacement or supplemental order has been accepted.** **Placer application: Used in the Replacement or Supplementation Request message; includes the assigned placer order number for the accepted replacement order.** **Filler application: Used in the Replacement or Supplementation Confirmation message in response to the Replacement or Supplementation Request message, when it was accepted.**

Value	Description of use
RD*	**"Recommendation declined". Identifies that this previously sent recommended replacement or supplemental order has been declined by the Placer.** **Placer application: Used in the Replacement or Supplementation Request message.** **Filler application: Used in the Replacement or supplementation Confirmation message in response to the Replacement or Supplementation Request message, when it was declined.**
RO	**"Replacement order". Used in Replacement Request messages for replacement orders that were not recommended by the Filler but added by Placer (existing HL7 code)**
SU*	**"Supplement order". Existing orders to be supplemented in Supplementation Recommendation and Supplementation Request messages.**
SQ*	**"Supplemented as requested". Supplementation confirmation message indicating that an order was supplemented as requested.**

**** Pre-adopted from HL7 V2.9***

ORC-5 Order Status (ID), conditional.

Condition predicate: This field shall be valued in all OML messages sent by the Order Filler. It represents the status of the order. This field shall not be valued in OML messages sent by the Order Placer.

The allowed values for this field within the Technical Framework are a subset of *HL7 table 0038 - Order Status:*

HL7 Table 0038 - Order Status: IHE Subset for all Transactions

Value	Description	Comment
A	Some, but not all, results available	
CA	Order was canceled	
CM	Order is completed	
IP	In process, unspecified	
SC	In process, scheduled	
HD	**Order is on hold**	**Indicates that the order is not currently being worked on but has been placed on hold waiting for additional communication. Filler application: used in the recommendation message sent to the Placer. Placer application: used in the replacement request message in response to the recommendation message from the Filler.**

Note: For the conditions of use of these values, please read PaLM TF-2.x: C10 "Correlations of status between ORC, OBR and OBX".

ORC-16 Order Control Code Reason (CE), ~~optional~~ **conditional**

Predicate: Usage is required, but may be empty, when MSH-21 (Message Profile ID is valued "[LAB-6]", else it is optional.

HL7 definition: This field contains the explanation (either in coded or text form) of the reason for the order event described by the order control code (HL7 Table 0119).

In the LCC [LAB-6] it may be used to communicate the reason for an order replacement or supplementation recommendation (see table below).

HL7 Table 0949 – Order Control Code Reason: IHE Subset for all Transactions

Value	Description	Comment
SV*	Specimen Volume	Specimen volume inadequate for requested testing, recommend a subset of tests appropriate for available volume
ST*	Specimen Type	Incorrect specimen type for requested testing, recommend testing that can use the submitted specimen type
UN*	Unavailable	Requested test unavailable, alternative testing proposed
CO*	Cost	Lower cost testing strategy proposed
(SR)	Screening Required	Screening test required prior to confirmatory test
~~(IT)~~	~~Indicated testing~~	~~Indicated follow-up testing based on initial results~~
(FO)	Future Order	Future order timed out without specimen
(IN)	Inappropriate	Requested testing not appropriate in this patient
(KI)	Known Interference	The requested testing will yield inaccurate results in this patient
(IY)	Improved Yield	Recommended testing improves diagnostic yield
(MO)	Missing Orders	Indicated orders missing from the target order group (supplemental orders)
(RF)	Rec. Followup	Recommended followup testing (supplemental orders)

**** Pre-adopted from HL7 V2.9***

() IHE Extension of HL7 user defined table

ORC-25 Order Status Modifier (CWE), ~~optional~~ **conditional**.

Predicate: Usage is required, but may be empty, when ORC-5 (Order Status) is valued "HD", else it is not supported.

HL7 definition: This field is a modifier or refiner of the ORC-5-Order status field. This field may be used to provide additional levels of specificity or additional information for the defined order status codes. Unlike the Order Status field, which is controlled by an HL7 defined table, this field is a CE data type allowing applications to support an unlimited library of Order Status Modifier codes.

The Technical Framework does not constrain the usage of this field. In the LCC [LAB-6] transactions it uses the code "EOT" (expiration on time) to indicate that the hold expires after the time specified in Order Status Date Range (ORC-36).

HL7 Table 0950 – Order Control Code Modifier: IHE Subset for all Transactions

Value	Description	Comment
EOT	**Expiration on time**	**The order status is timed and will auto-expire once the prescribed time interval has passed.** **For example this code would be used to indicate that the order is not currently being worked on but has been placed on a time limited hold awaiting a replacement order. If the hold time expires, default processing will resume.** **Usage Note: Filler Applications:** **In an order replacement setting, sent in a Replacement Recommendation message (OML), where ORC-5 = HD, indicating that the hold for a response to the recommendation is timed.**

ORC-32 Advanced Beneficiary Notice Date (DT), optional

HL7 Definition: This field contains the date the patient gave consent to pay for potentially uninsured services or the date that the Advanced Beneficiary Notice Code (ORC-20) was collected.

The Technical Framework does not constrain the usage of this field.

ORC-33 Alternate Placer Order Number (CX), optional

HL7 Definition: This field enables a shorter number to be communicated that is unique within other identifiers.

The Technical Framework does not constrain the usage of this field.

ORC-34 Order Workflow Profile (EI), optional

HL7 Definition: The Order Workflow Profile references/represents the information necessary to define the workflow variant when that is not fully described through the use of ORC-1 Order Control and MSH-21 Message Profile. This enables contributing systems to apply locally agreed to rules. See User-defined Table 0934 - Order Workflow Profile for a list of suggested values.

The Technical Framework does not constrain the usage of this field.

ORC-35 Action Code (ID), optional

HL7 Definition: This field reveals the intent of the message. Refer to HL7 Table 0206 - Segment Action Code for valid values.

The action code can only be used when an ORC is uniquely identified according to Chapter 2, Section 2.10.4.2.

The Technical Framework does not constrain the usage of this field.

ORC-36 Order Status Date Range (DR), conditional

Predicate: Usage is required, but may be empty, when ORC-5 (Order Status) is valued "HD", else it is not supported.

HL7 Definition: This field allows the sending application to identify the time span over which the order status described by ORC-5 (Order Status) and, if used, ORC-25 (Order Status Modifier) is effective. For example, this will be used by the filler in the case of an order replacement recommendation to indicate the start and end time the original order that is proposed to be replaced will be on hold while waiting for a response to the recommendation (ORC-5 = 'HD' and ORC-25 = 'EOT'). When the status is outside of the specified date range, it should be considered an unspecified status.

Add a new section for the REL segment definition in PaLM TF-2x as follows

C.X REL Segment

Pre-adopted base definition from V2.9 v per OO CR-855:

HL7 Attribute Table - REL – Clinical Relationship Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM #	ELEMENT NAME
1	1..4	SI	C			02240	Set ID – REL
2		CWE	R		HL70948	02241	Relationship Type
3		EI	R			02242	This Relationship Instance Identifier
4		EI	R			02243	Source Information Instance Identifier
5		EI	R			02244	Target Information Instance Identifier
6		EI	O			02245	Asserting Entity Instance ID
7		XCN	O			02246	Asserting Person
8		XON	O			02247	Asserting Organization
9		XAD	O			02248	Assertor Address
10		XTN	O			02249	Assertor Contact
11		DR	O			02250	Assertion Date Range
12	1..1	ID	O		0136	02251	Negation Indicator
13		CWE	O			02252	Certainty of Relationship
14	5=[2]	NM	O			02253	Priority No
15	5=[2]	NM	O			02254	Priority Sequence No (rel preference for consideration)
16	1..1	ID	O		0136	02255	Separability Indicator

[2] Is conformance length (CLEN)

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM #	ELEMENT NAME
17		ID	R		0203	TBD	Source Information Instance Object Type
18		ID	R		0203	TBD	Target Information Instance Object Type

REL-1 Set ID - REL (SI), required (conditional in HL7 V2.9, but condition predicate is not defined, so using required here).

Contains the Set ID of the specific relationship record – shall increment sequentially starting with the value '1' for each occurrence in the message or for each Order_Observation Group

REL-2 Relationship Type (CWE), required

Contains the type of the relationship for the instance identified in REL-3 between the source identified in REL-4 and the Target identified in REL-5. The values are drawn from user defined table HL70948.

Constrained HL7 Table 0948 - Relationship Type

Value	Description	Comment
SVTGT	Service target	Target universal service identifier is the object of the service identified by the source universal service identifier. Example: An order requests clarification or interpretation of a previous clinical laboratory test result.

REL-3 This Relationship Instance Identifier (EI), required

HL7 Definition: This field contains the instance identifier of this relationship.

REL-4 Source Information Instance Identifier (EI), required

HL7 Definition: This field contains the Instance ID of the Source Segment – for LCC it will carry the Placer order number for the current order.

REL-5 Target Information Instance Identifier (EI), required

HL7 Definition: This field contains the Instance ID of the Target Segment – for LCC it will carry either the Placer Group Number (ORC-4), Placer Order Number (ORC-2/OBR-2), or Observation Instance Identifier for the prior order group, order, or result, respectively. This is the object of interest for the fulfillment request.

REL-17 Source Information Instance Object Type (ID), required

HL7 Definition: This field contains the identifier type code drawn from coding system HL70203 describing the object identified by the Source Information Instance Identifier (REL-4).

REL-18 Target Information Instance Object Type (ID), required

HL7 Definition: This field contains the identifier type code drawn from coding system HL70203 describing the object identified by the Target Information Instance Identifier (REL-5).

Constrained HL7 Table 0203 - Identifier Type Code

Value	Description	Comment
FILL	Filler Identifier	An identifier for a request where the identifier is issued by the person, or service, that produces the observations or fulfills the request.
OBI	Observation Identifier	Unique and persistent identifier for an observation instance; e.g., OBX-21 (Observation Identifier) of the result for which a clarification is requested
PLAC	Placer Identifier	An identifier for a request where the identifier is issued by the person or service making the request.

C.X PRT Segment

Pre-adopted base definition from V2.9 to support [LAB-7]:

IHE does not further constrain the use of the fields in the PRT segment, except as described for the fields it replaces in the other segments. The following IHE defined fields are affected:

Fields listed as Required (R) by PaLM Technical Framework:

OBR-16 (Ordering Provider); when representing this as a PRT segment, PRT-4 will be coded as "OP^Ordering Provider^HL70912", PRT-5 will be valued

Fields listed as Conditional (C) by PaLM Technical Framework:

ORC-17 (Entering Organization); required in [LAB-1], RE in [LAB-3] and [LAB-4] (and [LAB-7]), PRT-4 will be coded as "RPO^Referring Provider Organization^HL70912"

OBX-23 (Performing Organization, PRT-4 will be coded as "PO^Performing Organization^HL70912"

Fields listed as Required Empty (RE) by PaLM Technical Framework:

OBR-10 (Collector), PRT-4 will be coded as "SC^SpecimenCollector^HL70912", need to send either name (PRT-5.2) or ID (PRT-5.1) or both

OBR-28 (Copy To), PRT-4 will be coded as "RCT^Results Copies To^HL70912", need to send either name (PRT-5.2) or ID (PRT-5.1) or both

OBX-16 (Responsible Observer), PRT-4 will be coded as RO^Responsible Observer^HL70912, need to link with OBX-15 to create a unique ID

- OBX-15 (Producer's ID), will be PRT-8.10 for the same PRT as created for OBX-16

Fields listed as Optional (O) by PaLM Technical Framework, but with some text constraints:

ORC-21 (Ordering Facility); PRT-4 will be coded as "OF^Ordering Facility^HL70912"[3], need to send either name (PRT-8.1) or ID (PRT-8.10) with PRT-8.7 valued "FI" or both

HL7 Attribute Table - PRT – Participation Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM #	ELEMENT NAME
1	1..4[4]	EI	C	[0..1]		02379	Participation Instance ID
2	2..2	ID	R	[1..1]	0287	00816	Action Code
3		CWE	O				Action Reason
4		CWE	R	[1..1]	0912	02381	Role of Participation
5		XCN	C	[0..*]		02382	Person
6		CWE	C	[0..1]		02383	Person Provider Type
7		CWE	C	[0..1]	0406	02384	Organization Unit Type
8		XON	C	[0..*]		02385	Organization
9		PL	C	[0..*]		02386	Location
10		EI	C	[0..*]		02348	Device
11		DTM				02387	Begin Date/Time (arrival time)
12		DTM				02388	End Date/Time (departure time)
13		CWE				02389	Qualitative Duration
14		XAD	C	[0..*]		02390	Address
15		XTN	O	[0..*]		02391	Telecommunication Address
16		EI	O			03476	UDI Device Identifier
17		DTM	O			03477	Device Manufacture Date
18		DTM	O			03478	Device Expiry Date
19		ST	O			03479	Device Lot Number
20		ST	O			03480	Device Serial Number
21		EI	O			03481	Device Donation Identification
22		CNE	C	[0..*]	0961	03483	Device Type
23		CWE	O			00684	Preferred Method of Contact
24		PLN	C	[0..*]	0328	01171	Contact Identifiers

PRT-1 Participation Instance ID (EI), conditionally required

HL7 Definition: This field contains a unique identifier of the specific participation record.

In the case of waypoints tracked for a shipment, it identifies the waypoint.

[3] IHE extended HL70912 table, Harmonization proposal planned for Mar 2019 cycle

[4] Is Conformance Length (CLEN)

Condition: The identifier is required when known, but there are times we may only know a name but do not have an identifier.

PRT-2 Action Code (ID), required

HL7 Definition: This field reveals the intent of the message. Refer to HL7 Table 0287 – Problem/goal action code for valid values.

PRT-3 Action Reason (CWE), optional

HL7 Definition: This field indicates the reason why the person, organization, location, or device is assuming (or changing) the role (e.g., shift change, new primary nurse, etc.).

PRT-4 Role of Participation (CWE), required

HL7 Definition: This field indicates the functional involvement with the activity being transmitted (e.g., Case Manager, Evaluator, Transcriber, Nurse Care Practitioner, Midwife, Physician Assistant, etc.). Refer to HL7 Table 0912 – Participation for valid values or user defined Table 0131 – Role as one uses the PRT segment instead of the ROL segment.

PRT-5 Person (XCN), conditionally required

HL7 Definition: This field contains the identity of the person who is represented in the participation that is being transmitted.

If this attribute repeats, all instances must represent the same person.

Condition: At least one of the Person, Organization, Location, or Device (and/or Device Type) fields must be valued.

PRT-6 Person Provider Type (CWE), conditionally required

HL7 Definition: This field contains a code identifying the provider type for the participating person. This attribute correlates to the following master file attribute: STF-4 Staff Type. Coded values from the correlated master file table are used; the user defined master file table is used as the coding system for this attribute. For example, if you are using values from STF-2 Staff Type, the coding system would be HL70182 which is the table number for the user defined Staff Type table. This field is included in this segment to support international requirements. When ROL is used in an encounter message, it is not intended as a master file update.

Condition: This field may only be valued if PRT-5 Person is valued.

PRT-7 Organization Unit Type (CWE), conditionally required

HL7 Definition: This field identifies the environment in which the participant acts in the role specified in PRT-3 Action Reason. In the case of a person, the environment is not the specialty for the provider. The specialty information for the provider is defined in the PRA segment.

This attribute is included in the PRT segment to allow communication of this data when the participant information may not have been communicated previously in a master file or to provide better context. Refer to User-defined table 0406 - Organization unit type. This field is included in this segment to support international requirements, and is not intended as a master file update.

Condition: This field may only be valued if PRT-5 Person is valued.

PRT-8 Organization (XON), conditionally required

HL7 Definition: The organization that is involved in the participation. If PRT-5 Person is valued, it reflects the affiliation of the individual participating as identified in PRT-4 Role of Participation. Otherwise the organization is directly participating as identified in PRT-4 Role of Participation.

If this attribute repeats, all instances must represent the same organization.

Condition: At least one of the Person, Organization, Location, or Device (and/or Device Type) fields must be valued.

PRT-9 Location (PL), conditionally required

HL7 Definition: This field specifies the physical location (e.g., nurse station, ancillary service location, clinic, or floor) that is participating. If either PRT-5 Person or PRT-8 Organization is valued, it reflects the location of the individual or organization participating as identified in PRT-4 Role of Participation. Otherwise the location is directly participating as identified in PRT-4 Role of Participation.

If this attribute repeats, all instances must represent the same organization.

Condition: At least one of the Person, Organization, Location, or Device (and/or Device Type) fields must be valued.

PRT-10 Device (EI), optional

HL7 Definition: Identifier for the device participating. This may reflect an unstructured or a structured identifier such as FDA UDI, RFID, IEEE EUI-64 identifiers, or bar codes.

Example: The device used to register the shipment at the waypoint.

If this attribute repeats, all instances must represent the same device.

Condition: At least one of the Person, Organization, Location, or Device (and/or Device Type) fields must be valued.

If this field contains an FDA UDI, it shall contain the entire Human Readable Form of the UDI. For example, a GS1-based UDI would be represented as follows:

|(01)00643169001763(17)160712(21)21A11F4855^^2.16.840.1.113883.3.3719^ISO|

A HIBCC-based example would be represented as follows:

|+H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C^^2.16.840.1.113883.3.3719^ISO

An ICCBBA-based example would be represented as follows:

|=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032\T\,1000000000000XYZ123^^2.16.840.1.113883.3.3719^ISO|

Or for ICCBBA (for blood bags only) an example would be represented as follows:

|=)1TE123456A\T\)RZ12345678^^2.16.840.1.113883.3.3719^ISO|

The identifier root shall be the OID assigned to UDI. For example, for FDA UDIs the root shall be 2.16.840.1.113883.3.3719, and the extension shall be the Human Readable Form appropriate for the style of content. When captured as a simple string, the string shall be the Human Readable Form appropriate for the style of content. The content style can be determined from the leading characters of the content:

UDIs beginning with:

‘(‘ are in the GS1 Human Readable style;

‘0-9’ are a GS1 DI (containing only the DI value, no PI or GS1 AI);

‘+‘ are in the HIBCC Human Readable style;

‘=‘ or ‘&’ are in the ICCBBA Human Readable style.

Note: If “&” is used in the UDI while one of the delimiters in MSH.2 includes “&” as well, it must be properly escaped per Chapter 2.7.

The exchange of UDI sub-elements in PRT-16 through PRT-21 is not required when the full UDI string is provided in PRT-10. Whether to include some or all these fields as well when PRT-10 is present with a UDI that the rules are subject to specific implementation guides that will have to consider the patient safety implications of potentially conflicting data.

When a UDI is provided and sub-elements are also provided, then for those sub-elements that are valued, the content must match the content encoded in the UDI if it is encoded within the UDI.

When communicating a UDI, the UDI may either be uniquely identifying an instance of a device, or a type of device. This can be asserted based on the inclusion or absence of a serial

number in the Product Identifier section of the UDI. When the serial number is present, PRT-10 must be used, while if it is absent, PRT-22 must be used.

Caution: The UDI may contain personally identifying information in the form of the device serial number which may be used to link to other information on a patient. Security and privacy consideration should be addressed, particularly when sending a UDI with a serial number, as that may inadvertently be able to identify a patient. Note: In the US realm that would be addressed by HIPAA.

Note: PRT-10 is a repeating field. Additional device identifiers, such as an IEEE EUI-64 may also be contained in this field.

PRT-11 Begin Date/Time (DTM), optional

HL7 Definition: This field contains the date/time when the participation began.

In the case of waypoints, this reflects the time a shipment arrives at the waypoint.

PRT-12 End Date/Time (DTM), optional

HL7 Definition: This field contains the date/time when the participation ended.

In the case of waypoints, this reflects the time a shipment departs from the waypoint.

PRT-13 Qualitative Duration (CWE), optional

HL7 Definition: This field contains the qualitative length of time for participation (e.g., until the next assessment, four days, until discharge, etc.).

PRT-14 Address (XAD), conditionally required

HL7 Definition: This field contains addresses associated with the participation. The address can repeat to indicate alternate addresses or an alternate expression of the same address.

Condition: The address must be present if the Participation is Performing Organization Medical Director.

PRT-15 Telecommunication Address (XTN), optional

HL7 Definition: The waypoint telecommunication address field carries telecommunications addresses for the waypoint. These telecommunications addresses are used to contact the waypoint for additional information regarding the receipt of the shipment. The address can repeat to indicate alternate addresses or an alternate expression of the same address.

PRT-16 UDI Device Identifier (EI), optional

HL7 Definition: Provides the U.S. FDA UDI device identifier (DI) element.

This is the first component in the UDI and acts as the look up key for the Global Unique Device Identification Database (GUDID), and may be used for retrieving additional attributes.

When exchanging Device Identifiers (DI) the root shall be the OID, or standards' appropriate corollary to the OID, assigned to DI and the extension shall be the Human Readable Form of the content. For example, for DIs the root shall be:

GS1 DIs: 2.51.1.1

HIBCC DIs: 1.0.15961.10.816

ICCBBA DIs: 2.16.840.1.113883.6.18.1.17 for Blood containers and 2.16.840.1.113883.6.18.1.34 otherwise.

Example: |00643169001763^^2.51.1.1^ISO|

PRT-17 Device Manufacture Date (DTM), optional

HL7 Definition: Date and time when the device was manufactured.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20140401|

PRT-18 Device Expiry Date (DTM), optional

HL7 Definition: Date and time when the device is no longer approved for use.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20160712|

PRT-19 Device Lot Number (ST), optional

HL7 Definition: Alphanumeric string that identifies the device's production lot number.

Example: |123ABC|

PRT-20 Device Serial Number (ST), optional

HL7 Definition: Manufacturer's serial number for this device.

CAUTION: See the related privacy considerations discussion in PRT-10.

Example: |21A11F4855|

PRT-21 Device Donation Identification (EI), optional

HL7 Definition: Identifies a device related to a donation (e.g., whole blood).

When exchanging Donation Identification Numbers (DIN) the root shall be the OID assigned to DIN and the extension shall be the Human Readable Form of the content. For example, for DINs the root shall be:

ICCBBA DINs: 2.16.840.1.113883.6.18.2.1

An ICCBBA DIN OID is available for reference where required, but is not required when the specific data element is scoped to ICCBBA DINs.

Example: | RA12345678BA123^^2.16.840.1.113883.6.18.1.34^ISO|

PRT-22 Device Type (CNE), conditionally required

HL7 Definition: This field contains the type of device used in the participation.

When communicating a UDI, the UDI may either be uniquely identifying an instance of a device, or a type of device. This can be asserted based on the inclusion or absence of a serial number in the Product Identifier section of the UDI. When the serial number is present, PRT-10 must be used, while if it is absent, PRT-22 must be used.

When communicating a UDI in this field, the coding system used is limited to FDA (FDAUDI), HIBCC (HIBUDI), ICCBBA (ICCUDI), and GS1 (GS1UDI) coding systems defined in HL7 Table 0396.

Condition: At least one of the Person, Organization, Location, or Device (and/or Device Type) fields must be valued.

See externally defined HL70961 in Chapter 2C for suggested values. This field can repeat.

PRT-23 Preferred Method of Contact (CWE), optional

HL7 Definition: This field contains the preferred method to use when communicating with the contact person. Refer to User-defined Table 0185 - Preferred Method of Contact in Chapter 2C, "Code Tables", for suggested values.

PRT-24 Contact Identifiers (PLN), conditional

HL7 Definition: This repeating field contains the contact's unique identifiers such as UPIN, Medicare and Medicaid numbers. Refer to User-defined Table 0338 – Practitioner. Condition: Can only be valued, when Person (PRT-4) is valued.

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Volume 2 Namespace Additions

NA

Volume 3 – Content Modules

NA

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

NA

