

Integrating the Healthcare Enterprise



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**IHE Radiology
Technical Framework Supplement**

10

**Clinical Decision Support
Order Appropriateness Tracking
(CDS-OAT)**

15

Rev. 1.5 – Trial Implementation

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

Foreword

30 This is a supplement to the IHE Radiology Technical Framework V17.0. 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 on April 25, 2019 for trial implementation and may be available for
testing at subsequent IHE Connectathons. The supplement may be amended based on the results
of testing. Following successful testing it will be incorporated into the Radiology Technical
35 Framework. Comments are invited and can be submitted at
http://www.ihe.net/Radiology_Public_Comments.

This supplement describes changes to the existing technical framework documents.

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

40 *Amend Section X.X by the following:*

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

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

Information about the IHE Radiology domain can be found at ihe.net/IHE_Domains.

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

50 The current version of the IHE Radiology Technical Framework can be found at
http://www.ihe.net/Technical_Frameworks.

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Introduction to this Supplement

145 This supplement contains the CDS-OAT Profile. It is intended to propagate the Clinical Decision
Support and Appropriate Use Criteria (AUC) information as received from the CDS Mechanism
(CDSM) on the order and charge transaction to the revenue cycle application that is responsible
to create a claim, using the existing HL7^{®1} v2.5.1 transactions in the Radiology Scheduled
Workflow.b (SWF.b) Profile. See RAD TF-1: 39.1.1.1.

150 The business driver for communicating AUC in the U.S. is the Department of Health and Human
Services (HHS) Centers for Medicare & Medicaid Service (CMS), although the solution in this
profile is intended to be broader than the CMS requirements. To accommodate communicating
AUC information consistently whether as part of a transaction within the IHE Radiology
Technical Framework or enhancing existing HL7 V2 based order and charge transactions, the
section OBX Segment for CDS Information defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX
155 Segment for CDS Information may also be used as part of an existing HL7 V2 based order and
charge transaction without needing to upgrade the entire transaction set and be conformant to the
Radiology Technical Framework.

Open Issues and Questions

1. Open Issue: When the HL7 CDS Hooks based implementation guide/profile is being
160 developed to replace the IHE PCC GAO Profile, data requirements must be synchronized
to ensure the CDSM can communicate all relevant data from the CDSM to the Order
Placer to populate the AUC data on the order and subsequent charge transaction. The
Radiology Technical Committee needs to ensure the CDS-OAT pre-conditions for its
transactions are appropriately satisfied by the CDS Hooks based implementation guide.

Closed Issues

1. The current profile reflects the decision to exclude all of the DICOM^{®2} transactions of
165 SWF.b Profile because the information is already being transmitted to the Report
Manager in the order message (does not need to be obtained from the DICOM image
header). Also, DICOM image objects and DMWL/MPPS messages do not currently have
defined data elements to contain the CDS information. Is this adequate? Closed:
170 Determined to be adequate.
2. Could there / should there be any interaction between OF and CDS? Or, should only the
OP have access to the CDS system? -> This is an IHE PCC CDS decision. We just need
to follow it here. Closed: The OF to CDS transaction will be added back in per the
eOrdering Coalitions Use Case document and discussions.

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

² DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards
publications relating to digital communications of medical information.

- 175 3. In Volume 3 of this Supplement, the CDS information is mapped to an OBX segment. Is there a different HL7 v2.5.1 message segment which would be more appropriate such as a Z segment or NTE segment. (Note: NTE segments are not structured fields.) Closed: OBX is the proper segment. An NTE is used for additional information within the OBX.
- 180 4. The “score” produced by a CDS system is not included as data which is mapped into the OBX segment. For example, some CDS systems may return multiple possible tests with a “score” option. A CT abdomen may receive a score value of “3”, but an ultrasound abdomen may receive a score value of “8” (higher). Does that score value need to be retained and propagated. Note that this score may still be available by reference of the instance uid/oid in the CDS system. Closed: The purpose of this profile is to transport results, not retain all variants of results for future analysis. The CDS service system should retain information for internal future analytics, if desired.
- 185 5. Should RAD-3 (Filler Order Management) be required for the DSS/OF and OP? Should RAD-3 (see Use Cases in Volume 1) become a Named Option? Requiring RAD-3 may severely limit the adoption from existing OP which only support Use Case 1 and 2. Also note that the transactions in this profile rely heavily on SWF.b and RAD-3 is required by SWF.b in its current state. Closed: Add RAD-3 back in based on eOrdering Coalition use case requirements.
- 190 6. Should we use [RAD-35] transaction to carry the additional/necessary CDS attributes? (or something other than a DFT message) Closed: DFT is proper segment, but must move up to HL7 v2.5.1.
- 195 7. We need to go through the exercise of an example where an order from an Order Placer contains multiple order codes. At the present time the “real world” often forces the user to preform Decision Support on each of the CPT4 contained within the Placer order. Closed: Will add example, but after the simple example.
- 200 8. There will be situations where an order is placed or modified at the DSS/OF. The workflow for these situations is handled by RAD-3 in SWF.b Profile. This transaction is not explicitly included in this profile to include the CDS payload (OBX). As such, if CDS information is obtained at the DSS/OF, it will not be propagated back to the Order Placer. (Note: the charge is posted from the DSS/OF so what is the need to the OP to have the CDS information.) Closed: Added.
- 205 9. Do we need a “flag” between the DSS/OF which effectively says, “This procedure was changed. Do we need new CDS information for this procedure?” (from discussion with Julie) If so, a new OBX data element will need to be added. Another way to look at this is “who defines if a change is significant or insignificant?” Closed: Solved when we added RAD-3 back in going to OP.
- 210 10. Volume 2 RAD-13 – does the CDS information need to be resent if there was no change to the CDS information (insignificant change or Update sent for some other reason, e.g., change in scheduled date)? Closed: Yes. Per eOrdering Coalition Use Cases. Verified that the text actually says that clearly.

- 215 11. Do we need to be able to handle this use case: It seems fairly common at many sites: The
procedure may be ordered and scheduled without the CDS information, but typically the
scan will not be completed without the CDS information in place (because it could affect
220 payment). In other words, Use Case 6 is included in this profile currently, but should it be
deleted. Closed: Use Case 6 (order received w/o CDS info) is very important and must
be kept.
12. RAD-35 DFT does not include Ordering Provider (OBR->PR1). Closed: This open issue
is incorrect. It is in the DFT FT1 segment “Ordered By Code”.
13. The IHE Radiology Technical Committee needs to decide what to do in terms of
documentation because there is no Volume 3 for Content Modules in the Radiology
225 Technical Framework. Volume 3 contains additional transactions. Closed: Dealt with as
Section 6.4.1.1 in Volume 3.
14. The Ordering Provider is assumed to be the same as the Ordering Provider identified in
ORC-12. Note: Either the NPI will be included in ORC-12 or, the Charge Processor
230 could fix after the fact. If the latter is acceptable, we need to document that. Resolution
3/31/2015: Stay open until the legislation gets clarified. The question is around the mid-
level provider (PA or nurse practitioner) – which NPI gets used. Will probably require
CP at some point. Resolution 5/7/2015: Whatever NPI is used on the order is what gets
used in CDS, including if it is a mid-level provider.
15. When the IHE PCC GAO Profile goes to Trial Implementation, determine whether there
235 are any Change Proposals needed to this supplement to keep the two profiles in sync.
Closed 11/13/2018: Currently the focus is shifting from the IHE PCC GAO Profile to a
still to be developed HL7 CDS Hooks based implementation guide/profile. A new issue is
opened to track this new specification.
16. AUC scores can be a simple numeric score on a scale, text, or coded categories based on
240 a coding system. Not all systems will be able to support all formats, and as data moves
across systems, re-formatting the data from, e.g., string into coded will be challenging
and unreliable. Closed: As the source data can be accessed directly from the CDSM, we
will only support the use of the ST (String) data type when communicating the actual
scoring of the appropriate use.

245

General Introduction

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

Appendix A – Actor Summary Definitions

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

255 No new actors.

Appendix B – Transaction Summary Definitions

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

260 No new transactions.

Glossary

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

Glossary Term	Definition
Clinical Decision Support	A clinical decision support (CDS) system is designed to assist physicians and other health care professionals with clinical decision making tasks. A CDS system implements an Appropriate Use Criteria (AUC) algorithm.
Appropriate Use Criteria	Appropriate Use Criteria (AUC) is an algorithm, typically evidence-based, which specifies the appropriateness of medical procedure(s) or service(s) based on the patient's presenting clinical indication(s).
Centers for Medicare & Medicaid Service	Centers for Medicare & Medicaid Service (CMS) is a department of the U.S. Health and Human Services (HHS).

265

Volume 1 – Profiles

Add new Section 39:

39 Clinical Decision Support - Order Appropriateness Tracking (CDS-OAT) Profile

270 The Clinical Decision Support - Order Appropriateness Tracking Profile (CDS-OAT) propagates the Clinical Decision Support (CDS) and Appropriate Use Criteria (AUC) information to actors in the Radiology Scheduled Workflow.b, Reporting Workflow, and Charge Posting Profiles.

275 Alternatively, the *MSH and OBX Segment for CDS Information* defined in RAD TF-3: 6.4.1.1 and 6.4.1.2 may be used as part of an existing HL7 v2 based order and charge transaction to promote consistency of communicating AUC information, without needing to upgrade the entire transaction set to be conformant to profiles in the IHE Radiology Technical Framework.

Appropriate Use Criteria are guidelines defined by professional societies (e.g., American College of Radiology (ACR)) or other groups. These guidelines are typically based on evidence that determines which imaging tests are the most suitable.

280 CDS systems implement AUC in computerized healthcare systems. A CDS system, also referred to as a clinical decision support mechanism (CDSM), is used by a referring, ordering physician, or staff member at the time that the order is placed, typically in a CPOE, EMR, HIS, or other order entry system.

285 As part of the process of assisting the ordering physician to order the most appropriate test, the CDS system produces a set of information, including an indication of appropriateness. Other information may include the AUC guidelines and version which were used, the vendor and software which implemented the CDS system, and other relevant information.

290 Some payers require the use of a CDS system in order to process payments. An example of this includes the U.S. Health and Human Services (HHS) Centers for Medicare & Medicaid Service (CMS) effective January 1, 2017, Protecting Access to Medicare Act. While this profile takes the CMS legislation into account, it is intended to be more broadly applicable.

295 The CDS-OAT Profile assumes that the CDS and AUC information has been obtained by some means, e.g., HL7 CDS Hooks. The CDS information can be obtained independently through manual initiation of a CDS system, by reviewing a paper or article, or via a fax or phone call. After this CDS information is obtained, the CDS-OAT Profile ensures that it is propagated accurately throughout the radiology workflow (ordering, scheduling, reporting, posting) so that the charge may be posted accurately.

This profile applies to both in-patient and outpatient scenarios. A referring/ordering physician may initiate an order via a phone call or a web portal. In either case, the CDS information is obtained in advance of creating an order.

300 CDS-OAT is both a “workflow profile” and a “content profile”. CDS-OAT is a “workflow profile” than can be an extension to the Scheduled Workflow (SWF.b) or the Charge Posting

305 profiles. The CDS-OAT Profile also defines “content” -- a common data set for the CDS information in the form of an HL7 v2.9 OBX segment. The CDS/AUC data propagated in this CDS-OAT Profile is consistent with the data generated by the Decision Support Requestor in the IHE PCC Guideline Appropriate Ordering (GAO) Profile. See Section 39.6: Cross Profile Considerations.

310 Also note that although there is additional information that is used in the CDS process which would also be very important to the radiologist reading a study, such as clinical indications and reason for study, this relevant information is out of scope for this profile. It is enumerated in the [IHE Code Mapping in IHE Radiology Profiles White Paper](#).

39.1 CDS-OAT 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 http://ihe.net/Technical_Frameworks.

315 Figure 39.1-1 shows the actors directly involved in the CDS-OAT Profile and the relevant transactions between them.

The Decision Support Service is shown here in dotted lines for completeness, but the transactions for these actors are provided in the IHE PCC Guideline Appropriate Ordering (GAO) Profile.

320

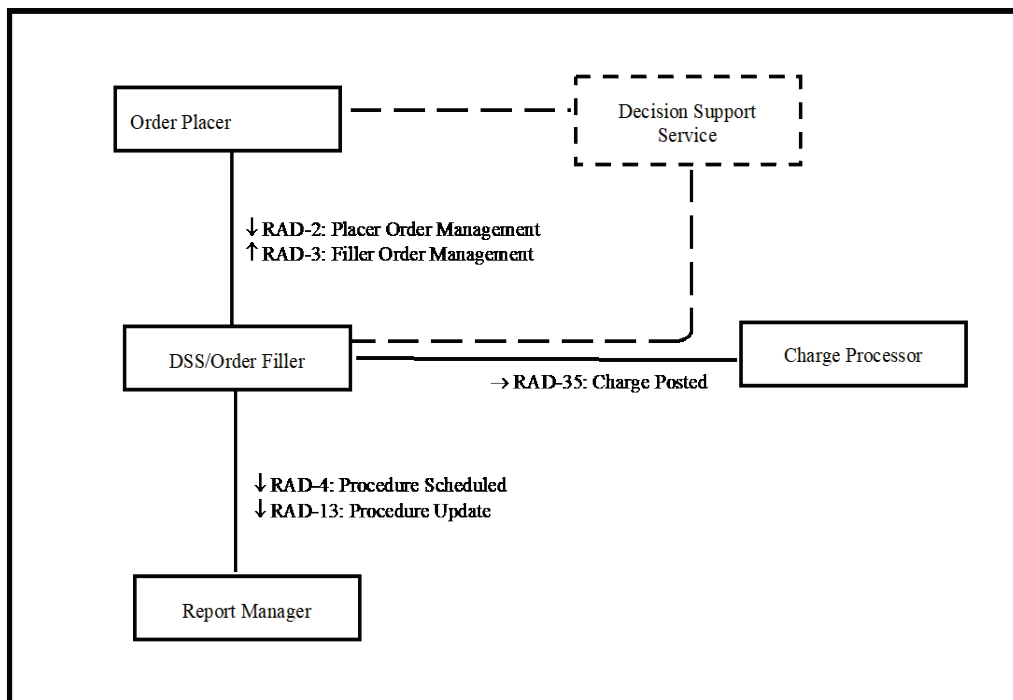


Figure 39.1-1: CDS-OAT Actor Diagram

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Table 39.1-1 lists the transactions for each actor directly involved in the CDS-OAT 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 39.1-1: CDS-OAT Profile - Actors and Transactions

Actors	Transactions	Optionality	TF Reference
Order Placer	Placer Order Management [RAD-2]	R	RAD TF-2: 4.2
	Filler Order Management [RAD-3]	R	RAD TF-2: 4.3
DSS/Order Filler	Placer Order Management [RAD-2]	R	RAD TF-2: 4.2
	Filler Order Management [RAD-3]	R	RAD TF-2: 4.3
	Procedure Scheduled [RAD-4]	R	RAD TF-2: 4.4 (see Note 2)
	Procedure Updated [RAD-13]	R	RAD TF-2: 4.13 (see Note 2)
	Charge Posted [RAD-35]	R	RAD TF-3: 4.35 (see Note 1)
Report Manager	Procedure Scheduled [RAD-4]	R	RAD TF-2: 4.4 (see Note 2)
	Procedure Updated [RAD-13]	R	RAD TF-2: 4.13 (see Note 2)
Charge Processor	Charge Posted [RAD-35]	R	RAD TF-3: 4.35 (see Note 1)

Note 1: The DSS/Order Filler and the Charge Processor shall support the HL7 v2.5.1 semantics of [RAD-35] transaction.

Note 2: The DSS/Order Filler and the Report Manager shall support the HL7 v2.5.1 semantics of the [RAD-2], [RAD-3], [RAD-4] and [RAD-13] transactions.

330

Table 39.1-2 lists the content module(s) defined in the CDS-OAT Profile. To claim support with this profile, an actor shall support all required content modules (labeled “R”) and may support optional content modules (labeled “O”).

Table 39.1-2: CDS-OAT Profile - Actors and Content Modules

Actors	Content Modules	Optionality	TF Reference
Order Placer	MSH Segment for CDS Information	R	RAD TF-3: 6.4.1.1
	HL7 v.2.9 OBX Segment for CDS Information	R	RAD TF-3: 6.4.1.2
DSS/Order Filler	MSH Segment for CDS Information	R	RAD TF-3: 6.4.1.1
	HL7 v.2.9 OBX Segment for CDS Information	R	RAD TF-3: 6.4.1.2

Actors	Content Modules	Optionality	TF Reference
Report Manager	MSH Segment for CDS Information	R	RAD TF-3: 6.4.1.1
	HL7 v.2.9 OBX Segment for CDS Information	R	RAD TF-3: 6.4.1.2
Charge Processor	MSH Segment for CDS Information	R	RAD TF-3: 6.4.1.1
	HL7 v.2.9 OBX Segment for CDS Information	R	RAD TF-3: 6.4.1.2

335

39.1.1 Actor Descriptions and Actor Profile Requirements

Requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3).

39.1.1.1 Support for HL7 v2.5.1 Message Semantics

- 340 • The Order Placer and DSS/OF shall use the HL7 v2.5.1 Message Semantics of the [RAD-2] and [RAD-3] transactions. See RAD TF-2: 4.2.1.2.2 and RAD TF-2: 4.3.4.1.2.2. These transactions shall include the HL7 v2.9 OBX Segment for CDS Information. See RAD TF-3: 6.4.1.2.
- 345 • The DSS/OF and Report Manager shall use the HL7 v2.5.1 Message Semantics of the [RAD-4] and [RAD-13] transactions. See RAD TF-2: 4.4.1.2.2 and RAD TF-2: 4.13.1.2.2. These transactions shall include the HL7 v2.9 OBX Segment for CDS Information. See RAD TF-3: 6.4.1.2.
- The DSS/OF and the Charge Processor shall use the HL7 v2.5.1 Message Semantics of the [RAD-35] transaction. This transaction shall include the HL7 v2.9 OBX Segment for CDS Information. See RAD TF-3: 6.4.1.2.

350 39.2 CDS-OAT Actor Options

Table 39.2-1: CDS-OAT - Actors and Options

Actor	Option Name	TF Reference
Order Placer	No options defined	-
Order Filler/Department System Scheduler	No options defined	-
Report Manager	No options defined	-
Charge Processor	No options defined	-

39.3 CDS-OAT Required Actor Groupings

355 Although there are no Required Actor Groupings for this profile, other actor groupings defined in Section 39.6 “Other Profile Considerations” are highly recommended.

39.4 CDS-OAT Overview

39.4.1 Concepts

This profile makes use of transactions defined in other IHE profiles, specifically:

- Radiology Scheduled Workflow (SWF.b)
- 360 • Radiology Charge Posting (CHG)

This profile introduces a content module for CDS information. This CDS information is defined in RAD TF-3: 6.4.1.1.

39.4.1.1 Ordering Physician

365 The Ordering Physician is identified in HL7 v2.5.1 elements ORC-12 and OBR-16 (those two elements are defined by [RAD-2], [RAD-3], and HL7 v2.5.1 to be identical).

The Ordering Physician carries special significance in this profile because this person, or his/her assigned representative, is responsible for ordering the test and obtaining the CDS information.

39.4.1.2 Obtaining the CDS information for an order

370 There are two primary ways in which an Order Placer or an Order Filler (DSS/OF) can obtain CDS information. If the Order Placer or DSS/OF is integrated with a CDS system, e.g., grouped with the IHE PCC GAO Authorization Requestor, the OP or DSS/OF system is responsible for accurately mapping the CDS information into the “HL7 v.2.9 OBX Segment for CDS Information” content module of this profile.

375 Alternatively, the OP or DSS/OF system may manually obtain the CDS information or obtain the CDS information through a non-integrated CDS system. The CDS information may be conveyed to the person entering the order as part of a faxed request or a phone call. In this case, the Order Placer or DSS/OF system is responsible for having a method to input the CDS system into the order such that the “HL7 v2.9 OBX Segment for CDS Information” content module can be accurately and adequately completed.

380 Independent of the method used to obtain the CDS Information, this information shall be conveyed from one system to the next without being altered unless the procedure ordered is changed.

39.4.1.3 Significant versus insignificant changes to an order or requested procedure

385 In general, if a “significant change” is made to an order or requested procedure, the clinical decision support algorithm will need to be re-run. In this case, the order is typically canceled and

the CDS information will be obtained anew when the new order is created (see specific Use Cases in Section 39.4.2.).

390 If an “insignificant change” is made to an order or requested procedure, the clinical decision support algorithm may not need to be re-run. In this case, the order is typically not canceled. This profile does not define a significant versus insignificant change; the definition of “significance” is defined by the AUC and/or payer.

39.4.1.4 Other order changes, not affecting CDS

395 There are reasons that an order may change, that do not affect the procedure or the CDS information. Examples of these include:

- Scheduled time is no longer convenient
- Pre-authorization not received
- Patient is ill
- Transportation
- 400 • Work issue

There are reasons that a procedure may need to be rescheduled after a patient has changed or the exam has begun. Examples of these include:

- Patient unable to hold still for exam
- Patient requires pre-mediation (allergies, claustrophobic, etc.)
- 405 • Patient cannot comply with technologist or radiologist instructions
- Patient does not wish to sign the appropriate consents
- Patient cannot confirm she is not pregnant

These changes do not affect the procedure or CDS information for the original order/procedure.

39.4.1.5 Timing of Charge Posting

410 As described in more detail in the Charge Posting Profile, there are two types of charges, professional fee (radiologist’s interpretation) and technical fee (modality acquisition). These charges are posted after a study is completed so that they may be coded properly. As such, the “change order” issue does not apply to the charge posting in the same manner in which it does to protocoling or procedure changes. Nonetheless, the DSS/OF is required to send CDS information
415 in the OBX segment, unchanged, to the Charge Processor, typically as the last transaction in the workflow.

39.4.2 Use Cases

It is expected that the reader of this profile is generally familiar with the Use Cases defined in the Scheduled Workflow (SWF.b) and Charge Posting (CHG) Profiles.

420 This section identifies Use Cases to illustrate CDS scenarios. Variations in these scenarios will occur. This section is informative and not normative.

39.4.2.1 Use Case 1: Simple Case- Order is placed with CDS information, report is created or charge is posted

425 An order is created at an Order Placer system (e.g., a CPOE, EMR, HIS, etc.). As part of the order creation, the ordering physician or administrative staff completes the Appropriate Use determination through the use of a Clinical Decision Support system (either in an integrated or manual fashion). In either case, all of the required CDS information is available.

The Order Placer sends the order [RAD-2], containing the CDS information, to the Department System Scheduler/Order Filler (DSS/OF) system (e.g., a RIS).

430 When the procedure is scheduled or protocolled, the DSS/OF sends a Procedure Scheduled [RAD-4] message to the Report Manager, often to assist with the reporting workflow. After the procedure is complete, the normal reporting workflow (worklist) occurs and a report may be generated for that study which includes the CDS information as narrative text or coded/structured information.

435 Additionally, at an appropriate time such as the procedure has been completed, the DSS/OF sends a Charge Posted [RAD-35] message to the Charge Processor.

In both [RAD-4] and [RAD-35], the DSS/OF sends the CDS information it obtained from the Order Placer [RAD-2] at the time of the order generation to the receiving system.

440 The Report Manager and the Charge Processor provide methods for posting technical and professional charges, depending on the institution. At some institutions, a billing administrator reviews the radiology reports and approves the charges for billing and claims filing purposes. At other institutions, a charge processing system is capable of receiving financial transactions and generating charges for billing and claims filing purposes. Because these variations exist, this profile includes the requirement for the DSS/OF to be able to send the CDS information to either
445 actor. The report creation and charge generation are outside the scope of this profile.

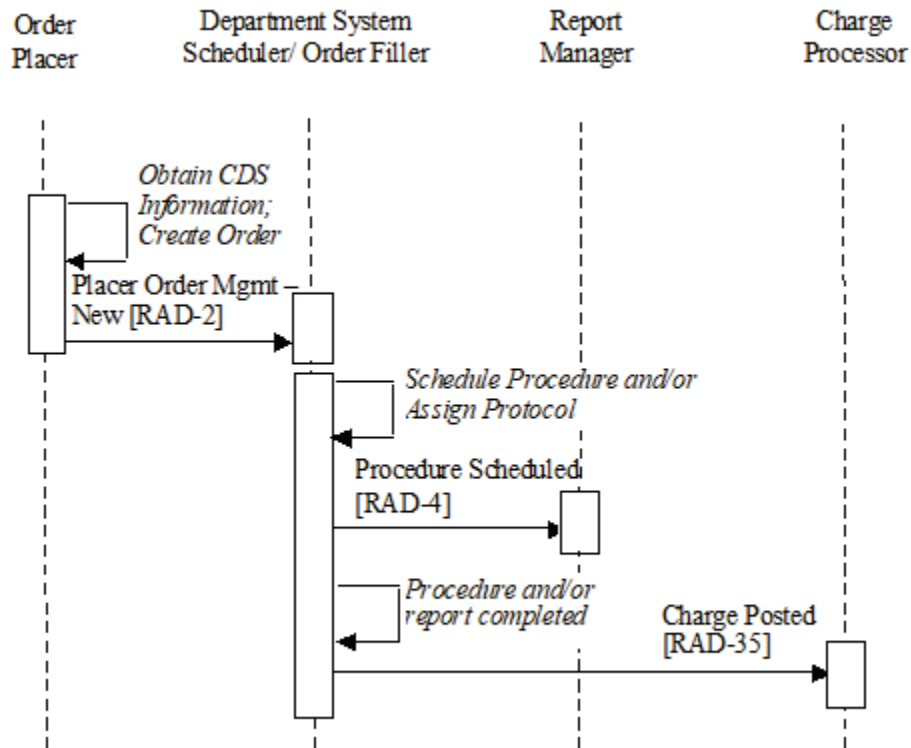


Figure 39.4.2.1-1: Use Case 1: Basic Process Flow in CDS-OAT Profile

39.4.2.2 Use Case 2: Procedure requires significant change, order canceled at the Order Placer

450 The Order Placer sends the order [RAD-2], containing the CDS information, to the Department System Scheduler/Order Filler (DSS/OF) system (e.g., a RIS).

However, during study protocoling or for some other reason, the imaging department requests a significant change by contacting the ordering physician. An example of a “significant change” is an additional body part is included in the study that changes the requested procedure, such as
 455 “CT Abdomen” becomes “CT Abdomen Pelvis”, or the patient reports an allergic reaction to contrast which necessitates a different study be performed.

Note: The definition of “significant” is defined by the AUC and/or payer, and is not addressed in this profile.

The ordering physician cancels the order at the Order Placer [RAD-2]. The ordering physician creates a new order for the correct procedure and again obtains the CDS information. (The CDS
 460 algorithm is re-run with the new order information.)

If the DSS/OF has already sent to the Report Manager a Procedure Scheduled [RAD-4] message with the original order and CDS information, the DSS/OF must send the Report Manager a Procedure Updated cancellation [RAD-13] message.

465 After the second (corrected) order is created, the simple workflow process is re-initiated (Use Case 1), including the charge posting after the study is completed.

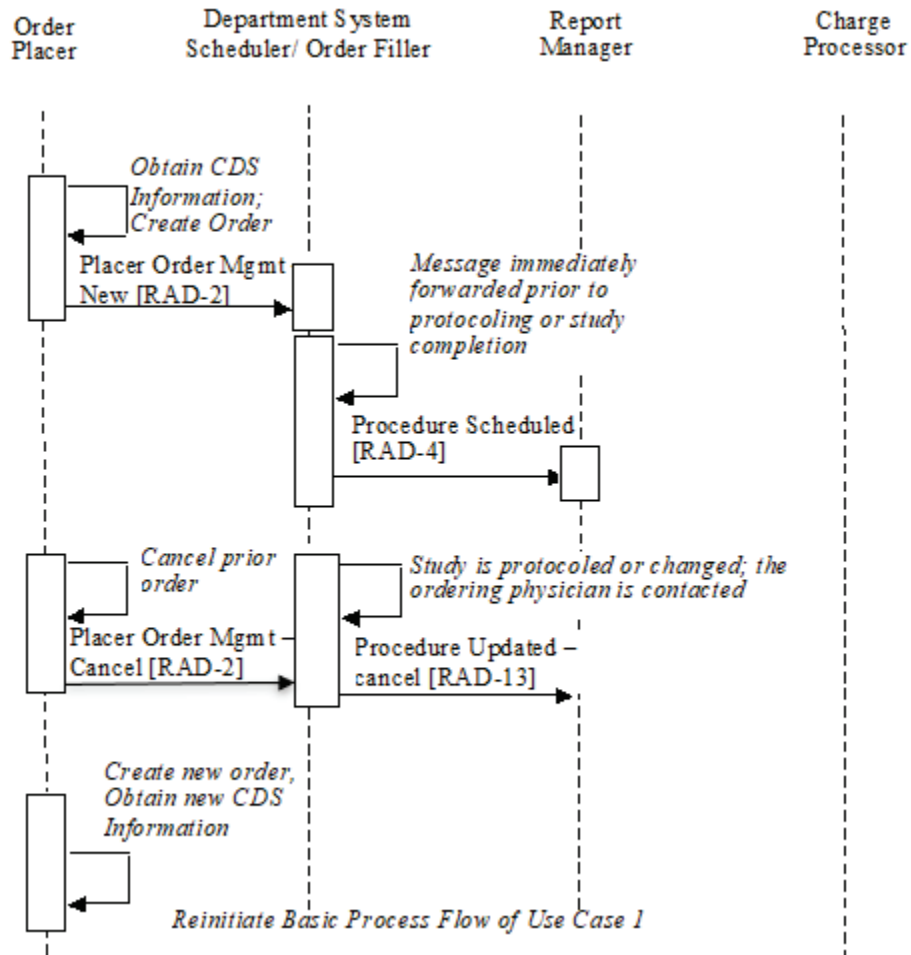


Figure 39.4.2.2-1: Use Case 2: Significant CDS Order Change in CDS-OAT Profile, order canceled at OP

470 **39.4.2.3 Use Case 3: Procedure requires significant CDS change, order canceled at DSS/OF, new order created at DSS/OF**

An order, containing CDS information, is created at the Order Placer and sent to the DSS/OF.

However, during study protocoling or for some other reason, the imaging department determines that a significant change is required and the procedure should not proceed as originally ordered.

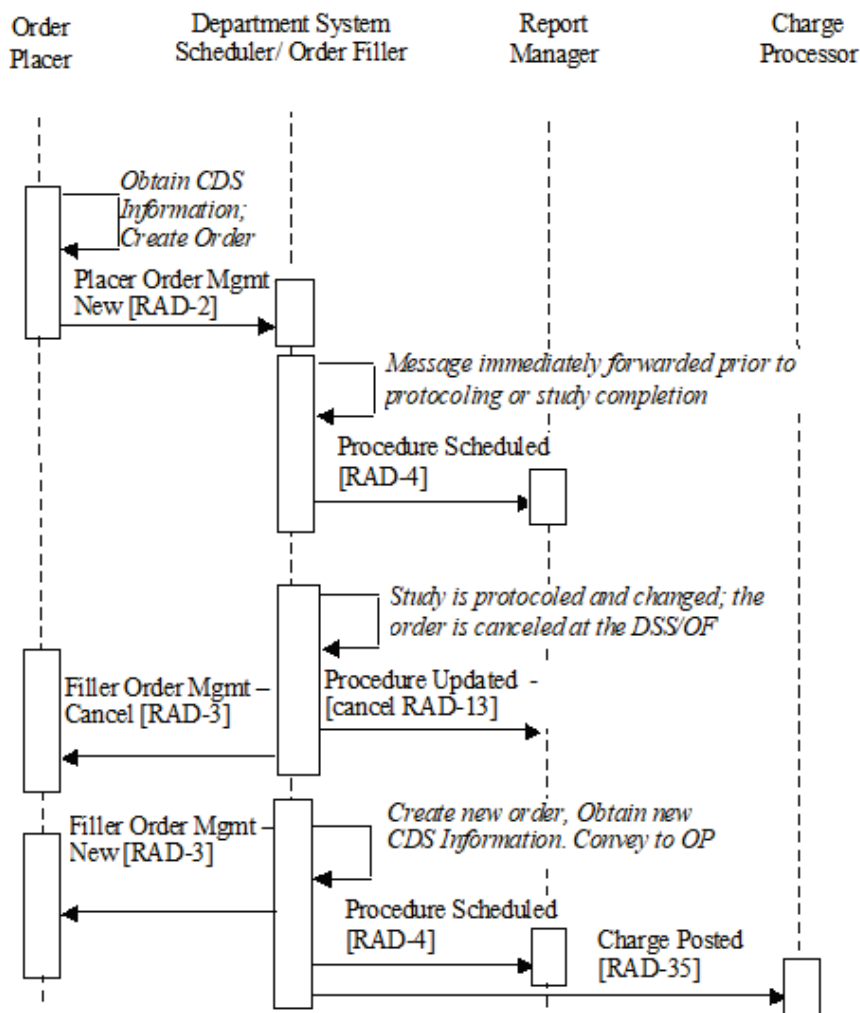
475 An example of a “significant change” is an additional body part is included in the study which changes the requested procedure, such as “CT Abdomen” becomes “CT Abdomen & Pelvis”. Another example of a significant change could be that a procedure was ordered “with contrast”,

but upon presenting, the patient is noted to be diabetic and the rendering physician (radiologist) chooses to change the order to be performed as a non-contrast study.

480 Note: The definition of “significant” is defined by the AUC and/or payer, and is not addressed in this profile.

The original order is canceled at the DSS/OF [RAD-3]. If the DSS/OF has already sent the Report Manager a Procedure Scheduled [RAD-4] message with the original order and information, the DSS/OF must send the Report Manager a Procedure Updated cancellation [RAD-13] message. The DSS/OF creates a new order and obtains the new CDS information. The
 485 DSS/OF notifies the Order Placer of the new order [RAD-3], including the new CDS information, and sends [RAD-4] with new order information to the Report Manager.

As in Use Case 1, the DSS/OF sends the Charge Posted [RAD-35] transaction after the study is completed.



490 **Figure 39.4.2.3-1: Use Case 3: Significant CDS Order Change in CDS-OAT Profile, order canceled at DSS/OF**

**39.4.2.4 Use Case 4: Procedure requires significant CDS change, new CDS
information at DSS/OF, order updated by DSS/OF**

An order, containing CDS information, is created at the Order Placer and sent to the DSS/OF.

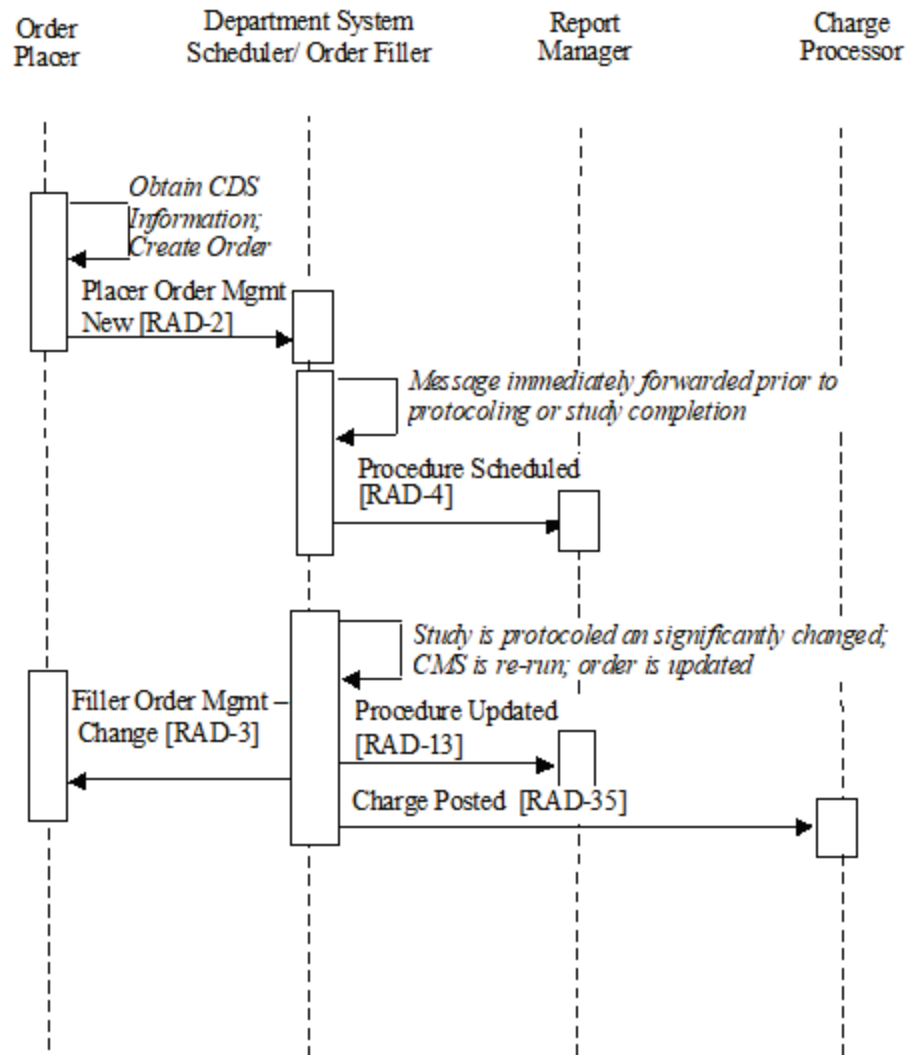
495 However, during study protocoling or for some other reason, the imaging department determines
that a significant change is required and the procedure should not proceed as originally ordered.
(See “significant change” examples in Use Case 3.)

Note: The definition of “significant” is defined by the AUC and/or payer, and is not addressed in this profile.

500 The original order is updated at the DSS/OF. The DSS/OF obtains the new CDS information.
The DSS/OF notifies the Order Placer of the updated order [RAD-3], including the new CDS
information. In the updated order message, the Ordering Provider (ORC-12/OBR-16) is also
updated to reflect the person who reran the CDS information.

505 If the DSS/OF has already sent the Report Manager a Procedure Scheduled [RAD-4] message
with the original order and information, the DSS/OF must send the Report Manager a Procedure
Updated [RAD-13] message.

As in Use Case 1, the DSS/OF sends the Charge Posted [RAD-35] transaction after the study is
completed.



510 **Figure 39.4.2.4-1: Use Case 4: Significant CDS Order Change in CDS-OAT Profile, new CDS information is obtained at DSS/OF, order updated by DSS/OF**

39.4.2.5 Use Case 5: Order requires insignificant CDS change, no order cancellation or CDS update

An order is created at the Order Placer and sent to the DSS/OF.

515 During study protocoling at the Order Filler, the imaging department requests a change to the order. A possible “insignificant change” example could be that an “MR pituitary gland” is changed to an “MR head” because the same CPT code is used for both procedures. Other examples which are “insignificant changes” regarding the CDS information could be scheduling changes or insurance numbers errors.

520 Note: The definition of “insignificant” is defined by the AUC and/or payer, and is not addressed in this profile.

The CDS information is not required to be updated.

There are no changes to the Use Case 1 “Simple Process Workflow” steps.

39.4.2.6 Use Case 6: Order received without CDS information

525 It is common practice within an imaging department to “hold a position” on a schedule. The procedure may be ordered and scheduled at the DSS/OF to be verified with the patient or ordering physician, but the order did not include the necessary CDS information.

This use case follows the same transactions as Use Case 1 of the Scheduled Workflow (SWF.b) Profile without including the required CDS content module required in this profile.

530 To comply with this profile, however, the order must be updated at some point to include the CDS information.

The ordering physician may be contacted to generate and verify the CDS information prior to the procedure being performed. This CDS information may then be transmitted via the phone, email, or some other mechanism. Alternatively, the CDS information may be obtained at a later time locally at the DSS/OF.

535 In either of those cases, the Order Placer or DSS/OF is notified that the order has been updated, including (potentially different/new) CDS information as well as other information.

540 It is also worth noting that this use case is especially important in the U.S., because the CMS legislation places the burden of completing CDS on the referring provider, but the risk of non-payment on the rendering provider (radiologist). Therefore, there will be a strong need for the rendering provider to be able to include the complete CDS information.

The Report Manager receives a Procedure Updated message prior to report completion.

As in Use Case 1, the charge posting is sent after the study is completed.

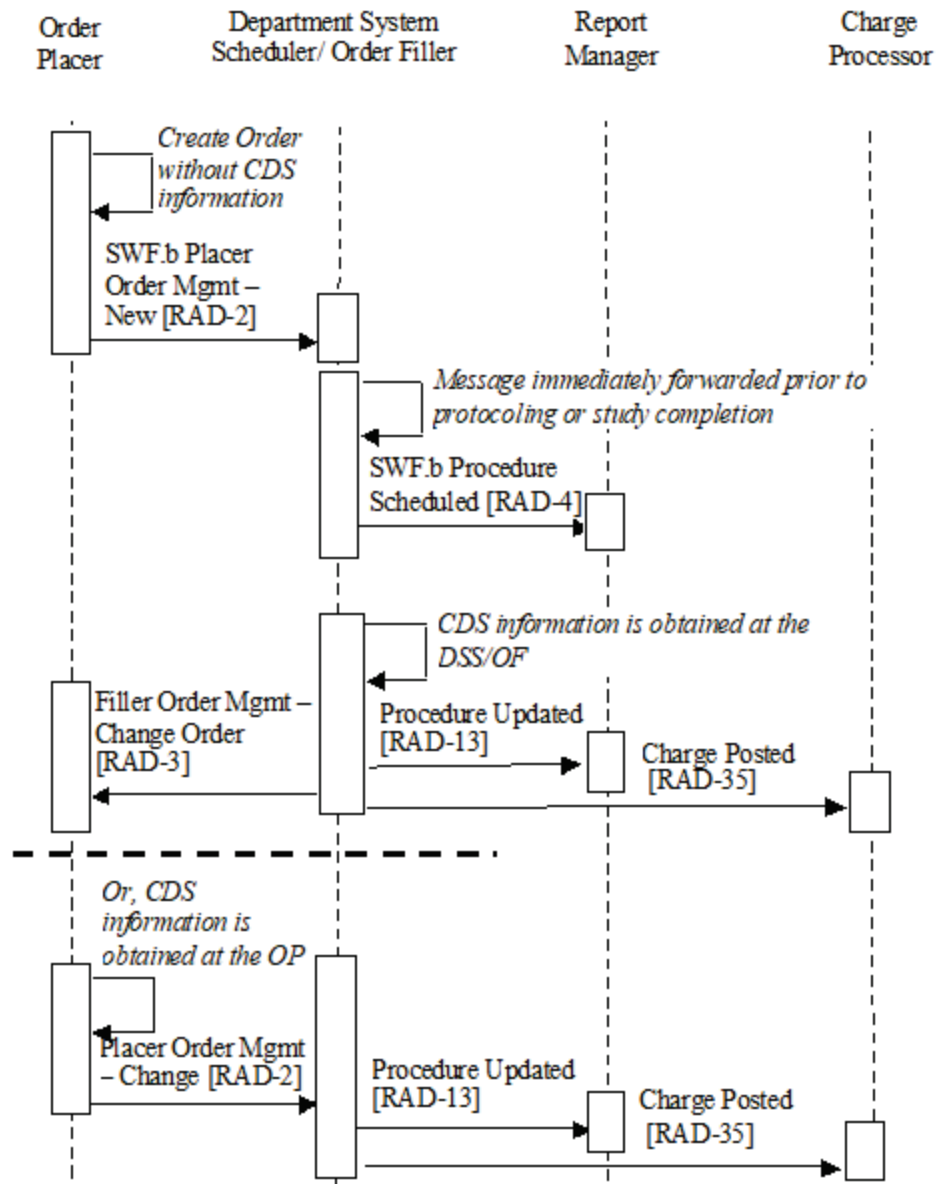


Figure 39.4.2.6-1: Use Case 6: Order received without CDS information

545 **39.4.2.7 Use Case 7: Procedure is changed while procedure is already in progress**

In this use case, the procedure is changed after the procedure has already begun. In this case the update to the CDS information is done after the study is completed and that process is site specific. Although this use case is outside the scope of this profile, it is explained in more detail for clarity.

550 Following the normal flow (Use Case 1 – Simple Process Workflow) in this profile, an order,
including the CDS information, is created at the Order Placer and sent to the DSS/OF. The
procedure is scheduled and begun. As the procedure is underway, it is determined to be
555 medically necessary to extend the procedure. For example, during a CT of the chest a tumor is
identified which extends into the abdomen. The radiologist chooses to extend the procedure to
include the abdomen while the patient is still in the scanner.

A variation of this use case is that procedure is completed, but when the radiologist is quality
checking the image set she chooses to immediately call the patient back for an additional
procedure to extend to the abdomen.

560 The handling of either of these cases is site specific, but the order may be canceled and re-
ordered “after the fact” (transaction flow defined in Use Case 2) or the payment may be appealed
at a later date because the CDS information will not apply to the procedure that was completed.

39.5 CDS-OAT Security Considerations

The SWF.b Security Considerations are summarized here and applied to this profile as well.
Please see the other profiles for additional details.

565 The summary of the security considerations for this profile include:

39.5.1 Fraud

As more payers and governmental agencies require use of Clinical Decision Support to validate
that orders are clinically appropriate, there will be an incentive for some to avoid profiling or
rejection of claims for excessive ordering outside of those guidelines.

570 The assets at risk with fraud are financial. Examples of fraud include:

1. Manual Entry: Manual entry of inaccurate or fake CDS/AUC information could occur at
the OP or DSS/OF.
2. Impersonation: Another, more lenient but unauthorized, system may “impersonate” the
CDS system.
- 575 3. Replay: In a replay attack, known good responses to challenges are repeated in order to
duplicate the positive outcome.
4. Gaming: Users of the system could be incited financially to generate patient data which
would be known to generate a positive response. This sort of gaming cannot readily be
prevented technologically, and is also fairly likely to occur.

39.5.2 Unauthorized Access to PHI

The Order Placer, DSS/Order Filler, Report Manager, and Charge Posting systems routinely
receive personal health information (PHI), making it a potential target of attack if its location is
widely known.

585 The assets at risk with PHI information are identity, and in turn, financial. Examples of these include:

- Inappropriate Use or Storage of PHI: Systems should store PHI only if absolutely necessary, else create a reference.
- Unsecure Communications: An unsecured communication channel could leak information about organizations, providers, patients which could be detrimental to the requesting or responding organization, either through damaged reputation, or fiscal penalties.
- Unauthorized Access: Access to information can occur by unauthorized users. Assets at risk include intellectual property (e.g., decisions made by the DSS), financial (e.g., use of the DSS without compensation), and possible PHI (e.g., state information about prior use of an imaging service).

39.6 CDS-OAT Cross Profile Considerations

The CDS-OAT Profile should also be closely integrated with the Scheduled Workflow (SWF.b) Profile.

600 The Order Placer and the Department System Scheduler/Order Filler (DSS/OF) Actors in the CDS-OAT Profile should be grouped with the corresponding Order Placer and DSS/OF Actors of the Scheduled Workflow (SWF.b) Profile. This grouping provides access to additional transactions which are necessary in real-world practice.

605 The CDS-OAT Profile could be integrated with the CDSM lookup once specifications are available (see Open Issues). (Note that a reference to the CDS Hooks Implementation Guide documentation will be included as soon as available).

To mitigate security considerations in Section 39.5, all actors of this profile could be grouped with a Secure Node or Secure Application in the IHE ITI Audit Trail and Node Authentication (ATNA) Profile.

Volume 2 – Transactions

610

*NOTE TO VOLUME EDITOR: The **order** of applying these CPs and supplements is very important. There are several CPs (e.g., getting rid of v2.3.1 and therefore the HL7 v2.5.1 “option”) and several of the IHE-J CPs which also affect these same sections. The updates below are made on RAD TF-2, version 17.0, where the section headings containing “(HL7 v2.5.1 option)” still exist. That is, the way that the sections are number below assumes (correctly or otherwise) that this supplement will be applied to the RAD TF-2 prior to CP- 309 and incorporating supplement SWF.b.*

615

4.2 Placer Order Management [RAD-2]

620

...

4.2.4.1.2.2 Message Semantics (HL7 v2.5.1 Option)

Add a new row to the bottom of the table specifying the OMG message segments: (note – this is also exactly the same as another IHE-J CP#309 – only OBX row add once). Also add NTE row.

...

625

OMG	General Clinical Order Message	Chapter in HL7 v2.5.1
MSH	Message Header	2
PID	Patient Identification	3
PV1	Patient Visit	3
ORC	Common Order	4
TQ1	Timing/Quantity	4
OBR	Order Detail	4
<u>[[OBX</u>	<u>Observation/results</u>	<u>7</u>
<u>]]NTE]] (See Note 1)</u>	<u>Note</u>	<u>2</u>

Note 1: Shall be able to support NTE, but can be omitted if no notes are applicable

Add – a new Section 4.2.4.1.2.2.1.1 and include all of the text below

4.2.4.1.2.2.1.1 MSH Requirements for CDS Information

630 Field *MSH-21 Message Profile Identifier* – An Order Placer in the CDS-OAT Profile shall populate this field with the profile identifier that indicates that this message contains AUC information. See RAD TF-3: 6.4.1.1 HL7 MSH Segment for CDS Information

Add new Section 4.2.4.1.2.2.4.1 and include all of the text below, including the table.

635 **4.2.4.1.2.2.4.1 ORC Requirements for CDS Information**

Field *ORC-12 Ordering Provider* - An Order Placer in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative. The value in ORC-12 shall be identical to the value of OBR-16 (Ordering Provider) as described in the table below.

640 **Table 4.2-7a: ORC-12 and OBR-16 XCN Identical Mappings**

ORC-12	OBR-16	LEN	DT	OPT	TBL#	Component Name
ORC-12.1	OBR-16.1	15	ST	R		ID Number (See Note 1)
ORC-12.2	OBR-16.2	194	FN	R		Family Name
ORC-12.3	OBR-16.3	30	ST	R		Given Name
ORC-12.4	OBR-16.4	30	ST	O		Second & Further Given Names or Initials
ORC-12.5	OBR-16.5	20	ST	O		Suffix
ORC-12.6	OBR-16.6	20	ST	R		Prefix
ORC-12.9	OBR-16.9	227	HD	R		Assigning Authority (See Note 1)
ORC-12.13	OBR-16.13	5	ID	O	0203	Identifier Type Code (See Note 1)

Note 1: See RAD TF-4: 5.2 for details on US National Extensions for these components.

Make the following updates to Section 4.2.4.1.2.2.6

645

4.2.4.1.2.2.6 OBR Segment (HL7 v2.5.1 Option)

...

650 Field *OBR-13-Relevant Clinical Info* shall be populated if the patient record contains any medical alerts that may be relevant to the order and, in particular, need to be communicated to the technologist.

Field *OBR-16 Ordering Provider* - An Order Placer in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative. The value in OBR-16 shall be identical to the value of ORC-12 as described in the mapping table in Section 4.2.4.1.2.2.4.1.

655

Field *OBR-27-Quantity/Timing* shall not be present. The date and time of the exam shall be carried in field *TQ1-7-Start Date/Time*.

...

Table 4.2-10: Identical Element Mappings between ORC and OBR Segments

Element Name	ORC Segment Element	OBR Segment Element
Placer Order Number	ORC-2	OBR-2
Filler Order Number	ORC-3	OBR-3
Parent	ORC-8	OBR-29
<u>Ordering Provider</u>	<u>ORC-12</u>	<u>OBR-16</u>

660

Add – a new section as numbered and include all of the text below

4.2.4.1.2.2.7 OBX and NTE Segments for CDS Information

665 An Order Placer in the CDS-OAT Profile shall include the OBX segment and may include an NTE segment as defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information.

There shall be one CDS OBX segment and zero or one NTE segment for that OBX per OBR segment in the OMG message.

670 *Add new Section 4.2.4.1.3.1 after Section 4.2.4.1.3*

4.2.4.1.3 Expected Actions

...

4.2.4.1.3.1 Expected Actions for CDS Information

675 A DSS/Order Filler in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information as well as retain the Ordering Provider (ORC-12/OBR-16) information.

680 The DSS/Order Filler shall include this CDS information and Ordering Provider as originally received from the Order Placer to other systems in the [RAD-4], [RAD-13], and [RAD-35] transactions.

4.3 Filler Order Management [RAD-3]

...

4.3.4.1.2.2 Message Semantics (HL7 v2.5.1 Option)

685 *Add new rows to the bottom of the table specifying the OMG message segments: (note – this is also exactly the same as another IHE-J CP#309 – only OBX row add once) Also add NTE row.*

...

OMG	General Clinical Order Message	Chapter in HL7 v2.5.1
MSH	Message Header	2
ORC	Common Order	4
TQ1	Timing/Quantity	4
OBR	Order Detail	4
<u> OBX</u>	<u>Observation/results</u>	<u>7</u>
<u>[NTE] (See Note 1)</u>	<u>Note</u>	<u>2</u>

Note 1: Shall be able to support NTE, but can be omitted if no notes are applicable

690

Add – new Section 4.3.4.1.2.2.1.1 and include all of the text below

4.3.4.1.2.2.1.1 MSH Requirements for CDS Information

695 Field *MSH-21 Message Profile Identifier* – A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the profile identifier that indicates that this message contains AUC information. See RAD TF-3: 6.4.1.1 HL7 MSH Segment for CDS Information.

Add – a new section as numbered and include all of the text below

4.3.4.1.2.2.5.1 ORC Requirements for CDS Information

700 Field *ORC-12 Ordering Provider*- A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative. The value in ORC-12 shall be identical to the value of OBR-16 as described in Section 4.2.4.1.2.2.4.1.

705 *Make the following updates to Section 4.3.4.1.2.2.7*

4.3.4.1.2.2.7 OBR Segment (HL7 v2.5.1 Option)

...

710 Field *OBR-13-Relevant Clinical Info* shall be populated if the patient record contains any medical alerts that may be relevant to the order and, in particular, need to be communicated to the technologist.

715 **Field *OBR-16 Ordering Provider* – A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative. The value in OBR-16 shall be identical to the value of ORC-12 as described in Section 4.2.4.1.2.2.4.1.**

Field *OBR-27-Quantity/Timing* shall not be present. The date and time of the exam shall be carried in field *TQ1-7-Start Date/Time*.

720 **Add – a new section as numbered and include all of the text below**

4.3.4.1.2.2.9 OBX Segment for CDS Information

A DSS/Order Filler in the CDS-OAT Profile shall include the OBX segment and may include an NTE segment as defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information.

725 There shall be one CDS OBX segment and zero or one NTE segment for that OBX per OBR segment in the OMG message.

Add new Section 4.3.4.2.3.1 after Section 4.3.4.2.3

730 **4.3.4.2.3 Expected Actions**

...

4.3.4.2.3.1 Expected Actions for CDS Information

An Order Placer in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information as well as retain the Ordering
 735 Provider (ORC-12/OBR-16).

4.4 Procedure Scheduled [RAD-4]

4.4.4.1.2.2 Message Semantics (HL7 v2.5.1 Option)

740 **Add new rows to the bottom of the table specifying the OMI message segments: (note – this is also exactly the same as another IHE-J CP#309 – only OBX row add once). Also add NTE row.**

OMI	Imaging Order Message	Chapter in HL7 v2.5.1
MSH	Message Header	2
PID	Patient Identification	3
PV1	Patient Visit	3
{ROL}	Role	15
{ORC	Common Order	4
TQ1	Timing / Quantity	4
OBR	Order Detail	4

OMI	Imaging Order Message	Chapter in HL7 v2.5.1
{IPC }	Imaging Procedure Control	4
<u>{OBX}</u>	<u>Observation/results</u>	<u>7</u>
<u>{NTE}</u> (See Note 1)	<u>Note</u>	<u>2</u>

Note 1: Shall be able to support NTE, but can be omitted if no notes are applicable

745

Add – a new Section 4.4.4.1.2.2.1.1 and include all of the text below

4.4.4.1.2.2.1.1 MSH Requirements for CDS Information

750 Field *MSH-21 Message Profile Identifier* – A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the profile identifier that indicates that this message contains AUC information. See RAD TF-3: 6.4.1.1 HL7 MSH Segment for CDS Information.

Make the following updates to Section 4.4.4.1.2.2.5

755

4.4.4.1.2.2.5 ORC Segment (HL7 v2.5.1 Option)

All of the fields in the ORC segment are optional, except those listed in Table 4.4-11. See Section 4.2.4.1.2.2.4 for the list of all fields of the ORC segment.

Table 4.4-11: IHE Profile - ORC Segment

SEQ	LEN	DT	OPT	TBL#	ITEM #	ELEMENT NAME
...						
12	250	XCN	R <u>See Note 1</u>		00226	Ordering Provider

760

Adapted from the HL7 Standard, version 2.5.1

Note 1: The CDS-OAT Profile promotes the optionality of ORC-12 from R2 to R. See Table 4.4-12.

...

Table 4.4-12: DSS Mappings of the ORC Segment

Element Name	Seq.	Element Shall Contain:	Notes
...			
Quantity/Timing	ORC-7	Shall not be valued: Date and time of the Scheduled Procedure Step shall be carried in the immediately following TQ1 segment.	
<u>Ordering Provider</u>	ORC-12	<u>A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative.</u>	Shall be copied from ORC-12 in the [RAD-2] or [RAD-3] order message.

765

Make the following updates to Section 4.4.4.1.2.2.7

4.4.4.1.2.2.7 OBR Segment (HL7 v2.5.1 Option)

770 All of the fields in the OBR segment are optional, except those listed in Table 4.4-14. See Section 4.2.4.1.2.2.6 for the list of all fields of the OBR segment.

Table 4.4-14: IHE Profile - OBR Segment

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
...						
16	120	XCN	R <u>See Note 1</u>		00226	Ordering Provider
...						

Note 1: The CDS-OAT Profile promotes the optionality of OBR-16 from R2 to R. See Table 4.4-15.

...

Table 4.4-15: DSS mappings of the OBR Segment (HL7 v2.5.1 Option)

Element Name	Seq.	Shall Contain:	Notes
Universal Service ID	OBR-4	The Universal Service ID of the Order.	Components 1-3 of OBR-4 shall be copied by the Order Filler from the components 1-3 of OBR-4 it obtains from the ORM message (OBR segment) conveyed to it by the Order Placer. Components 1-3 of OBR-4 in all OBR segments of an OMI or legacy ORM message shall have the same value. The related Requested Procedure Code/Description are sent in OBR-44. As the Order Filler may expand a single order into multiple Requested Procedures, multiple OMI messages may be sent for a single Order (with the same value for Components 1-3 of OBR-4).
<u>Ordering Provider</u>	<u>OBR-16</u>	<u>A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the person responsible for ordering the test and obtaining the CDS information, or their assigned representative.</u>	<u>Shall be copied from OBR-16 in the [RAD-2] or [RAD-3] order message.</u>
Procedure Code	OBR-44	Requested Procedure Code and Requested Procedure Description.	Components 1-3 shall contain the Requested Procedure Code for this OMI message. Optionally, component 5 may contain the Requested Procedure Description.
...			

775

Add – a new Section 4.4.4.1.2.2.9 and include all of the text below

4.4.4.1.2.2.9 OBX Segment for CDS Information

780 A DSS/Order Filler in the CDS-OAT Profile shall include the OBX segment and may include an NTE segment as defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information.

There shall be one OBX segment and zero or one NTE segment for that OBX per OBR segment in the OMI message.

785 **Add – the following new section after of Section 4.4.4.2.1 Expected Actions Use Cases.**

4.4.4.2 Expected Actions

4.4.4.2.1 Use Cases

...

790 4.4.4.2.2 Expected Actions for CDS Information

A Report Manager in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information as well as retain the Ordering Provider (ORC-12/OBR-16) information. The CDS-OAT Profile places no further requirements on the Report Manager, although the CDS information is available to the Report Manager for inclusion into the report content for charge posting.

795

4.13 Procedure Updated [RAD-13]

Edit Table 4.13-4 in Section 4.13.4.2.2 as follows

800 4.13.4.2.2 Message Semantics (HL7 v2.5.1)

...

The ORC and OBR elements given in Table 4.13-4 shall not be altered after the initial Procedure Scheduled message (Section 4.4), regardless of the type of control code.

Table 4.13-4: Procedure Update Elements that shall not be changed

Element Name	Element Number(s)
Placer Order Number	OBR-2, ORC-2
Filler Order Number	OBR-3, ORC-3
Placer Group Number	ORC-4
<u>Ordering Provider</u>	<u>ORC-12, OBR-16</u>
Study Instance UID	IPC-3

805

Add the following new Section 4.13.4.2.2.1 after Section 4.13.4.2.2

4.13.4.2.2.1 Message Semantics for CDS Information

810 A DSS/Order Filler in the CDS-OAT Profile shall include the OBX segment and may include an NTE segment as defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information.

There shall be one OBX segment and zero or one NTE segment for that OBX per OBR segment in the OMI message.

815 The DSS/Order Filler shall send CDS Information to the Report Manager even if there was no change to the CDS information.

Add new Section 4.13.4.3.1 after Section 4.13.4.3

4.13.4.3 Expected Actions

...

4.13.4.3.1 Expected Actions for CDS Information

825 A Report Manager in the CDS-OAT Profile shall retain and update the CDS information received in the RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information as well as retain and update the Ordering Provider (ORC-12/OBR-16) information. The CDS-OAT Profile places no further requirements on the Report Manager, although the CDS information is available to the Report Manager for inclusion into the report content for charge posting.

4.35 Charge Posted [RAD-35]

830 *Add new rows to the bottom of the table specifying the DFT message segment: Add OBX and NTE rows and fix column 1 heading. Note: Delete the end curly bracket after PR1 (highlighted in yellow for visibility).*

4.35.4.1.2 Message Semantics

DFT Segment Message	Detailed Financial Transaction Message	Chapter in HL7
MSH	Message Header	2
EVN	Event Type	3

DFT Segment Message	Detailed Financial Transaction Message	Chapter in HL7
PID	Patient Identification	3
[PV1]	Patient Visit	3 (Note 1 see note)
{FT1	Financial Transaction	6
[{PR1}]	Procedure	6
[[OBX	Observation/results	<u>7</u>
[[NTE]]] (See Note 2)	Note	<u>2</u>

835 **Note 1:** PV1 is required if use of PV1-19 Visit Number is required per the applicable regional or national extensions to the IHE Radiology Technical framework (see RAD TF-4).

Note 2: Shall be able to support NTE, but can be omitted if no notes are applicable.

Add – a new Section 4.35.4.1.2.1.1 and include all of the text below

840

4.35.4.1.2.1.1 MSH Requirements for CDS Information

Field *MSH-21 Message Profile Identifier* – A DSS/Order Filler in the CDS-OAT Profile shall populate this field with the profile identifier that indicates that this message contains AUC information. See Section 6.4.1.1 HL7 MSH Segment for CDS Information.

845

Add new Section 4.35.4.1.2.7 and include all of the text below

4.35.4.1.2.7 OBX and NTE Segments for CDS Information

A DSS/Order Filler in the CDS-OAT Profile shall include the OBX segment and may include an NTE segment as defined in RAD TF-3: 6.4.1.2: HL7 v.2.9 OBX Segment for CDS Information.

850 The repetition and content of these OBX and NTE segments shall be identical to those segments in the [RAD-2] and [RAD-3] order messages exchanged by the DSS/Order Filler.

Update Table 4.35-5 in Section 4.35.4.2 to add the section reference for the “Order By Code” field.

855 **4.35.4.2 Sources of Information**

Table 4.35-5: Mapping of the FT1 Message

FT1 Field	Field Definition	OPT	HL7 order messages– [RAD-2] and [RAD-3]	Modality Performed Procedure Step [RAD-7]	Manual Input / Department System Scheduler/Order Filler
...					
Order By Code	This field contains the composite number/name of the person/group that ordered the test/ procedure/transaction, etc.	R	ORC-12 Ordering Provider (ORM) <u>(See Section 4.35.4.2.1)</u>		
...					

Add new Section 4.35.4.2.1

860 **4.35.4.2.1 Additional Mapping for the FT1 Segment for CDS Information**

A DSS/Order Filler in the CDS-OAT Profile shall map the components from ORC-12 to FT1-21 “Order By Code” as described in Table 4.35-5.1.

865 *Add new Table 4.35.5-1. This new table will be inserted BETWEEN Table 4.35-5 and 4.35-6*

Table 4.35.5-1: ORC-12 to FT1-21 XCN Mappings

ORC-12 (from RAD TF-2: 4.2.4.1.2.2.4.1)	FT1-21	OPT	Field Value
ORC-12.1	FT1-21.1	R	ID Number
ORC-12.2	FT1-21.2	R	Family Name
ORC-12.3	FT1-21.3	R	Given Name
ORC-12.4	FT1-21.4	O	Second & Further Given Names or Initials
ORC-12.5	FT1-21.5	O	Suffix
ORC-12.6	FT1-21.6	R	Prefix
ORC-12.9	FT1-21.9	R	Assigning Authority
ORC-12.13	FT1-21.13	O	Identifier Type Code

Add the following new Section 4.35.4.3.1 after Section 4.35.4.3 Expected Actions (note that CP-RAD-331 changes the section number for Expected Actions from 4.35.4.2.1.1 to 4.35.4.3.

870 **4.35.4.3 Expected Actions**

...

4.35.4.3.1 Expected Actions for CDS Information

A Charge Processor in the CDS-OAT Profile shall retain:

- 875
- the CDS information received in the OBX Segment for CDS Information as defined in Section 6.4.1.2, and
 - the Order by Code (FT1-21) (Ordering Provider) information

The CDS-OAT Profile places no further requirements on the Charge Processor, although the CDS information is available to the Charge Processor for inclusion into the posted charge.

Volume 3 – Content Modules

880

6 Content Modules

Editor: Add an entire new Section 6.4 and all sub-sections under RAD TF-3:6. Note that the XDR-1 supplement has added RAD TF-3:6.1.

885 *This CDS-OAT Profile also adds an Appendix J to Volume 3.*

6.4 HL7 v2.x Content Modules

This section defines HL7 v2.x message segments.

6.4.1 HL7 v2.x Content Modules for CDS Information

890 Two HL7 message segments are customized for use in the Clinical Decisions Support – Order Appropriateness Tracking (CDS-OAT) Profile.

The MSH Segment is specified in Section 6.4.1.1.

895 The OBX Segment for CDS Information is specified in Section 6.4.1.2 and contains the Clinical Decision Support (CDS) information, and associated Appropriate Use Criteria (AUC), which is propagated throughout the imaging department. This section is either used in the context of the Radiology Technical Framework, or this section can be used on its own to inform how to communicate AUC information as part of an order or charge message based on any HL7 V2 version.

900 Each OBX Segment for CDS Information may have up to one NTE segment associated with it as specified in Section 6.4.1.2.1. The NTE segment cannot exist without the OBX segment.

To recognize that an order or charge message contains an AUC OBX (plus possible associated NTE), the MSH segment shall contain the appropriate Message Profile Identifier as specified in Section 6.4.1.1 HL7 MSH Segment for CDS Information.

905 See Appendix J (Clinical Decision Support (CDS) and Appropriate Use Criteria (AUC) Data Explanation) for an informative discussion on the source and intended use of the data defined in this OBX segment.

Add the following 6.4.1.1 section

910 **6.4.1.1 MSH Segment for CDS Information**

Table 6.4.1.1-1 specifies an addition requirement for the MSH segment in HL7 messages that contain CDS Information in an OBX segment as specified in Section 6.4.1.2.

915 As AUC data is not necessary in all order and charge messages, and that it can be used in messages that otherwise do not conform to the Radiology Technical Framework, and that the OBX carrying the AUC information uses an HL7 v2.9 definition, receivers could benefit from having awareness that the message includes at least one OBX that conforms to this guide, thus invoke the appropriate parser. MSH-21 Message Profile Identifier provides that information, thus shall be included in any message that uses the OBX specification in Section 6.4.1.2 to communicate AUC information.

920 **Table 6.4.1.1-1: IHE Profile – MSH Segment for CDS Information**

SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
21		EI	R	Y		01598	Message Profile Identifier

Specifically, the CDS Information MSH elements are defined as:

- *MSH-21 Message Profile Identifier* shall include the profile identifier for Order/Charge Message Containing AUC Information profile component
 - 925 ○ *MSH-21.1* – Value “CDS-OAT” for messages in the CDS-OAT Profile, or value “AUC_Information_Component” when only one or more AUC OBX/NTE is included in the message (i.e., any HL7 v2.x message is being used to convey AUC information).
 - 930 ○ *MSH-21.3* – Value “1.3.6.1.4.1.19376.1.1.1.39.1” for messages in the CDS-OAT profile or value “1.3.6.1.4.1.19376.1.1.1.39.2” when only one or more AUC OBX/NTE is included in the message (i.e., any HL7 v2.x message is being used to convey AUC information).
 - *MSH-21.4* – “ISO”

6.4.1.2 HL7 v.2.9 OBX Segment for CDS Information

935 To enable communication of all AUC information, the HL7 v2.9 OBX segment definition has been adopted. In particular, the Interpretation Code data type, Observation Instance Identifier field, Observation Type, and Observation Value Absent Reason are needed to fully represent AUC information.

940 Table 6.4.1.2-1 specifies the OBX segment for CDS Information, identifying the optional, required and prohibited elements. Several elements have been promoted from Optional in HL7

v2.9 to Required in this content module. IHE uses optionality “R+” to identify the elements that have been promoted. All OBX elements not listed in Table 6.4.1.2-1 are optional.

Table 6.4.1.2-1: IHE Profile – HL7 v2.9 OBX Segment for CDS Information

SEQ	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME
2	ID	C(X/R) (Note 2)		0125	00570	Value Type
3	CWE	R (Note 1)			00571	Observation Identifier
5	CWE	C(X/R)			00573	Observation Value
8	CWE	C(X/R)		0078	00576	Interpretation Codes
11	ID	R		0085	00579	Observation Result Status
13	ST	O			00581	User Defined Access Checks
15	CWE	C(X/R)			00583	Producer’s ID Reference
17	CWE	O			00936	Observation Method
19	DTM	C(X/R)			01480	Date/Time of the Analysis
21	EI	R+			02180	Observation Instance Identifier
29	ID	O		0936	03432	Observation Type
32	CWE	C(R/X)	Y		09604	Observation Value Absent Reason

Adapted from the HL7 Standard, version 2.9

945 Note 1: This is an HL7 v2.9 based table to enable communication of AUC information and is only used for an OBX that reports on an appropriate use consultation. The value of OBX-3 Observation Identifier being equal to 76515-6, LOINC 2.16.840.1.113883.6.1, “Requested Procedure is Appropriate” indicates to the receiver of the OMG that the content of the OBX should be interpreted per the specification in this table.

Note 2: The C(a/b) notation is defined according to HL7 v2.9 Chapter 2, Section 2.5.3.5. It states:

950 If the condition predicate associated with the element is true, follow the rules for a which shall be one of “R”, “RE”, “O” or “X”.
 If the condition predicate associated with the element is false, follow the rules for b which shall be one of “R”, “RE”, “O” or “X”.
 Values for a and b can be the same.

955

Specifically, the CDS Information OBX elements are defined as:

- *OBX-2 Value Type* shall be “ST” (String).

Condition C(X/R): If no AUC score was provided by the CDSM, then OBX-2 shall be empty and OBX-32 shall contain the reason for the exception.

- 960
- *OBX-3 Observation Identifier* shall contain the LOINC code for “Procedure Appropriate to Indication”.
 - *OBX-3.1* – “76515-6”
 - *OBX-3.2* – “Requested Procedure is Appropriate”

- *OBX-3.3* – “LN”
- 965
- *OBX-3.14* – “2.16.840.1.113883.6.1” (optional)
 - *OBX-5 Observation Value* shall contain the score as calculated by the CDSM for the AUC method used.
Condition C(X/R): If no AUC consultation was performed, then OBX-5 shall be empty and OBX-32 shall contain the reason for the exception.
- 970
- *OBX-8 Interpretation Codes* shall contain the interpretation of the observation to its appropriateness.
 - *OBX-8.1* – the interpretation code (required)
 - *OBX-8.2* – the description of the interpretation code (optional)
 - *OBX-8.3* – the coding system (required)
- 975
- Condition C(X/R): If no AUC consultation was performed, then OBX-8 shall be empty and OBX-32 shall contain the reason for the exception.
- *OBX-11 Observation Result Status* shall be “O” (Order Detailed Description).
 - *OBX-13 User Defined Access Checks* may contain the decision “branch number” which is specific to the Appropriate Use Criteria identified in OBX-17.
- 980
- *OBX-15 Producer’s ID Reference* shall contain the CDSM identifier.
 - *OBX-15.1* – the code for the CDSM (required)
 - *OBX-15.2* – the name of the CDSM (optional)
 - *OBX-15.3* – the code system used (required)
- 985
- Condition C(X/R): If no AUC consultation was performed, then OBX-15 shall be empty and OBX-32 shall contain the reason for the exception.
- *OBX-17 Observation Method* may contain the Appropriate Use Criteria method used.
 - *OBX-17.1* – code for the AUC method (required)
 - *OBX-17.2* – description of the AUC method (optional)
 - *OBX-17.3* – coding system defining the different AUC methods (required)
- 990
- If there is no common coding system for appropriate use criteria methods, then a local coding system shall be defined.
- *OBX-19 Date/Time of the Observation* shall contain the date and time when the EHR received the AUC information.
Condition C(X/R): If no AUC consultation was performed, then OBX-19 shall be empty and OBX-32 shall contain the reason for the exception.
- 995

- *OBX-21 Observation Instance Identifier* shall contain the unique identifier of the decision returned by the CDS system. If no AUC consultation was performed, then OBX-21 shall be empty and OBX-32 shall contain the reason for the exception.

1000

Note: In the HL7 v2.5.1 standard, OBX-21 is marked as “Reserved for harmonization with HL7 v2.6”, but is identified as “Observation Instance Identifier” in HL7 v2.6, which is used in Table 6.4.1.2-1 above.

- *OBX-21.1* – the identifier issued by the CDSM (required)
- *OBX-21.2* – the OID representing the CDSM that issued the identifier (required if known)

1005

- *OBX-29 Observation Type* may contain the type of observation this Observation/Result Segment is representing. When using observation types to easily distinguish various results in a message, e.g., actual results in response to an order from echoed back ask at order entry questions, or ask at order entry questions vs. supporting clinical information, it shall contain “SCI” for the OBX segment containing AUC information.

1010

- *OBX-32 Observation Value Absent Reason* shall contain the code for why the AUC consultation was not performed (e.g., hardship or unavailability of the CDSM).

- *OBX-32.1* – the code for the absent reason (required)
- *OBX-32.2* – the description of the absent reason (optional)
- *OBX-32.3* – the code system used (required)

1015

Condition (R/X): If an AUC consultation is not performed (and thus OBX-2, OBX-5, OBX-8, OBX-15, OBX-19, and OBX-21 are empty), then OBX-32 shall contain the absent reason. Otherwise, it shall be empty.

Note: OBX-32 shall be valued if an AUC consultation is required but no consultation was performed. However, if an AUC consultation is not required, e.g., inpatient hospital services, then the entire OBX is omitted.

1020

6.4.1.2.1 HL7 v.2.5.1 NTE Segment of OBX for CDS Information

There may only be one CDS NTE segment per CDS OBX segment. If a CDS NTE segment is included, it shall be persisted by the receiver.

Table 6.4.1.2.1-1 specifies the NTE segment for CDS Information. All NTE elements not listed in the table are optional.

1025

Table 6.4.1.2.1-1: IHE Profile – HL7 v2.5.1 NTE Segment for CDS Information

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
2	8	ID	R+	0105	00097	Source of Comment
3	65536	FT	R+		00098	Comment

Adapted from the HL7 Standard, version 2.5.1

Specifically, the CDS Information NTE elements are defined as:

- 1030
- *NTE-2 Source of Comment* shall contain the value “O” (Other system) taken from HL7 Table 0105 – Source of Comment.
 - *NTE-3 Comment* is a free format text field. It shall contain comments by the ordering provider regarding the AUC information.

1035

Note: The CDS service is distinct from the AUC rules. An AUC rule set might be implemented by multiple CDS services, and, conversely, a CDS service might evaluate against multiple AUC rules.

Note: In the U.S. it is assumed that Centers for Medicare & Medicaid Service (CMS) will provide a coding scheme to identify the various CDS mechanisms (CDSM). Other code schemes may be used for other payers.

1040

Note: In the United States, the Department of Health and Human Services will certify and register specific CDS software or services for advanced imaging procedures, and that CDSM identifier might be used as the id extension with HHS as the assigning authority root.

Appendices

1045

Editor: Add new Appendix to Volume 3 as Appendix J.

Appendix J – Clinical Decision Support (CDS) and Appropriate Use Criteria (AUC) Data Explanation

1050 The purpose of this appendix is to explain the source of use of the CDS and AUC information which is propagated throughout the imaging department in the Clinical Decisions Support – Order Appropriateness Tracking (CDS-OAT) Profile. This appendix is informative.

The following is being used to identify the CDS information:

- The question asked is “Is the Procedure Appropriate to Indication?”
- 1055 • The response is typically a score that is interpreted as one of:
 - Yes
 - No
 - No criteria available

The AUC/CDS information being captured is:

- 1060 • CDS score
- CDS Response on appropriateness (yes, no, no criteria available)
- Some CDS systems respond with the “branch of logic” which was used to provide the CDS response. (optional data element)
- The date and time that the EHR received the AUC information.
- 1065 • The name and identifier of the mechanism or technology (software implementation) that was used to obtain the CDS result.
- The name and identifier of the Appropriate Use Criteria (AUC) method/guidelines that were used by the CDS mechanism to obtain the CDS result (optional data element).
- 1070 • A unique identifier generated by the CDS system when this CDS result (instance) was obtained. This unique identifier may be used as an index back into the CDS to identify other parameters.

Note: In the U.S., the CMS legislation currently requires the following data elements to be recorded for submission to CMS:

- Which CDS system (mechanism) was used?

- 1075
- What was the CDS result (adheres, does not adhere, no criteria available)?
 - National Provider Identify (NPI) of the ordering physician

Additional information in the order transactions for the U.S. include:

- 1080
- The Ordering Provider is assumed to be the same as the Ordering Provider identified in ORC-12. In the U.S., the Ordering Physician can be a mid-level provider (e.g., a nurse practitioner or physician assistant).

Note: Either the NPI will be included in ORC-12 or, the Charge Processor could obtain after the fact, as is done today.

- The Requested Procedure Code that defines the requested service that the CDS system shall be the same as identified in OBR-4.

- 1085
- It is the intent of the CDS-OAT Profile that the information described above is captured in the OBX segment for CDS Information.

<i>Add new Section 5.2 to RAD TF-4.</i>

1090

5 National Extensions for IHE United States

...

5.2 CDS-OAT Profile Extensions

- 1095
- Order Placer Actors in the Clinical Decisions Support – Order Appropriateness Tracking (CDS-OAT) Profile encode details about the Ordering Provider in ORC-12 and OBR-16 as specified in RAD TF-2: 4.2.4.1.2.2.4.1.

In the US, the components of ORC-12 and OBR-16 are restricted as follows:

- 1100
- *ORC-12.1, OBR-16.1 and FTI-21.1 ID Number* shall contain the National Provider Identifier (NPI) value. This NPI value may represent a mid-level provider such as a nurse practitioner (NP) or physician’s assistant (PA).
 - *ORC-12.9, OBR-16.9 and FTI-21.9 Assigning Authority* shall contain the NPI Assigning Authority values for the Universal ID, and the Universal ID Type.
 - i.e., *ORC-12.9 and OBR-16.9* shall contain:
 &2.16.840.1.113883.4.6&ISO
 - *ORC-12.13, OBR-16.13 and FTI-21.13 Identifier Type Code* shall contain “NPI”.

1105