

Integrating the Healthcare Enterprise



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**IHE Radiology
Technical Framework Supplement**

10

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

15

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 V15.0. 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 September 9, 2016 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
35 Technical 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.

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<i>Amend Section X.X by the following:</i>
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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.

45

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
50 <http://ihe.net/Profiles>.

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

There are two profiles within IHE to support Clinical Decision Support (CDS), one each in the Radiology and PCC domains.

- 145 1. The CDS Profile in IHE Patient Care Coordination (PCC) – Guideline Appropriate Ordering (GAO) -- focuses on obtaining the CDS information and the interaction between the Order Placer and the CDS system.
2. The CDS Profile in IHE Radiology -- Clinical Decision Support Order Appropriateness Tracking (CDS-OAT) -- focuses on the downstream workflow and data propagation.

150 This supplement contains the CDS-OAT Profile. It is intended to propagate the Clinical Decision Support and Appropriate Use Criteria (AUC) information throughout the existing Radiology Scheduled Workflow transactions.

The business driver for CDS in the U.S. is the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Service (CMS), although the solution in these two profiles is intended to be broader than the CMS requirements.

155 Open Issues and Questions

1. Open Issue: When the IHE PCC GAO Profile goes to Trial Implementation, determine whether there are any Change Proposals needed to this supplement to keep the two profiles in sync. Resolution 5/7/2015: Wait for IHE PCC GAO to be published for TI, targeted for Aug/Sep 2015.

160 Closed Issues

- 165 1. The current profile reflects the decision to exclude all of the DICOM^{®1} transactions of 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: Determined to be adequate.
- 170 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.
3. In Volume 3 of this Supplement, the CDS information is mapped to an OBX segment. Is there a different HL7^{®2} v2.5.1 message segment which would be more appropriate such

¹ DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

² HL7 is the registered trademark of Health Level Seven International.

- 175 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 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.
- 220 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”.
- 225 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 IHE Radiology. The IHE Radiology Volume 3 contains additional Volume 2 transactions. Closed: Dealt with as Section 6.X.1.1 in Volume 3.
- 230 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 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.

235 **General Introduction**

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

Appendix A – Actor Summary Definitions

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

240

No new actors.

Appendix B – Transaction Summary Definitions

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

245

No new transactions.

Glossary

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

250

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).

Volume 1 – Profiles

Add new Section 39:

255 **39 Clinical Decision Support - Order Appropriateness Tracking (CDS-
OAT) Profile**

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

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.

265 CDS systems implement AUC in computerized healthcare systems. A CDS system 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.

270 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 confirmation of appropriateness. Other information includes the AUC guidelines and version which were used, the vendor and software which implemented the CDS system, and other relevant information.

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.

275 The CDS-OAT Profile assumes that the CDS and AUC information has been obtained using the IHE PCC Guideline Appropriate Ordering (GAO) Profile or by some other means. 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.

280 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.

285 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 profiles. The CDS-OAT Profile also defines “content” -- a common data set for the CDS information in the form of an HL7 v2.5.1 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 X.6: Cross Profile
290 Considerations.

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

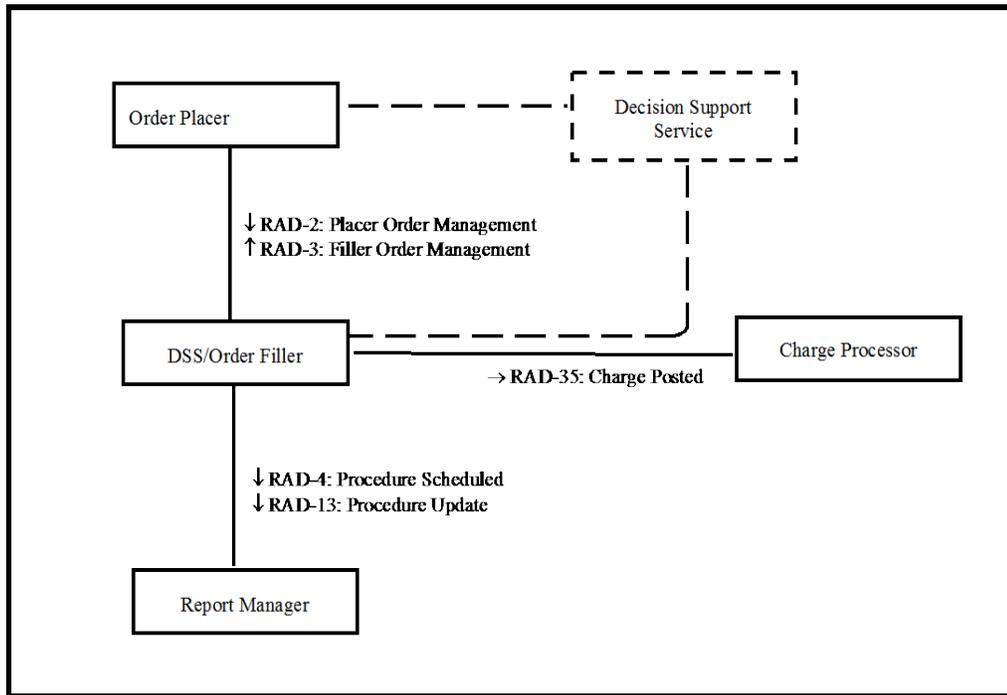
reason for study, this relevant information is not included in this profile. It is enumerated in the [IHE Code Mapping in IHE Radiology Profiles White Paper](#).

295 **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.

300 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.



305

Figure 39.1-1: CDS-OAT Actor Diagram

310 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	IRAD 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)
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-4] and [RAD-13] transactions.

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320

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	HL7 v.2.5.1 OBX Segment for CDS Information	R	RAD TF-3: 6.X.1.1
DSS/Order Filler	HL7 v.2.5.1 OBX Segment for CDS Information	R	RAD TF-3: 6.X.1.1
Report Manager	HL7 v.2.5.1 OBX Segment for CDS Information	R	RAD TF-3: 6.X.1.1
Charge Processor	HL7 v.2.5.1 OBX Segment for CDS Information	R	RAD TF-3: 6.X.1.1

39.1.1 Actor Descriptions and Actor Profile Requirements

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

325 **39.1.1.1 Support for HL7 v2.5.1 Message Semantics**

- 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-3:4.3.4.1.2.2. These transactions shall include the HL7 v.2.5.1 OBX Segment for CDS Information. See RAD TF-3: 6.X.1.1.
- 330 • 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 v.2.5.1 OBX Segment for CDS Information. See RAD TF-3: 6.X.1.1.
- 335 • 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 v.2.5.1 OBX Segment for CDS Information. See RAD TF-3: 6.X.1.1.

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	-

340

39.3 CDS-OAT Required Actor Groupings

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

345 **39.4.1 Concepts**

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

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

350 This profile introduces a content module for CDS information. This CDS information is defined in RAD TF-3: 6.x.1.1.

39.4.1.1 Ordering Physician

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).

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

39.4.1.2 Obtaining the CDS information for an order

360 There are two primary ways in which an OP or a DSS/OF can obtain CDS information. If the OP 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.2.5.1 OBX Segment for CDS Information” content module of this profile.

365 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 OP or DSS/OF system is responsible for having a method to input the CDS system into the order such that the “HL7 v.2.5.1 OBX Segment for CDS Information” content module can be accurately and adequately completed.

370 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

375 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.).

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.

380 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

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

- 385
- Scheduled time is no longer convenient
 - Pre-authorization not received

- Patient is ill
- Transportation
- Work issue

390 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.)
- Patient cannot comply with technologist or radiologist instructions

395

- 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

400 As described in more detail in the IHE Radiology 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 in the OBX segment, unchanged, to the Charge Processor, typically as the last
405 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.

410 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

415 An order is created at an Order Placer (OP) 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).

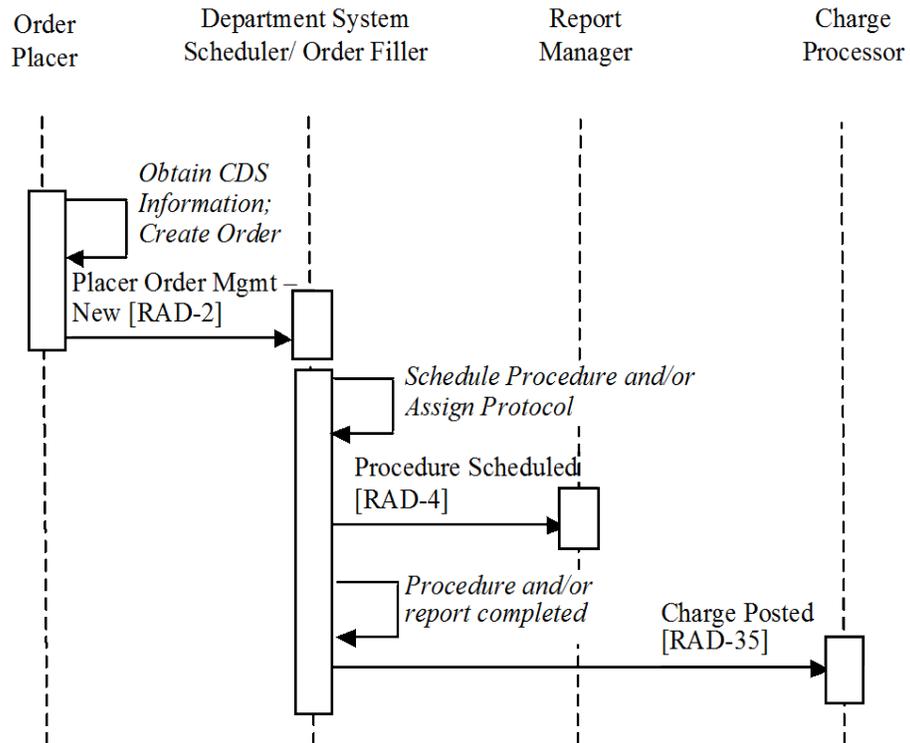
420 When the procedure is scheduled or protocolled, the DSS/OF sends a Procedure Scheduled [RAD-4] message to the Report Manager, often to assist with the reporting workflow. After the

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.

425 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.

430 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 actor. The report creation and charge generation are outside the scope of this profile.



435

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

440 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
445 “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
450 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 message [RAD-13].

455 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.

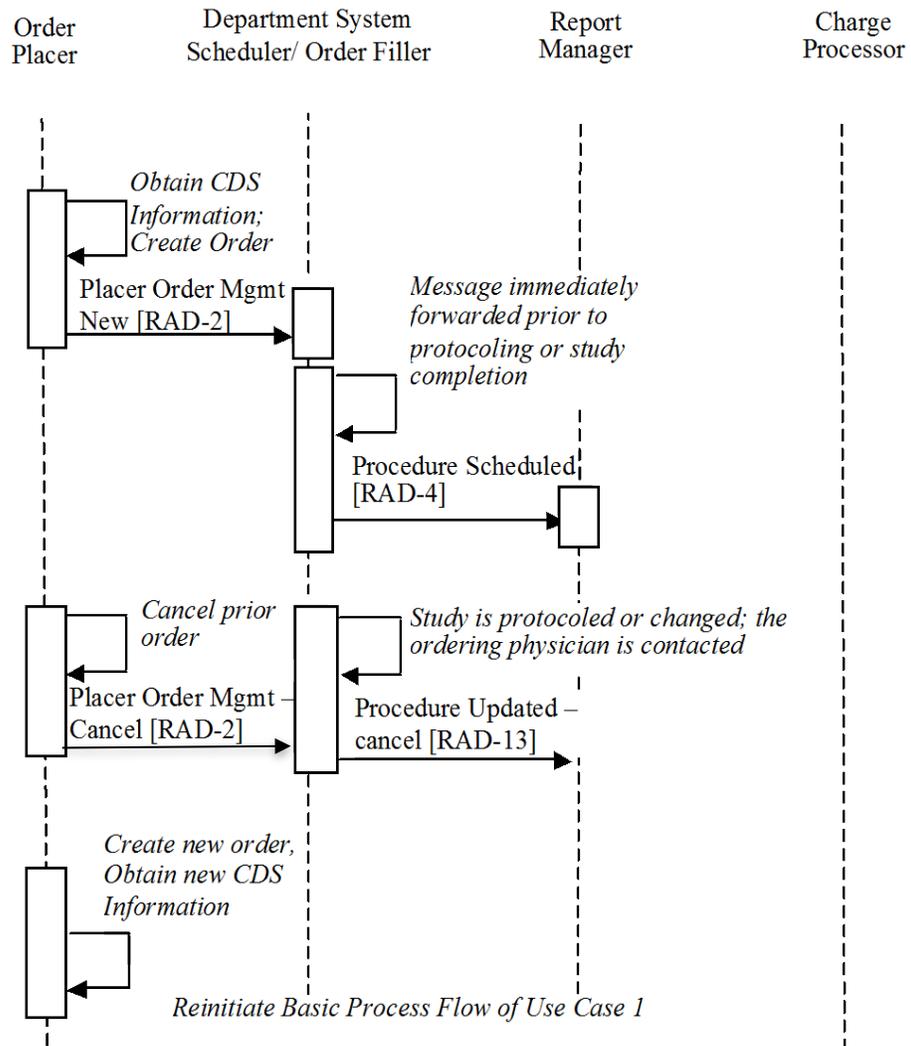


Figure 39.4.2.2-1: Use Case 2: Significant CDS Order Change in CDS-OAT Profile, order canceled at OP

460 **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.

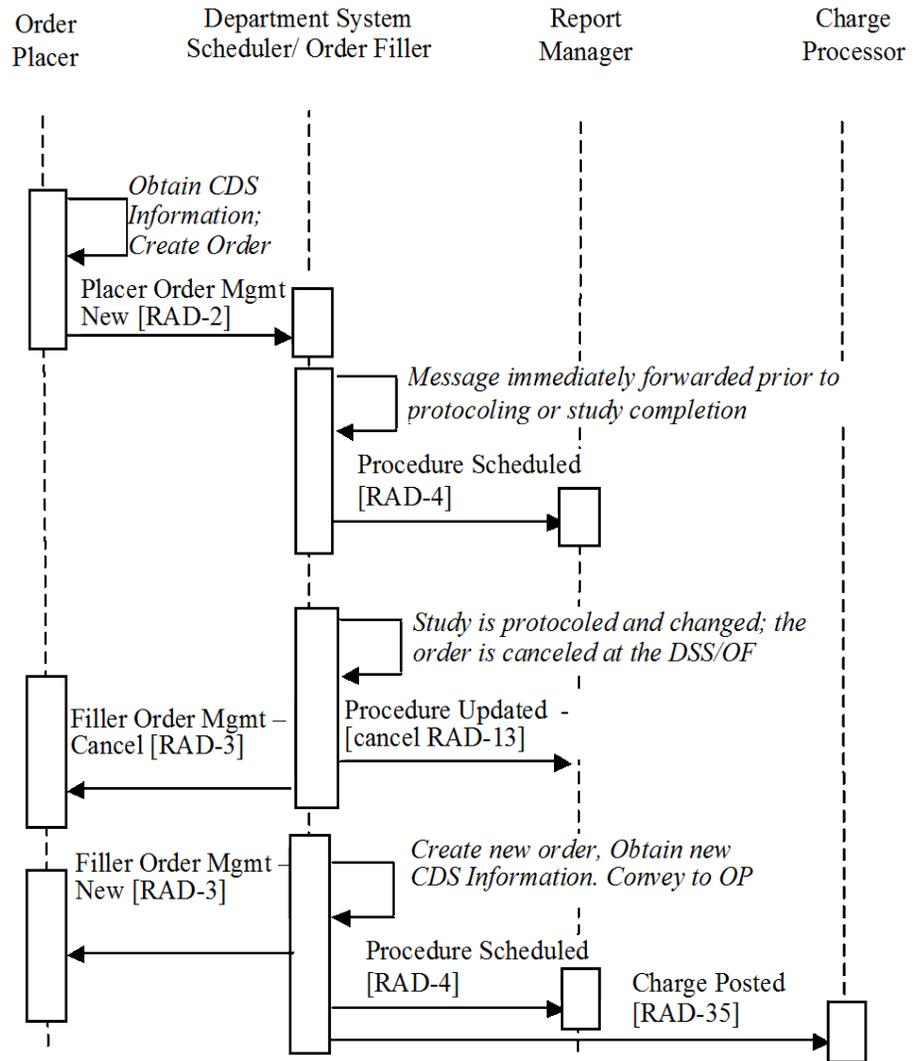
465 An example of a “significant change” is an additional body part is included in the study which

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.

470 *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
475 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 Posting [RAD-35] transaction after the study is completed.



480

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

485

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.

490 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.

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

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.

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

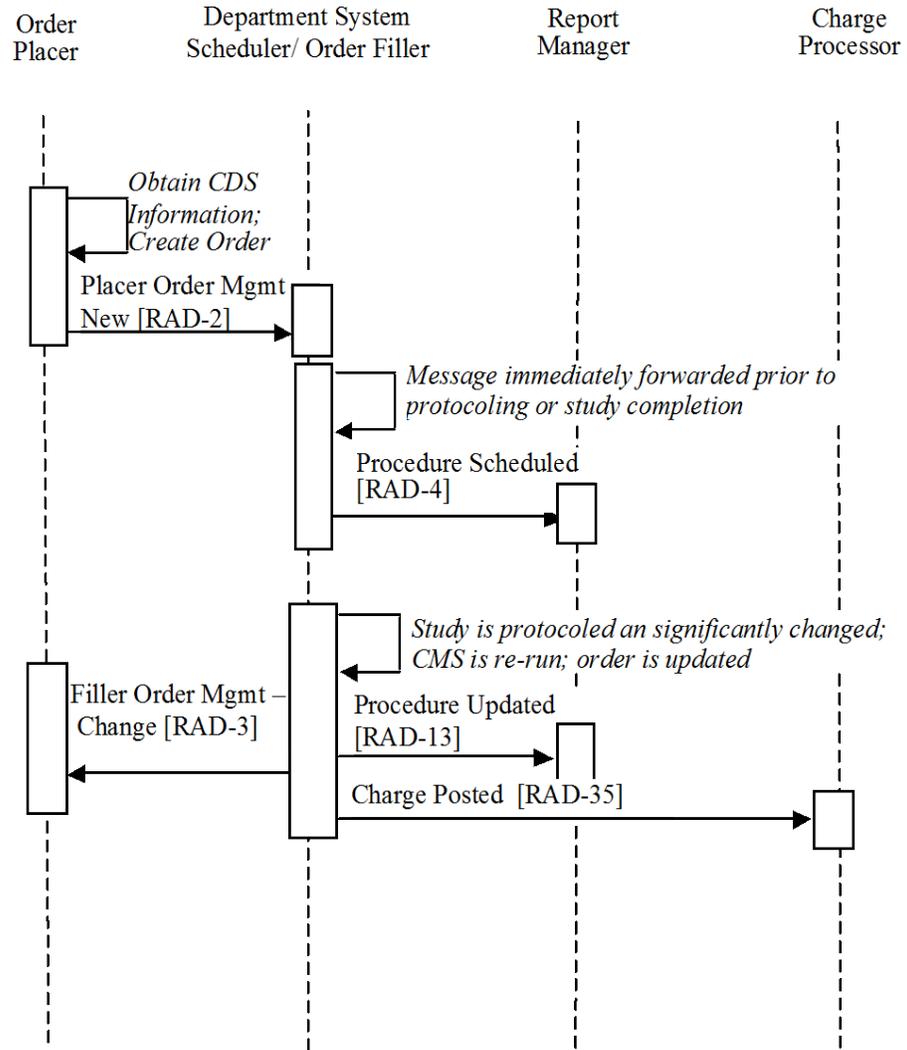


Figure 39.4.2.4-1: Use Case 4: Significant CDS Order Change in CDS-OAT Profile, new CDS information is obtained at DSS/OF, order updated by DSS/OF

505

510 **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.

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.

520 **39.4.2.6 Use Case 6: Order received without CDS information**

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.

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

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

530 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.

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.

535 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.

540

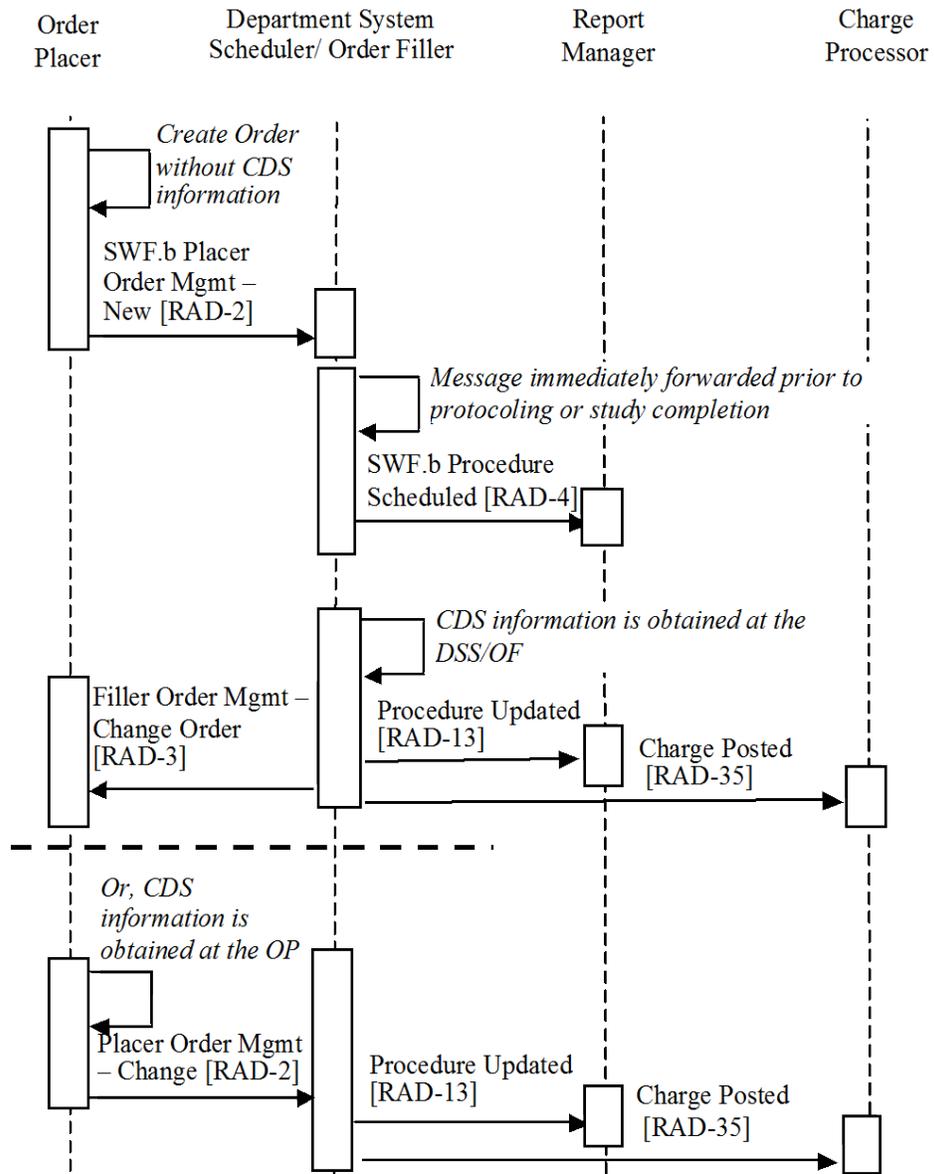


Figure 39.4.2.6-1: Use Case 6: Order received without CDS information

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 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.

555

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

565

The Radiology SWF.b Security Considerations and the IHE PCC GAO Security Considerations are summarized here and apply to this profile as well. Please see the other profiles for additional details.

The summary of the security considerations for this profile include:

39.5.1 Fraud

570

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.

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

575

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.
3. Replay: In a replay attack, known good responses to challenges are repeated in order to duplicate the positive outcome.

- 580 4. Gaming: Users of the system could be incented 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

585 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.

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.
- 590 • 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.
- 595 • 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

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

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 IHE Patient Care Coordination Guideline Appropriate Ordering (GAO) Profile.

If the CDS-OAT Order Placer also supports for the Authorization Requestor in IHE PCC Guideline Appropriate Ordering Profile, the Order Placer will have direct access to the CDS information obtained in the IHE PCC GAO Profile.

610 The IHE PCC GAO Authorization Requester could be grouped with both the CDS-OAT Order Placer (OP) and the CDS-OAT Department System Scheduler/Order Filler (DSS/OF).

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.

615

Volume 2 – Transactions

620

*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 15.0, 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.*

625

4.2 Placer Order Management [RAD-2]

...

4.2.4.1.2.2 Message Semantics (HL7 v2.5.1 option)

630

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.

...

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]]</u>	<u>Note</u>	<u>2</u>

635

Add – a new section as numbered and include all of the text below, including the table. Note that the new table does not have a table number. This was done for consistency since none of the smaller mappings tables in this section have table numbers.

4.2.4.1.2.2.4.1 ORC Requirements for CDS Information

640 **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.**

ORC-12 and OBR-16 XCN Identical Mappings

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

Note 1: In the U.S.:

- 645
- **Component 1 shall contain the National Provider Identifier (NPI) ID value**
 - **Component 9 shall contain the NPI Assigning Authority including the Assigning Authority ID, the Universal ID, and the Universal ID Type. This NPI ID value may represent a mid-level provider such as a nurse practitioner (NP) or physician’s assistant (PA).**
- 650
- **Component 13 shall contain Identifier Type Code “NPI”**

Make the following updates to Section 4.2.4.1.2.2.6

655 **4.2.4.1.2.2.6 OBR Segment (HL7 v2.5.1 option)**

...

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.

660 **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.**

665 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*.

...

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>

670

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

4.2.4.1.2.2.7 OBX Segment – CDS Information

675 **An Order Placer in the CDS-OAT Profile shall include the OBX and NTE segments as defined in RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information.**

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

680 *Add new Section 4.2.4.1.3.1 below at the bottom of Section 4.2.4.1.3*

4.2.4.1.3 Expected Actions

...

4.2.4.1.3.1 Expected Actions – CDS Information

685 **A DSS/Order Filler in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information as well as retain the Ordering Provider (ORC-12/OBR-16) information.**

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.

690

4.3 Filler Order Management [RAD-3]

...

4.3.4.1.2.2 Message Semantics (HL7 v2.5.1 option)

695

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.

...

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]]</u>	<u>Note</u>	<u>2</u>

700

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

705

Field ORC-12 Ordering Provider- A DSS/OF 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.

Make the following updates to Section 4.3.4.1.2.2.7

710 **4.3.4.1.2.2.7 OBR Segment (HL7 v2.5.1 option)**

...

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* - 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 Section 4.2.4.1.2.2.4.1.**

720 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*.

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

4.3.4.1.2.2.9 OBX Segment – CDS Information

725 **A DSS/Order Filler in the CDS-OAT Profile shall include the OBX and NTE segments as defined in RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information.**

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

730 *Add new Section 4.3.4.2.3.1 at the bottom of Section 4.3.4.2.3*

4.3.4.2.3 Expected Actions

...

4.3.4.2.3.1 Expected Actions – CDS Information

735 **An Order Placer in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information as well as retain the Ordering Provider (ORC-12/OBR-16).**

4.4 Procedure Scheduled [RAD-4]

740 4.4.4.1.2.2 Message Semantics (HL7 v2.5.1 option)

Add a new row 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
{ IPC } }	Imaging Procedure Control	4
<u>[[OBX</u>	<u>Observation/results</u>	<u>7</u>
<u>NTE]]</u>	<u>Note</u>	<u>2</u>

745

Make the following updates to Section 4.4.4.1.2.2.5

4.4.4.1.2.2.5 ORC Segment (HL7 v2.5.1 Option)

750 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

Adapted from the HL7 Standard, version 2.5.1

755 **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/OF 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.

760

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)

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.

765

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.

770

...

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

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Element Name	Seq.	Shall Contain:	Notes
			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/OF 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.
...			

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

4.4.4.1.2.2.9 OBX Segment – CDS Information

775

A DSS/Order Filler in the CDS-OAT Profile shall include the OBX and NTE segments as defined in RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information.

There shall be one OBX segment and one NTE segment per OBR segment in the OMI message.

780

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

4.4.4.2 Expected Actions

4.4.4.2.1 Use Cases

...

785 **4.4.4.2.2 Expected Actions – CDS Information**

A Report Manager in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.X.1.1: HL7 v.2.5.1 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.

790

4.13 Procedure Updated [RAD-13]

Edit Table 4.13-4 in Section 4.13.4.2.2 as follows

795 **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.

800 **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

Add – the following new section after the bottom of Section 4.13.4.2.2

4.13.4.2.2.1 Message Semantics – CDS Information

805 **A DSS/Order Filler in the CDS-OAT Profile shall include the OBX and NTE segments as defined in RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information.**

There shall be one OBX segment and one NTE segment per OBR segment in the OMI message.

810 **The DSS/Order Filler shall send CDS Information to the Report Manager even if there was no change to the CDS information. That is, the OBX and NTE segments shall be included in every [RAD-13] transaction in the CDS-OAT Profile.**

Add new Section 4.13.4.3.1 below at the bottom of Section 4.13.4.3

815 **4.13.4.3 Expected Actions**

...

4.13.4.3.1 Expected Actions – CDS Information

820 **A Report Manager in the CDS-OAT Profile shall retain and update the CDS information received in the RAD TF-3: 6.X.1.1: HL7 v.2.5.1 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.**

825 *Editor: Please note that CP-RAD-322 “Extend RAD-35 for HL7 v2.5 Semantics should be incorporate into this supplement first. Else, CP-RAD-322 is required to be added at the same time as this CDS-OAT Supplement!*

4.35 Charge Posted [RAD-35]

830

Add a new row to the bottom of the table specifying the DFT message segment: Add OBX and NTE rows and fix column 1 heading.

4.35.4.1.2 Message Semantics

<u>DFT Segment Message</u>	Detailed Financial Transaction Message	Chapter in HL7 2.3.1 and HL7 2.5
MSH	Message Header	2
EVN	Event Type	3
PID	Patient Identification	3
[PV1]	Patient Visit	3 (see note)
{FT1} <u>{FT1}</u>	Financial Transaction	6
[[PR1]]	Procedure	6
<u>{OBX}</u>	<u>Observation/results</u>	<u>7</u>
<u>{NTE}}</u>	<u>Note</u>	<u>2</u>

835

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

4.35.4.1.2.7 OBX and NTE Segments – CDS Information

840

A DSS/Order Filler in the CDS-OAT Profile shall include the OBX and NTE segments as defined in RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information. 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.

Add the section reference for the “Order By Code” field.

845

4.35.4.2 Sources of Information

Table 4.35-5: Mapping of the FT1 Message

FT1 Field	Field Definition	OPT	HL7 – ADT and ORM Segments	Modality Performed Procedure Step	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

850

4.35.4.2.1 Additional Mapping for the FT1 Segment – CDS Information

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

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

855

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

<u>ORC-12</u> <u>(from RAD</u> <u>TF-</u> <u>2:4.2.4.1.2.</u> <u>2.4.1)</u>	<u>FT1-21</u>	<u>OPT</u>	<u>Field Value</u>
<u>ORC-12.1</u>	<u>FT1-21.1</u>	<u>R</u>	<u>ID Number</u>
<u>ORC-12.2</u>	<u>FT1-21.2</u>	<u>R</u>	<u>Family Name</u>
<u>ORC-12.3</u>	<u>FT1-21.3</u>	<u>R</u>	<u>Given Name</u>
<u>ORC-12.4</u>	<u>FT1-21.4</u>	<u>O</u>	<u>Second & Further Given</u> <u>Names or Initials</u>
<u>ORC-12.5</u>	<u>FT1-21.5</u>	<u>O</u>	<u>Suffix</u>
<u>ORC-12.6</u>	<u>FT1-21.6</u>	<u>R</u>	<u>Prefix</u>
<u>ORC-12.9</u>	<u>FT1-21.9</u>	<u>R</u>	<u>Assigning Authority</u>
<u>ORC-12.13</u>	<u>FT1-21.13</u>	<u>O</u>	<u>Identifier Type Code</u>

Add – the following new section to the bottom of 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.

860 **4.35.4.3 Expected Actions**

...

4.35.4.3.1 Expected Actions – CDS Information

865 **A Charge Processor in the CDS-OAT Profile shall retain the CDS information received in the RAD TF-3: 6.X.1.1: HL7 v.2.5.1 OBX Segment for CDS Information as well as retain 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

870 **6 Content Modules**

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

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

875

6.X HL7 v2.5.1 Content Modules

This section defines HL7 v2.5.1 message segments.

6.X.1 HL7 v2.5.1 Content Modules for CDS Information

880 The OBX Segment for CDS Information is specified in Section 6.X.1.1 and contains the Clinical Decision Support (CDS) information, and associated Appropriate Use Criteria (AUC), which is propagated throughout the imaging department.

Each OBX Segment for CDS Information shall have one and only one NTE segment associated with it as specified in Section 6.X.1.2. The NTE segment cannot exist without the OBX segment.

885 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.

6.X.1.1 HL7 v2.5.1 OBX Segment for CDS Information

890 Table 6.X.1.1-1 specifies the OBX segment for CDS Information. Optional, required and prohibited elements are specified. Several elements have been promoted from Optional in HL7 v2.5.1 to Required in this content module. IHE uses optionality “R+” to identify the elements that have been promoted. HL7 v2.5.1 uses optionality “X” to identify the elements which shall not be sent. All OBX elements not listed in Table 6.X.1.1-1 are optional.

Table 6.X.1.1-1: IHE Profile – HL7 V2.5.1 OBX Segment - CDS Information

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
2	2	ID	R+	0125	00570	Value Type
3	250	CE	R		00571	Observation Identifier
5	9999	CE	R+		00573	Observation Value
8	5	ID	X	0078	00576	Abnormal Flag
11	1	ID	R	0085	00579	Observation Result Status
13	20	ST	O		00581	User Defined Access Checks
14	26	TS	O		00582	Date/Time of the Observation
15	250	CE	X		00583	Producer’s ID Reference
17	250	CE	R+		00936	Observation Method

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
21	427	EI	R+		02180	V2.6 Observation Instance Identifier

895

Adapted from the HL7 Standard, version 2.5.1

Specifically, the CDS Information OBX elements are defined as:

900

- Element OBX-2 Value Type shall be “CE” (Coded Entry).
- Element OBX-3 Observation Identifier shall contain the LOINC code for “Procedure Appropriate to Indication”. (76515-6, LOINC 2.16.840.1.113883.6.1, “Requested Procedure is Appropriate”)
- Element OBX-5 Observation Value -The observation value shall contain the Appropriate Use Criteria’s determination as Yes, No, or Not Applicable. (NOTE: OBX-5 is the answer to the question “Is the imaging procedure deemed to be appropriate?”)

905

- The value for OBX-5 shall be one of:
 - Yes (LA33-6, LOINC 2.16.840.1.113883.6.1, “Yes”)
 - No (LA32-8, LOINC 2.16.840.1.113883.6.1, “No”)
 - No Criteria Available (LA4720-4, LOINC 2.16.840.1.113883.6.1, “Not Applicable”)

910

- Element OBX-8 Abnormal Flags –A value for Abnormal Flag shall not be sent.
- Element OBX-11 Observation Result Status shall be “O” (Order Detailed Description).
- Element OBX-13 User Defined Access Checks - may contain the decision “branch number” which is specific to the Appropriate Use Criteria identified in OBX-17.
- Element OBX-14 Date/Time of the Observation - may contain the date and time at which the CDS system returned the appropriateness decision.

915

- Element OBX-15 Producer’s ID Reference –A value for Producer’s ID Reference shall not be sent. (See NTE segment below.)
- Element OBX-17 Observation Method shall identify the Appropriate Use Criteria method used.

920

- Note: In the U.S., it is assumed that CMS will provide a coding scheme to identify the various AUC methods.

925

- Element OBX-21 Observation Instance Identifier– shall contain the unique identifier of the decision returned by the CDS system.
 - Note when referencing the HL7 v2.5.1 standard: OBX-21 is marked as “Reserved for harmonization with HL7 v2.6” in HL7 v2.5.1, but is identified as “Observation Instance Identifier” in HL7 v2.6, which is used in the table above.

6.X.1.1.1 HL7 v.2.5.1 NTE Segment of OBX for CDS Information

930 Typically, OBX-15 would contain the Producer’s ID Reference of type CE. For the purposes of CDS, this Producer’s ID Reference would contain the mechanism (technology) which provides the CDS service, as a unique identifier (e.g., oid or uid). However, although the format and content of this Producer’s ID Reference is not yet defined by U.S. CMS legislation, the multiple pieces of data in this element do not lend themselves to a coded value of type CE. As a result, the Producer’s ID Reference, shall be included in a Note (NTE) Segment after the OBX Segment for CDS Information.

There shall be only one CDS NTE segment per CDS OBX segment.

935 Table 6.X.1.1.1-1 specifies the NTE segment for CDS Information. All NTE elements not listed in Table 6.X.1.1.1-1 are optional.

Table 6.X.1.1.1-1: IHE Profile – HL7 V2.5.1 NTE Segment - 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

940 Specifically, the CDS Information NTE elements are defined as:

- Element NTE-2 Source of Comment shall be taken from HL7 Table 0105 – Source of Comment as:
 - “O”, Other system is Source of Comment
- Element NTE-3 Comment is a free format text field. It shall contain information such as the CDS system, interface type (e.g., web/html), software version number, manufacturer, etc. The format of this field is currently undefined.
 - 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. Other code schemes may be used for other payers.
 - 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 registration number might be used as the id extension with HHS as the assigning authority root. It is recommended that the NTE segment should include sufficient information to identify the specific instance of the CDS software, e.g., the name and version number of the software, and its execution location (e.g., as part of a local EMR instance, or as a remote web service).

- 960
- Note: Until the content of NTE-3 is defined through the IHE Change Proposal process, it is recommended, but optional, to use the following field definition of values separated by commas as a text string: “CDS System, CDS Vendor, Interface Type, Version Number, Certification number of CDS solution, Other Data”. Also note that this may be an IHE U.S. National Extension only.

965 **6.X.1.1.2 Example of HL7 v.2.5.1 OBX/NTE Segments for CDS Information**

An example of a CDS OBX Segment is given in the figure below. This CDS OBX Segment could be part of an Order (OMG or OMI) Message or Discrete Financial Transaction (DFT) Message. Note that there may be multiple OBX segments in an HL7 v2.5.1 message and that a value of (76515-6, LOINC 2.16.840.1.113883.6.1, “Requested Procedure is Appropriate”) in OBX-3 identifies this OBX segment as the one containing the CDS information. In the HL7 v2.5.1 data stream, the NTE immediately follows the associated OBX segment as a form of association.

975

```

OBX|1|...
OBX|2|...
NTE|1|...
NTE|2|...
NTE|3|...
NTE|4|...
OBX|3|...
OBX|4|CE|76515-6^REQUESTED PROCEDURE IS APPROPRIATE^LN|1|CODE^NAME OF
AUC CONTENT PROVIDER^HEALTH_PROVIDERS_AUC|||O|B409|20151027155700|
||98234.22.1|||1.2.840.5677912.434.56.78.8.9.0.1223
NTE|1|O|ACME CDS System v1.0, XYZ Hospital,
1.2.840.5356356345.3454245.245234523
    
```

OBX|1|...

Figure 6.X.1.1.2-1: CDS OBX/NTE Example

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Appendices

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

985

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

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 –
990 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?”
- The possible responses to the question “Is the procedure appropriate?” are:
 - Yes
 - 995 • No
 - No criteria available

The AUC/CDS information being captured is:

- CDS Response on appropriateness (yes, no, no criteria available)
- 1000 • 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 CDS system returned the CDS result (optional data element).
- The name and identifier of the mechanism or technology (software implementation) that was used to obtain the CDS result.
- 1005 • The name and identifier of the Appropriate Use Criteria (AUC) guidelines that were used by the CDS mechanism to obtain the CDS result.
- 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.

1010 Note: In the U.S., the CMS legislation currently requires the following data elements to be recorded for submission to CMS:

- Which AUC criteria were used?
- Which CDS system (mechanism) was used?

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

1015 Additional information in the order transactions include:

- 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).

1020

- 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.

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