Foreword

This is a supplement to the IHE Radiology Technical Framework V13.0. 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 February 19, 2015 for Public Comment. Comments are invited and may be submitted at http://www.ihe.net/Radiology_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by March 21, 2015.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

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

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

Information about the IHE 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.

The current version of the IHE Radiology Technical Framework can be found at: http://www.ihe.net/Technical_Frameworks.
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### Volume 3 – Content Modules

6 Content Modules

6.X.1 HL7 v.2.5.1 Content Modules

6.X.1.1 HL7 v.2.5.1 OBX Segment for CDS Information

Appendices
Introduction to this Supplement

There are two supplements being developed within IHE to support Clinical Decision Support (CDS), one each in the Radiology and PCC domains. The business driver for CDS in the U.S. is the Department of Health and Human Services (HHS) Centers for Medicaid and Medicare Services (CMS), although the solution is intended to be broader than the CMS requirements.

The CDS Profile being developed by IHE Radiology focuses on the downstream workflow and data propagation.

The CDS Profile being developed by IHE Patient Care Coordination (PCC) focuses on obtaining the CDS information and the interaction between the Order Placer and the CDS system.

Open Issues and Questions

1. The current profile reflects the decision to exclude all of the DICOM 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?

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.

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.)

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.

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.

6. Should we use [RAD-35] transaction to carry the additional/necessary CDS attributes? (or something other than a DFT message)
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.

8. 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.

9. 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.)

10. 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?”

11. 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)?

12. 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 4 is included in this profile currently, but should it be deleted.

13. RAD-35 DFT does not include Ordering Provider (OBR->PR1).

14. Need a complete OBX example in Volume 3- Content Modules.

15. 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.

16. Create an example where there are multiple OBR and multiple OBX segments in Volume 3.

**Closed Issues**

None
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:

No new actors.

Appendix B - Transaction Summary Definitions

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

No new transactions.

Glossary

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

<table>
<thead>
<tr>
<th>Glossary Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Decision Support</td>
<td>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.</td>
</tr>
<tr>
<td>Appropriate Use Criteria</td>
<td>Appropriate Use Criteria (AUC) is an algorithm (often a document), typically evidence based, which specifies when it is appropriate to perform a medical procedure or service. An “appropriate” procedure is one for which the expected health benefits exceed the expected health risks by a wide margin.</td>
</tr>
</tbody>
</table>
Volume 1 – Profiles
X Imaging Clinical Decision Support Workflow (ICDSW) Profile

This profile, Imaging Clinical Decision Support Workflow (ICDSW) is intended to propagate the Clinical Decision Support (CDS) and Appropriate Use Criteria (AUC) information throughout the existing Radiology Scheduled Workflow.

Appropriate Use Criteria are guidelines that have been defined by professional societies (e.g., American College of Radiology (ACR)), or other groups that determine, based on a specific set of clinical indications and patient or social demographics, which imaging tests are the most effective, based a set of evidence.

Clinical Decisions Support (CDS) systems implement AUC in computerized healthcare systems. This CDS system is used by a referring or ordering physician or staff member at the time that the order is placed, typically in a CPOE, EMR, HIS, or other order entry system.

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, an instance uid of when the CDS algorithm was used, etc. 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 Medicaid and Medicare (CMS) legislation that is planned to go into effect on January 1, 2017, through the Protecting Access to Medicare Act. While this profile takes the CMS legislation into account it is intended to be more broadly applicable.

This Radiology profile assumes that the CDS and AUC information has already been obtained through some other method, either by through manual initiation of a CDS system or through the IHE PCC Clinical Decision Support Profile. The focus of this IHE Radiology profile is to ensure that this information is propagated accurately throughout the radiology workflow (scheduling, protocoling, viewing, reporting) so that the charge may be accurately posted.

This profile applies to both in-patient and out-patient scenarios. An order may be initiated by a referring/ordering physician via a phone call or a web portal. In any case, the CDS information is obtained in advance.

ICDSW is both a “workflow profile” and a “content profile”. ICDSW is a “workflow profile” as an extension to the IHE Rad Scheduled Workflow (SWF.b) and the Charge Posting profiles. However, the ICDSW Profile also defines a common data set for the CDS information in the form of an HL7 v2.5.1 OBX segment. It is important that the data generated by the IHE PCC CDS Profile be consistent with the data to be propagated here. It is also important that this same set of data is properly retained in imaging reports as structured and coded data, such as DICOM/HL7 Supplement 155.

Also note that there is additional information that is used in the CDS process, such as clinical indications and reason for study, which would also be very important to the radiologist reading a
study. This relevant information is not included in this profile, but is enumerated in the IHE Code Mapping in IHE Radiology Profiles White Paper.

X.1 ICDSW 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.

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

The Clinical Decision Support System Actor is shown here in dotted lines for completeness, but the transactions for these actors are provided in the IHE PCC Clinical Decision Support Profile.

Figure X.1-1: ICDSW Actor Diagram

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

<table>
<thead>
<tr>
<th>Actors</th>
<th>Transactions</th>
<th>Optionality</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Placer</td>
<td>Placer Order Management [RAD-2]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.2</td>
</tr>
<tr>
<td>DSS/Order Filler</td>
<td>Placer Order Management [RAD-2]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.2</td>
</tr>
<tr>
<td></td>
<td>Procedure Scheduled [RAD-4]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.4</td>
</tr>
<tr>
<td></td>
<td>Charge Post [RAD-35]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.35</td>
</tr>
<tr>
<td>Report Manager</td>
<td>Procedure Scheduled [RAD-4]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.4</td>
</tr>
<tr>
<td>Charge Processor</td>
<td>Charge Posted [RAD-35]</td>
<td>R</td>
<td>IHE RAD TF-2: 4.35</td>
</tr>
</tbody>
</table>

X.1.1 Actor Descriptions and Actor Profile Requirements

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

X.2 ICDSW Actor Options

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

Table X.2-1: ICDSW - Actors and Options

<table>
<thead>
<tr>
<th>Actor</th>
<th>Option Name</th>
<th>Optionality</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Placer</td>
<td>No options defined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order Filler/Department System Scheduler</td>
<td>No options defined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Manager</td>
<td>No options defined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charge Processor</td>
<td>No options defined</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

X.3 ICDSW Required Actor Groupings

The Order Placer and the Department System Scheduler/Order Filler (DSS/OF) actors are required to be grouped with the corresponding OP and DSS/OF actors of the IHE Radiology Scheduled Workflow (SWF.b) Profile. This grouping provides access to additional transactions.
which are necessary in real-world practice. Specifically, this grouping provides the ability to perform order cancellations from the DSS/OF to the Order Placer (RAD-3 cancel).

If the Order Placer also claims support for the IHE PCC Clinical Decision Support Profile, the Order Placer in this profile shall have direct access to the CDS information obtained in the IHE PCC CDS Profile (as described in RAD TF-3:6.X.1).

### Table X.3-1: ICDSW - Required Actor Groupings

<table>
<thead>
<tr>
<th>&lt;this Profile Acronym&gt; Actor</th>
<th>Actor to be grouped with</th>
<th>Reference</th>
<th>Content Bindings Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department System Scheduler/Order Filler (DSS/OF)</td>
<td>IHE RAD Scheduled Workflow (SWF.b) Department System Scheduler/Order Filler (DSS/OF)</td>
<td>RAD TF-1:3</td>
<td>RAD TF-3:6.X.1</td>
</tr>
<tr>
<td>Order Placer</td>
<td>IHE RAD Scheduled Workflow (SWF.b) Order Placer</td>
<td>RAD TF-1:3</td>
<td>RAD TF-3:6.X.1</td>
</tr>
<tr>
<td></td>
<td>IHE PCC Clinical Decision Support (CDS), if also claiming support for IHE PCC CDS</td>
<td>PCC TF-1:XXXXX</td>
<td>See Note 1</td>
</tr>
</tbody>
</table>

Note 1: The CDS information obtained by the Order Placer in the IHE PCC Clinical Decision Support Profile should be directly accessible to the Order Placer Actor in this Profile.

### X.4 ICDSW Overview

#### X.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)

This profile introduces a new data set in several of the transactions defined by these profiles called “CDS Information”. This CDS information is defined and required for this ICDSW Profile.

The CDS Information conveyed from one system to the next should not be altered unless the procedure order itself is altered or changed. In the latter case, the CDS verification may need to be rerun and new CDS information will need to be transmitted to be valid.
X.4.2 Use Cases

It is expected that the reader of this profile is generally familiar with the Use Cases defined in the related profiles listed in the section above.

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

X.4.2.1 Use Case 1: Simple Case- Order is placed with CDS information, report is created or charge is posted

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 and may be either manually entered into the order generation screen or is internally incorporated into the order. Note that the CDS information may even be obtained as part of a fax or phone call when an order is created.

The order is sent to the Department System Scheduler/Order Filler (DSS/OF) system (e.g., a RIS) and scheduled.

At an appropriate time, perhaps when the procedure is scheduled or protocoled, a procedure scheduled message is sent to the Report Manager, often to assist with the reporting workflow. Additionally, perhaps after the procedure has been completed, the DSS/OF sends a charge posted message to the Charge Processor. In both cases, the CDS information obtained at the time of the order generation is propagated to the next system.

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.

At any point in time, the DSS/OF may also send additional transactions, such as order messages, to the Charge Processor as a reconciliation mechanism. Those transactions are out of the scope of this profile and not shown here.
X.4.2.2 Use Case 2:  Procedure requires significant change, order canceled at DSS/OF

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

An order, containing CDS information, is created at the Order Placer and sent to the DSS/OF. However, during study protocling or for some other reason, the imaging department requests a significant change. A possible “significant change” example could be that an additional body part is added on which changes the requested procedure, such as “Chest Abdomen” becomes “Chest Abdomen Pelvis.

The original order is canceled at the DSS/OF. Optionally, the original order could also be canceled at the Order Placer.
If the Report Manager has already been sent a Procedure Scheduled message with the original order and information, the DSS/OF must send the Report Manager a Procedure Updated message.

At the Order Placer, the CDS system is consulted again, and a new order is created with the requested procedure from the imaging department.

The simple workflow process is re-initiated (Use Case 1).

**Figure X.4.2.2-1: Significant Order Change in ICDSW Profile**
X.4.2.3 Use Case 3: Order requires insignificant change, no order cancellation

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

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

During study protocoling, the imaging department requests a change to the order. A possible “insignificant change” example could be that an “MR head without contrast” is changed to an “MR head with contrast”. (Do we need a less controversial example there?)

The CDS information is not required to be updated.

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

X.4.2.4 Use Case 4: Order received without CDS information

<This use case is also listed as an Open Issue, but do we need to support this use case? Right now, we do not.>

Within the imaging department it may be identified that a procedure has been ordered and scheduled to hold the date and time, but the order did not include the necessary CDS information. In this case, 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.

In either of those cases, the OP is notified that the order has been updated, including (potentially different/new) CDS information as well as other information.

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

X.4.2.5 Use Case 5: Procedure is changed while procedure is already in progress

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.

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

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.
X.5 ICDSW Security Considerations

The security considerations for this profile are dependent upon the security provisions defined by the affinity domain and within the other related profiles.

X.6 ICDSW Cross Profile Considerations

There are no specific Cross Profile Considerations other than those defined in the Concepts section X.4.1.
Volume 2 – Transactions

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. The updates below are made on RAD TF-2, version 13, where the section headings containing “(HL7 v2.5.1 option)” still exist.

4.2 Placer Order Management [RAD-2]

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).

<table>
<thead>
<tr>
<th>OMG</th>
<th>General Clinical Order Message</th>
<th>Chapter in HL7 v2.5.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSH</td>
<td>Message Header</td>
<td>2</td>
</tr>
<tr>
<td>PID</td>
<td>Patient Identification</td>
<td>3</td>
</tr>
<tr>
<td>PV1</td>
<td>Patient Visit</td>
<td>3</td>
</tr>
<tr>
<td>ORC</td>
<td>Common Order</td>
<td>4</td>
</tr>
<tr>
<td>TQ1</td>
<td>Timing/Quantity</td>
<td>4</td>
</tr>
<tr>
<td>OBR</td>
<td>Order Detail</td>
<td>4</td>
</tr>
<tr>
<td>OBX</td>
<td>Observation/results</td>
<td>7</td>
</tr>
</tbody>
</table>

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

4.2.4.1.2.2.7 OBX Segment (HL7 v2.5.1 Option) – CDS Information

Actors supporting the ICDSW Profile shall include the OBX segment as defined in RAD TF-3:6.X.1.1 HL7 v2.5.1 Clinical Decision Support (CDS) OBX Segment

An Order Placer participating in the CDS Profile shall populate the CDS information in the RAD-4 and RAD-13 transactions using information obtained from the CDS system.
4.4 Procedure Scheduled [RAD-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).

<table>
<thead>
<tr>
<th>OMI</th>
<th>Imaging Order Message</th>
<th>Chapter in HL7 v2.5.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSH</td>
<td>Message Header</td>
<td>2</td>
</tr>
<tr>
<td>PID</td>
<td>Patient Identification</td>
<td>3</td>
</tr>
<tr>
<td>PV1</td>
<td>Patient Visit</td>
<td>3</td>
</tr>
<tr>
<td>{ ROL }</td>
<td>Role</td>
<td>15</td>
</tr>
<tr>
<td>{ ORC }</td>
<td>Common Order</td>
<td>4</td>
</tr>
<tr>
<td>TQ1</td>
<td>Timing / Quantity</td>
<td>4</td>
</tr>
<tr>
<td>OBR</td>
<td>Order Detail</td>
<td>4</td>
</tr>
<tr>
<td>{ IPC }</td>
<td>Imaging Procedure Control</td>
<td>4</td>
</tr>
<tr>
<td>[{OBX}]</td>
<td>Observation/results</td>
<td>7</td>
</tr>
</tbody>
</table>

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

4.4.1.2.2.9 OBX Segment (HL7 v2.5.1 Option) – CDS Information

An Order Filler participating in the ICDSW Profile shall include the OBX segment as defined in RAD TF-3:6.X.1.1 HL7 v2.5.1 Clinical Decision Support (CDS) OBX Segment.

4.4.2 Expected Actions

Add – the following text to the bottom of this section.

A Report Manager Actor participating in the ICDSW Profile shall ensure that the CDS information is present in the radiology report.

4.13 Procedure Updated [RAD-13]

4.13.1.2.2 Message Semantics (HL7 v2.5.1 option)
<refers to OMI Table in RAD-4, so there is no table to update and add OBX segment, already done>

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

4.13.4.2.2.1 OBX Segment (HL7 v2.5.1 Option) – CDS Information

Actors supporting the ICDSW Profile must include the OBX segment as defined in RAD TF-3:6.X.1.1 HL7 v2.5.1 Clinical Decision Support (CDS) OBX Segment

4.35 Charge Posted [RAD-35]

4.35.4.1.2 Message Semantics

Add – to bottom row of table OBX segment in brackets as: (note – this is also exactly the same as another IHE-J CP).

<table>
<thead>
<tr>
<th>DFT Segment</th>
<th>Detailed Financial Transaction Message</th>
<th>Chapter in HL7 2.3.1</th>
</tr>
</thead>
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<tr>
<td>MSH</td>
<td>Message Header</td>
<td>2</td>
</tr>
<tr>
<td>EVN</td>
<td>Event Type</td>
<td>3</td>
</tr>
<tr>
<td>PID</td>
<td>Patient Identification</td>
<td>3</td>
</tr>
<tr>
<td>[PV1]</td>
<td>Patient Visit</td>
<td>3 (see note)</td>
</tr>
<tr>
<td>{FT1}</td>
<td>Financial Transaction</td>
<td>6</td>
</tr>
<tr>
<td>[{PR1}]</td>
<td>Procedure</td>
<td>6</td>
</tr>
<tr>
<td>[{OBX}]</td>
<td>Observation/results</td>
<td>7</td>
</tr>
</tbody>
</table>

Note: PV1 is required if use of PV1-19 Visit Number is required per the applicable regional or national appendices to the IHE Technical framework (See RAD TF-4)

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

4.35.4.1.2.7 OBX Segment – CDS Information

An Order Filler participating in the ICDSW Profile shall include the OBX segment as defined in RAD TF-3:6.X.1.1 HL7 v2.5.1 Clinical Decision Support (CDS) OBX Segment (**provide reference when available IHE Rad TF3:6.3.2xx).
Appendices

No new appendices in Volume 2.

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Volume 3 – Content Modules
6 Content Modules

Editor: Add new Section 6.X.1 and all sub-sections under RAD TF-3:6. Note that the XDR-1 supplement has added RAD TF-2:6.1

6.X.1 HL7 v.2.5.1 Content Modules
This section of IHE RAD TF-3 defines HL7 v2.5.1 message segments.

6.X.1.1 HL7 v.2.5.1 OBX Segment for CDS Information
This content module contains the Clinical Decision Support (CDS), and associated Appropriate Use Criteria (AUC), information that must be propagated throughout the imaging department.

The following information is being used to identify the CDS information:

- The LOINC code for “Procedure Appropriate to Indication” which is “VALUE TBD/FORTHCOMING”.
- The LOINC codes in response to the question “Is the procedure appropriate?”:
  - Yes
  - No
  - No criteria available

The AUC/CDS information being captured is:

- 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 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.
- The name and identifier of the Appropriate Use Criteria (AUC) that was 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.

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

Additional information in the order transactions include:

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

The OBX Segment shall be constructed as defined in ITI TF-2b:3.30.5.7 OBX – Observation/Result Segment.

When the ICDSW Information Profile is supported, an additional OBX segment shall be present as specified in Table 6.X.1.1-1.

Additional optional, required and conditionally required fields are specified in Table 6.X.1.1-1. Several elements have been promoted from Optional in HL7 v2.5.1 to Required by the IHE Radiology ICDSW Profile. IHE uses the “R+” indicators to identify the elements that have been promoted.

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

<table>
<thead>
<tr>
<th>SEQ</th>
<th>LEN</th>
<th>DT</th>
<th>OPT</th>
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<th>ITEM#</th>
<th>ELEMENT NAME</th>
</tr>
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</tr>
<tr>
<td>3</td>
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<td>CE</td>
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<td>00571</td>
<td>Observation Identifier</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>99999</td>
<td>CE</td>
<td>R+</td>
<td>00573</td>
<td>Observation Value</td>
<td></td>
</tr>
<tr>
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<td>5</td>
<td>ID</td>
<td>X</td>
<td>0078</td>
<td>00576</td>
<td>Abnormal Flag</td>
</tr>
<tr>
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<td>1</td>
<td>ID</td>
<td>R</td>
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<td>00579</td>
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<tr>
<td>13</td>
<td>20</td>
<td>ST</td>
<td>O</td>
<td>00581</td>
<td>User Defined Access Checks</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>26</td>
<td>TS</td>
<td>O</td>
<td>00582</td>
<td>Date/Time of the Observation</td>
<td></td>
</tr>
<tr>
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<td>CE</td>
<td>R+</td>
<td>00583</td>
<td>Producer’s Reference</td>
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<tr>
<td>17</td>
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<td>CE</td>
<td>R+</td>
<td>00936</td>
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<tr>
<td>21</td>
<td>427</td>
<td>EI</td>
<td>R+</td>
<td>02180</td>
<td>V2.6 Observation Instance Identifier</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from the HL7 Standard, version 2.5.1

Specifically, the CDS Information OBX elements are defined as:

- Element OBX-2 Value Type is shall be type Coded Entry (CE).
Element OBX-3 Observation Identifier is a Coded Entry (CE) which shall contain the LOINC code for “Procedure Appropriate to Indication”. NOTE: will be LOINC Codes, already request by Sup 155. Forthcoming. EXAMPLE here.

Element OBX-5 Observation Value - The observation value is a Coded Entry (CE) which shall contain the Appropriate Use Criteria’s determination as Yes, No, or Not Applicable. NOTE: This is the answer to the question “Is the imaging procedure deemed to be appropriate?”

- The possible codes for OBX-5 include:
  - YES (need LOINC code)
  - NO (need LOINC code)
  - NO CRITERIA AVAILABLE (what code?)

Element OBX-8 Abnormal Flags - The Abnormal Flag shall be absent.

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.

Element OBX-15 Producer’s Reference is of type CE and shall contain the mechanism (technology) which provided the CDS service.

- 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 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 DHHS as the assigning authority root. It is recommended that OBX-15 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).

Element OBX-17 Observation Method is of type CE and shall identify the Appropriate Use Criteria method used.

- Note: In the U.S., it is assumed that CMS will provide a coding scheme to identify the various AUC methods.
• Element OBX-21 Observation Instance Identifier—shall contain the unique identifier of the decision returned by the CDS system.

• Note: 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.

Example: (there can be multiple OBX segment, OBX-3 identifies the CDS information OBX)

```
OBX|1|...
OBX|2|...
OBX|3|...
```

```
OBX|4|CE|123^AUC CRITERIA NAME|1|LOINC CODE^AUC CONTENT PROVIDER^xxx|||N
```
Appendices

No new appendices in Volume 3.

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