Integrating the Healthcare Enterprise



IHE Patient Care Coordination Technical Framework Supplement

10 Guideline Appropriate Ordering (GAO)

Trial Implementation

20Date:August 5, 2015Author:PCC Technical CommitteeEmail:pcc@ihe.net

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Foreword

This is a supplement to the IHE Patient Care Coordination Technical Framework V10.0. 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 August 5, 2015 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 Patient Care

35 Coordination Technical Framework. Comments are invited and may be submitted at <u>http://www.ihe.net/PCC_Public_Comments</u>.

This supplement describes changes to the existing technical framework documents.

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

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

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

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

Information about the IHE Patient Care Coordination domain can be found at: <u>http://ihe.net/IHE_Domains</u>.

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

The current version of the IHE IT Infrastructure Technical Framework can be found at: <u>http://ihe.net/Resources/Technical_Frameworks</u>.

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Introduction to this Supplement

This supplement updates the PCC Technical Framework Volumes 1, 2 and 3 to incorporate changes necessary to add the Guideline Appropriate Ordering Profile (GAO) to the framework. The purpose of the GAO Profile is to support communication of decision support guidance on whether or not an order is appropriate from EHR, hospital or departmental information systems, and enable receivers to validate that decision support was used to determine the appropriateness of those orders according to guidelines.

135 **Open Issues and Questions**

Closed Issues

- 1. What standards could be used for this profile? We evaluated several standards and IHE profiles, including HL7® FHIR®, Request Form for Data Capture, Health eDecisions, and Structured Data Capture using ITI's standards evaluation template. The end result of that evaluation can be found <u>here</u> and was that FHIR® was the best candidate.
- 2. Is Authorize Order the right transaction name? What about Review Order? Is another name appropriate? The name has been change to Evaluate Order.

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:

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Actor	Definition	
Order Evaluation Requester	An actor that requests evaluation of a proposed action to determine whether it may or should be initiated.	

Appendix B - Transaction Summary Definitions

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

Transaction	Definition
PCC-19 Evaluate Order	Evaluates an order against guidelines and/or policies to determine its appropriateness in a given context.
PCC-20 Invoke Questionnaire	Displays the CDS questionnaire using HTML web pages and returns the result invoker.

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Volume 1 – Profiles

X Guideline Appropriate Ordering (GAO) Profile

The Guideline Appropriate Ordering Profile supplies a mechanism by which EHR and
 departmental systems can evaluate orders to determine whether these orders conform to
 guidelines. The profile enables the results of the evaluation to be stored and transmitted, and the
 receiver of those results to verify that an order was evaluated with regard to appropriateness.

Under a new US law¹, starting in 2017, providers ordering imaging procedures must use physician approved appropriateness guidelines to reduce unnecessary imaging in patients for

165 whom it is not appropriate. In order to be paid for Medicare outpatient care, facilities and physicians who perform certain imaging procedures (either the technical or the clinical component) have to be able to show that decision support was used in the ordering process². The European Society of Cardiology and the European Association of Cardiovascular Imaging have also identified a need for use of appropriateness criteria in cardiovascular imaging³.

170 X.1 GAO 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 <u>http://ihe.net/Technical_Frameworks/</u>.

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



Figure X.1-1: GAO Actor Diagram

¹ H.R.4302. Protecting Access to Medicare Act of 2014. 03-JAN-15. Available on the web at http://www.gpo.gov/fdsys/pkg/BILLS-113hr4302enr/pdf/BILLS-113hr4302enr.pdf

² Burhmal, R. New Law Mandates Use of Imaging Appropriateness Criteria. RSNA. 01-JUN-14. Available on the web at http://rsna.org/NewsDetail.aspx?id=12360

³ Garbi, M et al. Appropriateness criteria for cardiovascular imaging use in heart failure: report of literature review. European Heart Journal – Cardiovascular Imaging (2015) 16, 147–153. 30-DEC-14. Available on the web at http://www.escardio.org/communities/EACVI/publications/Documents/EHJCI-appropriateness-criteria-garbi.pdf

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

Actors	Transactions	Optionality	Reference
Order Evaluation Requester	Evaluate Order	R	PCC TF-2: 3.19
	Invoke Questionnaire	0	PCC TF-2: 3.20
Decision Support Service	Evaluate Order	R	PCC TF-2: 3.19
	Invoke Questionnaire	0	PCC TF-2: 3.20

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

X.2 GAO Actor Options

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Table X.2-1: GAO Actor Options

Actor	Option	Reference
Order Evaluation Requester	Conversational Interaction	PCC TF-1: X.2.1
Decision Support Service	Conversational Interaction	PCC TF-1: X.2.1

X.2.1 Conversational Interaction Option

The Conversational Interaction Option provides a mechanism by which an Order Evaluation
 Requester can request an interactive session from the Decision Support Service to complete a questionnaire to obtain the decision support result. Actors supporting this option must support the [PCC-20] Invoke Questionnaire transaction.

X.3 GAO Required Actor Groupings

There are no required actor groupings for this profile.

195 **X.4 GAO Overview**

The Guideline Appropriate Ordering Profile is intended to support use cases where the use of CDS to evaluate an order for appropriateness to guidelines must be demonstrated and communicated in an order. This profile is intended to address evaluation of an order at the time of order entry. It does not address the case where orders are proposed by a CDS system prior to order entry, because in these cases, the CDS system is presumed to have already ensured that

those orders are appropriate, and can include the necessary information.

The focus of this profile is on ensuring that the data necessary to perform the evaluation can be communicated to a clinical decision support service. As far as the profile is concerned, the decision support service is a black box. How it works inside is out of scope. This profile does not

205 specify the algorithms by which orders are evaluated according to guidelines, or the formats used to express clinical decision support in guidelines. There are numerous ways by which these evaluations can be performed. Implementers of a decision support service are free to use historical knowledge about the patient where available, or to interact with the EHR to query for data about a patient. This profile does not address the mechanisms by which this occurs.

210 X.4.1 Concepts

X.4.1.1 Evaluation

Evaluation is the process of comparing a proposed order to clinical guidelines, and providing a judgment about whether the order is inside or outside of guidelines.

X.4.1.2 Guideline

215 A guideline specifies what clinical care should be provided to a patient according to their situation based on clinical evidence. Guidelines may also be referred to as Appropriate Use Criteria, referring to US Federal Legislation associated with advance imaging orders.

X.4.1.3 Proposed Order

A proposed order is one which has been drafted but not yet acted upon or submitted by a physician. All orders in this profile are proposed orders, rather than official orders which have been submitted by a physician. The initial order drafted by the physician is still a proposed order at the time it is conveyed to the Decision Support Service. The Decision Support Service may propose alternative orders that would be approved, either by adding required information to the original order, or by suggesting that the physician consider an alternative service.

225 X.4.1.4 Using the Results

Results of the clinical decision support service evaluation of the order can be conveyed when the order is placed by an EHR or other system acting as an order placer to the receiving system used by the performing provider and acting as the order filler. As in all cases when using clinical decision support, the information provided by the decision support service should be treated as

an aid to physician and patient decision making, rather than as a substitute for it. The physician should still be able to easily place their originally specified order. Furthermore, any alternatives proposed by the Decision Support Service must still be reviewed and authorized by the ordering physician.

X.4.2 Use Cases

235 X.4.2.1 Use Case #1: Ordering an Imaging Procedure not Needing More Information



Figure X.4.2.1-1: Basic Process Flow in GAO Profile

240 **Pre-conditions:**

The Order Evaluation Requester collects the current data necessary to make the clinical decision, e.g., the relevant patient problems, medications, allergies, vital signs and laboratory results, as well as the proposed imaging procedure or procedures.

The physician ordering the procedure(s) has been authenticated to the system and has a unique identifier.

The Decision Support Service is configured with appropriate guidelines.

Main Flow:

1. The Order Evaluation Requester performs [PCC-19] Evaluate Order from the Decision Support Service by submitting the proposed imaging procedure, clinical data and ordering provider identifier to the service.

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- 2. The Decision support service validates that the requested procedure is appropriate according to clinical guidelines.
- 3. The Decision Support Service creates a response containing the provider identifier, procedure identifier, the Decision Support Service identifier, identifiers for the relevant clinical
- 255 guidelines, the result of the decision and confirmation of appropriateness and returns it to the Order Evaluation Requester.

4. The Decision Support Service digitally signs the result and includes that in provenance associated with the resource.

Post-conditions:

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260 The procedure description and its confirmation of appropriateness have been created and can be passed to other actors who can verify that decision support was used and what the result was.

The Decision Support Service need not retain any data about the interaction. The provider's system has a digital signature associated with the decision response that can be used to verify that the response was created by a Decision Support Service in possession of the certificate used to sign the response.

X.4.2.2 Use Case #2: Ordering an Medication with Weight Based Dosing



Figure X.4.2.2-1: Processing an Evaluation with Questions

270 **Pre-conditions:**

The Order Evaluation Requester collects the current data necessary to make the clinical decision, e.g., the indication for treatment, as well as the proposed medication and dosing instructions.

The physician ordering the medication has been authenticated to the system and has a unique identifier.

275 The Decision Support Service is configured with appropriate guidelines.

Main Flow:

- 1. The provider's EHR calls on the Decision Support Service to evaluate the order by submitting the proposed medication prescription, indications and ordering provider identifier to the service.
- 280 2. The Decision Support Service validates that the requested medication is appropriate according to clinical guidelines. Because the patient is 8 years old, the service indicates

that it cannot evaluate the order without more information, and returns a questionnaire requesting the patient's weight.

- 3. The provider's EHR displays the question to the provider, who answers it.
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- 4. The provider's EHR requests reevaluation of the order with the answer supplied to the question.
 - 5. The Decision Support Service returns the result, noting that the order is appropriate.

Alternate Flow 1:

At step 3, the provider's EHR recognizes that this question is asking for the patient's weight. It retrieves the weight from the patient record and resumes the main flow at step 4.

Alternate Flow 2:

At step 3, the provider's EHR request that the questionnaire be processed by the Decision Support Service as a web page. After getting the patient's weight, the Decision Support Service reevaluates the order. The Main Flow resumes at step 5.

295 Alternate Flow 3:

At step 1, the provider's EHR includes the answer to the weight question it knows it will be asked if not provided. The main flow resumes at step 5.

Alternate Flow 4:

At step 5, the Decision Support Service notes that the order is overdosing the patient. That order 300 is evaluated as inappropriate. However, the Decision Support Service suggests a new order that has an appropriate dose and returns that as an alternate order with the result.

Post-conditions:

A weight appropriate medication order has been evaluated by the Decision Support Service and is available to the provider's EHR to submit in a prescription.

305 X.4.2.3 Use Case #3: Prior Authorization is Required

In this use case, the Decision Support Service is provided by an authorizer (e.g., an insurer or other payer for services).

Pre-conditions:

The Order Evaluation Requester collects the current data necessary to make the clinical decision, e.g., the indication for treatment, as well as the proposed order to evaluate. It also includes patient demographics, such as name, address, and the payer's identifier for the patient.

The physician placing the order has been authenticated to the system and has a unique identifier.

The Decision Support Service is implemented by the payer and is configured with appropriate guidelines.

315 The connection between the Decision Support Service and the Order Evaluation Requester is secured and encrypted due to the inclusion of PHI (patient name and identifiers).

Main Flow:

The main flow proceeds as described in the use cases above. During the evaluation,

- 1. The Decision Support Service also looks up the patient's coverage using the supplied patient demographics (e.g., name, birthdate, gender and identifier).
- 2. The evaluation is performed by the Decision Support Service.
- 3. The order is found to be within guidelines.
- 4. The order is also found to be covered by the patient's policy.
- 5. The Payer issues a prior authorization for the order. The business identifier of the prior authorization is also used as the business identifier for the evaluation result.
- 6. These results are returned to the Order Evaluation Requester

Alternate Flow:

Steps 1-3 are completed as above. The flow continues below at step 4.

- 4. The order is not covered by the patient's policy. For example, the payer does not choose to pay for the specific brand of medication found in the order, only generic medications of similar composition.
 - 5. The Decision Support Service evaluates this order as being "not covered" and does not provide an identifier associated with the request.
 - 6. The Decision Support Service creates a proposal for an alternate generic medication and includes that proposed alternate order in the response.
 - 7. The Payer issues a prior authorization for the alternative proposed. The business identifier of the prior authorization is also used as the business identifier for the evaluation result for the proposed alternative.
 - 8. These results are returned to the Order Evaluation Requester

340 **Post-conditions:**

An appropriate medication order has been evaluated by the Decision Support Service and is available to the provider's EHR to submit in a prescription.

X.5 GAO Security Considerations

X.5.1 Fraud

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

Various methods could be attempted, including Impersonation, Repudiation, Replay and Gaming. These are discussed in more detail below.

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X.5.1.1 Impersonation 350

A Decision Support Service Actor might be impersonated (e.g., to commit fraud) with a more forgiving implementation. Simply reporting the Decision Support Service or guideline used by identifier is insufficient to guarantee that a conforming Decision Support Service applied appropriate guidelines. The identity of the Decision Support Service must be able to be verified.

The asset at risk is money, where the payer ends up paying more for unnecessary services. Given 355 that the money spent on imaging services can amount to a great deal, and given the existing likelihood of fraud in some regions already, the likelihood that this risk would be encountered is almost certain.

Digital Certificates assigned to Decision Support Service manufacturers enable the manufacturer to create certificates for systems that they install which could verifiably prove that the Decision 360 Support Service Actor was made by the possessor of that certificates private key. However, wide distribution of that certificate and private key by the manufacturer to all organizations which have that Decision Support Service installed introduces a risk to the manufacturer's identity. Thus, we recommend that Decision Support Service actors have a node certificate that is

provided to it, and is signed by the manufacturer's certificate, creating a trust chain, but 365 eliminating the risk to the manufacturer's original certificate.

X.5.1.2 Repudiation

Because the evaluation can represent that an order is eligible for payment, there are financial incentives to challenge whether or not an evaluation is valid for a particular service. This profile

- 370 enables the evaluating party or system to digitally sign an evaluation. The digital signature signs the evaluation identifier, the type of evaluation given, the validity period of the evaluation, the identity of the ordering provider, the placer order identifier, and the ordered services. The use of the digital signature enables the requester and receivers of an evaluation to verify that the evaluation was issued by the identified Decision Support Service without having to query that 375 service.

X.5.1.3 Replay

In a replay attack, known good responses to challenges are repeated in order to duplicate the positive outcome. So, a positive response to a proposed order, which resulted in an approved request could simply be used the next time that same order was proposed for a different

380 individual. Another form of replay is when an evaluation is given, but it is not used until after the condition for which it was needed has resolved.

Again, the assets at risk are financial, as the payer would be funding unnecessary services.

The same evaluation might be given to more than one order filler, and each order filler may not know which services the other performed. There are legitimate cases where multiple services

385 may be ordered together, yet multiple providers could perform different components of these services under the same evaluation. This is already the case for example, in Medicare, where a single evaluation might be used to evaluate both the technical component (capturing an image), and the professional component (interpreting the image).

It is not possible to determine when an evaluation is consumed without some form of storage associated with the evaluation. Addressing this issue is out of scope for this profile.

X.5.1.4 Gaming

The aforementioned attacks all provide mechanism whereby weaknesses in the system are attacked in order to generate a positive result showing that a procedure is within guidelines. However, another risk is that the rules by which evaluations are positively reviewed are well

known, as would be the case for published guidelines. Thus, 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.

Other mitigations must be used to make them more likely to be detected, and use of appropriate
 corrective actions (e.g., financial penalties) can be a deterrent. Periodic sampling of past uses of
 decision support (auditing), and behavioral profiling can help detect such occurrences.

X.5.2 Unauthorized Access to PHI

X.5.2.1 Inappropriate Use or Storage of PHI

The Decision Support Service Actor may routinely receive PHI, making it a potential target of 405 attack. Growing use of cloud services which are not necessarily designed for use in Healthcare environments can increase the risk that these systems could be accessed. If such a system stores PHI, even if for only a short time, it could be at risk of disclosure, resulting in damage of reputation, financial penalties, or social or actual harm to patients.

410 One way to prevent this risk is to only exchange the information that is necessary to support the service that is being provided, and to mask other information, so as to limit the exposure.

This profile does not provide guidance upon PHI must be present or not in making the clinical decision support request. It limits the required patient demographics to non-PHI data (gender and a date of birth which can have limited precision). We recommend that organizations using this profile perform a risk analysis on the data needed, and exchange only that data that is necessary to make the decision.

X.5.2.2 Communications Security and Integrity

The communications channel over which PHI is transmitted is threatened by many forms of attack. 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.

If a secure communications channel cannot be created between two <u>known</u> systems, information is at risk. If only the responder had a node certificate (as is typical in many https configurations), data is still at risk because the Decision Support Service could preserve state about a particular decision which may affect future requests, and subsequent requests by an unidentified system could expose that state, this may be less likely but would still be a concern

425 could expose that state, this may be less likely but would still be a concern.

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The use of node certificates at the requesting and responding system is a generally accepted mitigation which ensures that the content is encrypted.

The IHE ATNA Profile can be used to secure the communications channel, and ensure that both parties in the communication are known entities.

X.5.2.3 Unauthorized Access 430

Unauthorized access to information can occur when a user attempts to access a Decision Support Service Actor for which he/she is unauthorized for. Assets at risk include intellectual property (e.g., decisions made by the Decision Support Service), financial (e.g., use of the Decision Support Service without compensation), and possible PHI (e.g., state information about prior use of an imaging service).

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This profile should require that ordering providers accessing the Decision Support Service through this profile be authenticated by the Order Evaluation Requester, which uses the Decision Support Service, and that system must also authenticate with the Decision Support Service.

The ATNA Profile can be used to secure the communications channel. It requires that both 440 parties in the channel be known entities, and that users accessing services are authenticated.

X.5.2.4 Availability

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The Decision Support Service represents a single point of failure which could prevent orders from being evaluated when it is not available. The service can be replicated across multiple servers, and an Order Evaluation Requester can be configured to use multiple servers in cases where communications to a single Decision Support Service breaks down.

This profile also enables manual evaluations to be issued out-of-band, and the evaluation identifier to be communicated to enable ordering under special circumstances (e.g., natural disasters). The manual evaluation process does not provide the same security capabilities as the automated process. Users of manual evaluations must assess the risks associated with accepting them and implement appropriate policies regarding their use.

X.6 GAO Cross Profile Considerations

When used with the IHE Radiology Scheduled Workflow (SWF.b) Profile, the PCC GAO Order Evaluation Requester can be grouped with the Order Placer (OP) and/or Department System Scheduler (DSS/OF) actors to confirm that it has used decision support to determine that the imaging order is within clinical guidelines.

In turn, the IHE Radiology Clinical Decision Support - Order Accountable Tracking (CDS-OAT) Profile can be used by the grouped Order Placer/Order Evaluation Requester and/or Order Filler/Order Evaluation Requester to ensure that the adequate and correct content is passed downstream.

460 It can also work with other profiles that support ordering of services where there may be concerns about appropriateness, such as Laboratory Workflow (from the IHE Laboratory domain), or Hospital Medication Workflow and Community Medication Prescription and Dispense (from the IHE Pharmacy Domain).

Volume 2 – Transactions

465 Add Section 3.19

3.19 Evaluate Order

3.19.1 Scope

This transaction is used to evaluate an order to determine if it is appropriate according to guidelines. The Order Evaluation Requester Actor provides the order and clinical data associated
 with that order. The Decision Support Service Actor evaluates the order and returns a result indicating whether the order is appropriate according to guidelines.

3.19.2 Actor Roles



Figure 3.19.2-1: Use Case Diagram

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Table 3.19.2-1: Actor Roles

Actor:	Order Evaluation Requester
Role:	The Order Evaluation Requester provides clinical details necessary to make a determination whether the requested diagnostic or intervention is appropriate according to guidelines.
Actor:	Decision Support Service
Role:	The Decision Support Service determines whether the requested diagnostic or intervention is appropriate according to the guidelines it is aware of and returns a decision as to whether the ordered service is appropriate based on those guidelines.

3.19.3 Referenced Standards

HL7® Fast Healthcare Information Resources (FHIR®) DSTU 2.0 (work in progress)⁴

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3.19.4 Interaction Diagram



Figure 3.19.4-1: Simple Evaluation of an Order

485 The figure above illustrates a simple request/response message in which Order Evaluation Requester proposes and order and the Decision Support Service evaluates it and returns an evaluation response. In this sequence, the Order Evaluation Requester does not try to improve the result, either because the result shows that the order is within guidelines, or because an acceptable alternate order was returned.

⁴ The version to use for this Trial Implementation can be found at ftp:// ftp.ihe.net/TF_Implementation_Material/PCC/fhir/FHIR-08-2015.zip



Figure 3.19.4-2: Processing an Evaluation with Questions

The figure above illustrates sequence of messages in this transaction when the Decision Support Service has additional questions about the order. In this sequence, a proposed order is evaluated by the Decision Support Service Actor. The Decision Support Service indicates in the returned result that the order is not within guidelines, but also indicates that if some questions were answered, the evaluation response might be improved. The Order Evaluation Requester can either answer the questions directly, or it can make a request to the Decision Support Service to 500 interact with the user to complete the evaluation process.

3.19.4.1 Evaluate Order

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The Evaluate Order transaction is implemented through the FHIR® \$evaluate operation described below under Message Semantics. That operation identifies which appropriateness guidelines are relevant to the service requested, evaluates the order according to those guidelines. It then returns a response indicating whether or not the order would be authorized according to those guidelines, or that no guidelines are applicable.

3.19.4.1.1 Trigger Events

An order for services is about to be requested, or an order has been received for fulfillment, or an order is being reevaluated after questions have been answered.

510 3.19.4.1.2 Message Semantics

The message is a FHIR® operation with the input and output parameters shown below in Table 3.19.4.1.2-1. The name of the operation is \$evaluate, and it is applied to Order resources. It is sent synchronously in JSON format from the Order Evaluation Requester Actor to the Decision Support Service Actor using an HTTP or HTTPS POST request.

515 The URL for this operation is: [base]/Order/\$evaluate

Where [base] is the base URL for the Decision Support Service provider.

Parameter	Card.	Data Type	Description			
	Input Parameters					
order	11	Order	The order to evaluate			
coverage	0*	Coverage	Optional resources describing the patient's coverage.			
answers	0*	QuestionnaireAnswers	Answers to any questions which have been or may be posed by the Decision Support Service			
		Outpu	it Parameters			
order	11	Order	The order that was evaluated. This SHALL be a copy of the order provided on input.			
answers	0*	QuestionnaireAnswers	Answers to any questions posed by the Decision Support Service. This SHALL be a copy of the answers provided on input.			
result	11	Basic	A Basic resource indicating the status of the evaluation produced by evaluating the order.			
alternative	0*	Basic	Basic resources indicating the status of evaluations produced by evaluating alternative orders suggested by the Decision Support Service Actor.			
provenance	0*	Provenance	 Provenance resources for the Result and Alternatives that can be used to verify that those Resources came from a specific Decision Support Service. If the Decision Support Service implements the Digital Signature Option, there SHALL be one Provenance resource for each Result or Alternate present in the output parameters. 			
dss	1*	Device	The Device resource shall identify the Decision Support Service device or devices which evaluated the appropriateness of the order.			
questions	0*	Questionnaire	A reference to one or more Questionnaire resources, which, if completed might generate a different response from the Decision Support Service.			
questionaireURI	01	uri	Specifies a web endpoint where Questionnaire Resources returned by the Decision Support Service can be invoked interactively. When the Decision Support Service implements the Conversational Interaction Option and the questions parameter is populated, this field SHALL be populated.			

520 **3.19.4.1.2.1 Order**

The Order to be evaluated is passed as an input contained within the **order** parameter of the Parameters resource passed in to the operation. Requirements of this resource and any of its referenced resources are described below in Table 3.19.4.1.2.1-1. All resources referenced below are passed in as contained resources within the Order. The **order** parameter must be populated in both the call to the \$evaluate operation, and in the response returned from that operation.

Attribute	Card.	Data Type	Description/Notes			
Order Resour Use of the Ord medications, pr provider placin	Order Resource Use of the Order resource enables this profile to be extended to support other kinds of resources beyond diagnostic tests (e.g., medications, procedures, referrals, et cetera). The Order resource links the order details to the reason(s), date, patient and provider placing the order.					
identifier	11	Identifier	The placer order identifier that will be associated with the order if it is placed shall be provided so that the receiver of the evaluation can verify that the order being placed was the same as an order that was authorized.			
date	11	dateTime	The date associated with the order SHALL be provided so that the receiver of the evaluation can verify that the order was produced within a reasonable time period for accepting the evaluation according to local policies, and to enable the Decision Support Service to apply relevant guidelines. The value shall be precise to the day.			
subject	11	Patient <contained></contained>	The patient for whom the order is being placed SHALL be provided so that relevant demographics, such as age and gender can be used to evaluate appropriateness.			
source	11	Practitioner <contained></contained>	The identifier of the provider SHALL be provided in order for the receiver of the evaluation to verify that the evaluation given is associated with the correct order.			
reason[x]	1*	CodeableConcept Any <contained></contained>	This field contains either a code or a contained resource that gives the reason (a.k.a. indication) for the order. This could include screening, signs or symptoms, diagnoses, diagnostic results, medications or procedures ⁵ , or other resources. This information must be supported and SHALL be provided.			
detail	11	(DiagnosticOrder ReferralRequest MedicationPrescription ProcedureRequest) <contained></contained>	The details of the order (e.g., service performed) SHALL be provided in order to evaluate them for appropriateness.			
Patient Resource						
The patient resource is required to provide relevant demographics associated with the patient. Other details may be provided according to local implementation requirements.						
gender	11	code	The patient gender SHALL be provided. This demographic is commonly used to determine appropriateness of orders.			
birthDate	11	date	The date of birth SHALL be provided. This demographic is commonly used to determine appropriateness of orders. Precision of this field may be limited to ensure compliance with local policy.			

Table 3.19.4.1.2.1-1: Order Parameter Semantics

⁵ Use of some medications or performance of some procedures may require certain tests to ensure effectiveness or avoid adverse reactions.

Attribute	Card.	Data Type	Description/Notes			
Practitioner Re	Practitioner Resource					
The practitioner	resource is 1	equired to identify the provider pla	cing the order.			
identifier	1*	Identifier	At least one identifier SHALL be provided that uniquely identifies the ordering provider. Local policy may specify the identify domain associated with this identifier (e.g., a national provider id may be required in some locales).			
DiagnosticOrd	er					
The diagnostic of additional detail	order resources that may be	e is required to identify the diagnost e necessary to evaluate the order fo	stic service or services that were ordered, and to provide r appropriateness.			
clinicalNotes	01	String	Sometimes a text justification must be provided instead of coded and structured data. This field must be supported and SHALL be provided if known ⁶ .			
supporting Information	0*	(Observation Condition DocumentReference) <contained></contained>	Supporting information SHALL be provided if known. This field may be required to facilitate evaluation of appropriateness. The supportingInformation field assists with interpretation of the results, and is not intended to provide the reason or indication for the order (see reason[x] above in the Order resource).			
item	1*	Element	At least one item SHALL be present in the order to describe the service being performed.			
item.code	11	CodeableConcept	The service being requested SHALL be provided. This is the service being evaluated against guidelines.			
item.bodySite Codeable Concept	01	CodeableConcept	The body site SHALL be provided when relevant to the order (e.g., MRI of upper joint, where the location is the shoulder or elbow and the laterality is left or right) ^{Error! Bookmark not} defined.			
item.bodySite Reference	00	BodySite	Body site SHALL NOT be specified as a reference to a BodySite resource. The body site used on orders should be simple enough to capture as a codeableConcept, enabling a Decision Support Service to evaluate it more readily.			

⁶ Order Evaluation Requester actors must demonstrate that they can populate this field.

Attribute	Card.	Data Type	Description/Notes			
ReferralReque The referral requ	ReferralRequest The referral request resource is required to identify the referral service or services that were ordered, and to provide additional					
details that may	be necessary	to evaluate the order for appropria	teness.			
reason	11	CodeableConcept	The reason for the referral SHALL be provided.			
service Requested	1*	CodeableConcept	At least one service requested SHALL be provided.			
supporting Information	1*	Any <contained></contained>	Some supporting information supporting the order SHALL be provided.			
MedicationPrescription The medication prescription resource is required to identify the medications ordered, and to provide additional details that may be necessary to evaluate the order for appropriateness.						
reason Codeable Concept	11	CodeableConcept	The reason for the prescription SHALL be provided.			
medication	11	CodeableConcept Medication	The medication being prescribed SHALL be described.			
doseage Instruction	1*	Element	At least one dosage instruction SHALL be provided.			
ProcedureRequest						
The procedure request resource is required to identify the procedures that were ordered, and to provide additional details that may be necessary to evaluate the order for appropriateness.						
type	11	CodeableConcept	The type of procedure to be performed SHALL be provided.			
indication	1*	CodeableConcept	At least one indication for the procedure SHALL be provided.			

3.19.4.1.2.2 Answers

530 The **answers** parameter is used to contain one or more QuestionnaireAnswers resources which contain the answers to questions that either have been or may be posed by the Decision Support Service Actor to determine the appropriateness of the order.

• · · · •• · ·				
Attribute	Card.	Data Type	Description/Notes	
QuestionnaireA	Inswers Res	ource		
A Questionnaire have asked preve emptively provid	A QuestionnaireAnswers resource may be included to answer questions that the Decision Support Service Actor might ask or have asked previously in order to determine the appropriateness of the order. An Order Evaluation Requester Actor may pre- emptively provide answers to questions for orders it suspects may be necessary.			
group.linkId	11	string	Each group in the QuestionnaireAnswers resource must be linked back to the group in the Questionnaire to which it corresponds.	
question. linkId	11	string	Each question in the QuestionnaireAnswers resource must be linked back to the question in the Questionnaire to which it corresponds.	
question. answer. value[x]	1*	See notes	Each question that is responded to in the QuestionnaireAnswers resource SHALL have an answer. If the question is not answered, it simply doesn't appear in the resource. Attachments and other Resources SHALL NOT be used as answer values in this profile.	

Table 3.19.4.1.2.2-1: Answers Parameter Semantics

540 **3.19.4.1.2.3 Result**

The **result** parameter is an output containing a Basic resource structured as defined in Table 3.19.4.1.2.3-1below. The basic resource identifies the Decision Support Service, the type of evaluation provided, and the order that was subject of the evaluation. It also identifies the guideline against which the order was evaluated.

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Table 3.19.4.1.2.3-1: Result Parameter Semantics

Attribute	Card.	Data Type	Description/Notes			
Basic Resource	Basic Resource					
identifier	01	Identifier	This is a business identifier associated with the evaluation for the order. It is a unique identifier issued by the evaluator associated with this transaction. An identifier SHALL be provided unless the code is "incomplete", "cannot be evaluated" or "not covered". Note that this identifier may be associated with multiple evaluations.			
code	11	CodeableConcept	The code SHALL be provided.			

Attribute	Card.	Data Type		Description/Notes
code.coding. code	11		Code SHALL be s values:	elected from one of the following seven
			Code	Description
			Within	Order is within identified guidelines.
			Outside	Order is outside of identified guidelines.
			No guidelines	No guidelines apply.
			Incomplete	Evaluation was not completed (e.g., because more information is necessary).
			Cannot evaluate	Cannot evaluate this order ⁷ .
			Manual	The evaluation was issued through a manual process.
			Not covered	The requested service is not covered for this patient ⁸ .
code.coding. codeSystem	11	uri	This SHALL be se	et to http://www.ihe.net/pcc/GAO/2015
subject	01	Order	A reference to th Unless the evalu- is optional. This parameters result	e order being evaluated SHALL be provided ation was issued manually, in which case it SHALL be a reference to the order in the $\frac{9}{2}$.
gao:score	01	decimal	An optional valu associated with t this value may va Support Service improvement eff	e which can be used to record a score he evaluation process. The interpretation of ary depending upon guidelines and Decision actors used. It is present to enable quality orts related to ordering.
gao:period	01	Period	The period over provided unless t which case it is c	which the evaluation is valid SHALL be the evaluation was issued manually, in optional.
gao:item	1*	Element	The services that	are to be ordered SHALL be provided.
gao:item. code	11	CodeableConcept	The service SHAI	L be identified by a code.
gao:item. bodySite Codeable Concept	01	CodeableConcept	The body site ass it is relevant to th	sociated by the service SHALL be provided if ne evaluation.
gao:guideline	0*	uri	A reference to th evaluation was c evaluation was is	e guidelines or policies under which the reated SHALL be provided unless the ssued manually, in which case it is optional.

⁷ Typically this would occur in the case where multiple items are ordered and multiple guidelines apply. The solution in this situation is for the Order Evaluation Requester to make a simpler request instead of trying to authorize multiple ordered services.

⁸ This code is used instead of Outside to indicate that the service is not covered by the payer for this patient rather than it being outside of guidelines. Non-covered services may still be ordered by the provider, but the payer evaluating the request is indicating that it will not pay for it, and thus does not provide an identifier which might be used to reflect their prior authorization.

⁹ This element is also used in the Alternatives parameter with different constraints.

Attribute	Card.	Data Type	Description/Notes
gao:device	01	Device <reference></reference>	A reference to the Device resource describing the Decision Support Service Actor SHALL be provided unless the evaluation was issued manually, in which case it is optional. This SHALL be a reference to one of the Devices specified in the Device parameter.
gao: practitioner	01	Identifier	An identifier representing the ordering practitioner SHALL be provided unless the evaluation was issued manually, in which case it is optional.
gao:signature	01	Signature	A digital signature MAY be provided.

Note: Should it be possible to report a result for evaluation against multiple guidelines? How would this interact with orders for multiple items?

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3.19.4.1.2.4 Alternative

The **alternative** parameter is an output containing a Basic resource structured as defined in Table 3.19.4.1.2.3-1 above. This parameter is like Result, but rather than evaluating the input order, it evaluates an alternative order constructed by the Decision Support Service. This enables the service to suggest and evaluate alternative diagnostic tests instead of a proposed test that may be outside of guidelines, or simply less desirable according to some measure.

There are a few differences in the constraints on the Basic resource when it appears in the **alternative** parameter. The code value is restricted to the value "within" because it makes no sense to propose an alternative order that would not be appropriate in response to an evaluation

560 request. The order being referenced shall be to a contained resource because it is constructed by the Decision Support Service Actor.

3.19.4.1.2.5 Provenance

The **provenance** parameter is an output containing a Provenance resource structured as defined in Table 3.19.4.1.2.5-1below. The provenance resource provides a digital signature for the Result and Alternative resources provided in the output. This parameter must be present when the Decision Support Service implements the Digital Signature Option.

Attribute	Card.	Data Type	Description/Notes
Provenance Res	source		
target	11	Basic	Each provenance resource SHALL have exactly one target which shall be one of the basic resources referenced by the Result or Alternative parameters.

Table 3.19.4.1.2.5-1: Provenance	Parameter Semantics
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Attribute	Card.	Data Type	Description/Notes
recorded	11	instant	The recorded instant SHALL be present and indicate when the Result or Alternative resource was created through the \$evaluate operation.
agent	11	Element	There SHALL be one agent specified where the following elements are present.
agent.role	11	Coding	The role of this agent SHALL be author.
agent.actor	11	Device <reference></reference>	This SHALL contain a reference to the Device that authored the target referred to in this provenance resource.
signature	11	Signature	A digital signature traceable to the Device that authored the target resource SHALL be provided.

570 **3.19.4.1.2.6 Questions**

The **questions** parameter is an output containing a Questionnaire resource which, if populated, could result in a more favorable evaluation of the proposed order.

Attribute	Card.	Data Type	Description/Notes	
Questionnaire	Resource			
group.linkId	11	string	Each group in the Questionnaire resource SHALL have a link so that it can be referenced in a QuestionnaireAnswers resource.	
question. linkId	11	string	Each question in the Questionnaire resource SHALL have a link so that it can be referenced in a QuestionnaireAnswers resource.	
question.type	11	code	Each question SHALL specify the answer type. The answer type SHALL NOT be Attachment or Resource.	

Table 3.19.4.1.2.6-1: Questions Parameter Semantics

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3.19.4.1.2.7 questionnaireURI

The **questionnaireURI** parameter is used to return a URL from which the Questionnaire resources returned in the response can be dynamically invoked via the web. This parameter SHALL be populated when the Decision Support Service implements the Conversational

580 Interaction Option and the **questions** parameter is present in the response. See Section 3.19.4.2 Invoke Questionnaire message below for more details on the use of the **questionnaireURI** parameter.

3.19.4.1.3 Expected Actions

- 585
- The Order Evaluation Requester SHALL synchronously call the \$evaluate operation associated with Order resources using an HTTP or HTTPS POST with a FHIR® Parameters resource containing the appropriate content as described in Section 3.19.4.1.2 Message Semantics above. It SHALL only populate the input parameters.

	2.	The Decision Support Service Actor SHALL identify which guidelines to apply to the order.
590	3.	If none of the guidelines are applicable, the Decision Support Service Actor SHALL return a result parameter indicating that no applicable guidelines applied.
595	4.	If one or more of the guidelines is applicable to the order, and the order is for only one item, the Decision Support Service Actor SHALL select the guidelines applicable based on policy and return a result parameter that indicates whether the order is appropriate against those guidelines.
	5.	When a DiagnosticOrder contains multiple items to evaluate, there are three possible cases that must be considered:
		a. None of the items in the DiagnosticOrder is addressed by a guideline. This case is addressed by step 3 above.
600		b. One or more of the items in the DiagnosticOrder are addressed by relevant guidelines known to the Decision Support Service Actor, and other items are not addressed by conflicting guidelines known to the Decision Support Service. This case is addressed as for step 4 above.
605		c. One or more of the items are addressed by a set of relevant guidelines known to the Decision Support Service Actor, and one or more other items are addressed by conflicting guidelines, also known to the Decision Support Service Actor. In this case, the service may not be able to perform the evaluations necessary in order to determine appropriateness of the order. It cannot make an individual determination for the entire order, because there is no single guideline against
610		which the entire evaluation can be performed. The Decision Support Service SHALL return a result parameter which indicates that the order items together are cannot be evaluated together. It MAY also return multiple orders in the alternatives parameter in which the different subsets of ordered items are evaluated against a single guideline.
615		In all of the above cases, if the Decision Support Service needs additional input from the end user to identify the applicable guideline, it may respond with a request for additional information.
620	6.	If there are alternative services which might also be applicable in the situation covered by the guideline identified in step 2 above, the Decision Support Service Actor MAY propose an order for that alternative and return it in the alternatives parameter. This would usually be done when the ordered service does not conform to the guideline, but an alternative order might. For example, when the order is for an MRI of the knee, but the guideline indicates that an X-ray of the knee is appropriate,
625		but an MRI is not, the Decision Support Service Actor may propose an alternative order for an X-ray of the knee, and provide an evaluation for this service. Providing evaluations for alternative orders allows subsequent order management activities to potentially change the order without requiring a re-evaluation.

630	7.	If the evaluation cannot be completed without the additional information being provided, the Decision Support Service SHALL populate the code in the result parameter with "incomplete" to indicate that the evaluation process is not yet finished.
635	8.	If the evaluation can be evaluated without additional information, but more information could change the result, the Decision Support Service SHOULD populate the code in the result parameter with the result of the evaluation without that additional information. This enables the Order Evaluation Requester to decide whether or not to pursue a better result by providing that information.
	9.	If providing more information could result in a different decision according to the selected guideline, the Decision Support Service MAY return one or more Questionnaire Resources which would solicit the necessary information.
640		a. If a Questionnaire resource is provided, and the Decision Support Service implements the Conversational Interaction Option, it SHALL populate the endpoint output parameter. See the following section for more details on the use of this parameter.

3.20 Invoke Questionnaire

645 3.20.1 Scope

This transaction is used to invoke an interactive questionnaire to aid the Decision Support Service to further evaluate an order.

3.20.2 Actor Roles



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Figure 3.20.2-1: Use Case Diagram

Table 3.20.2-1: Actor Roles

Actor:	Order Evaluation Requester
Role:	The Order Evaluation Requester invokes the questionnaire in an interactive session between the end user and the Decision Support Service.
Actor:	Decision Support Service
Role:	The Decision Support Service interacts with the end user in a browser session and then returns the evaluated order information to the Order Evaluation Requester.

3.20.3 Referenced Standards

655 HL7® Fast Healthcare Information Resources (FHIR®) DSTU 2.0 (work in progress)¹⁰

HTML

HTTP

¹⁰ The version to use for this Trial Implementation can be found at ftp:// ftp.ihe.net/TF_Implementation_Material/PCC/fhir/FHIR-08-2015.zip

3.20.4 Interaction Diagram



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Figure 3.20.4-1: Questionnaire Invocation

The figure above shows the Order Evaluation Requester Actor invoking a form using a URL supplied by the Decision Support Service. The Decision Support Service Actor returns a form. This form, once submitted may invoke other forms. When the Decision Support Service Actor is finished asking questions, it returns control to the Order Evaluation Requester, passing back a URL where it can retrieve the results of the evaluation through a redirect URL supplied by the Order Evaluation Requester in the Invoke Questionnaire message. The Order Evaluation

Requester then retrieves these results.

3.20.4.1 Invoke Questionnaire

670 This message is used to invoke an interactive session in a way that the Order Evaluation Requester can complete the process of obtaining an evaluation.

3.20.4.1.1 Trigger Events

When the Order Evaluation Requester receives a response indicating that more questions need to be answered, it may use this message to complete the evaluation request.

675 3.20.4.1.2 Message Semantics

The Order Evaluation Requester Actor issues an HTTP (or HTTPS) POST request to the end point specified in the Questionnaire Resource. The body of the request is a FHIR® Parameters Resource containing the parameters described below in Table 3.20.4.1.2-1.

Parameter	Card.	Data Type	Description
		Input	Parameters
order	11	Order	The order to evaluate, the same order provided in the \$evaluate transaction.
coverage	0*	Coverage	Optional resources describing the patient's coverage, identical to those in the \$evaluate transaction.
questions	1*	Questionnaire	A reference to the Questionnaire resources returned in the original \$evaluate response.
answers	0*	QuestionnaireAnswers	Answers to any questions which have been or may be posed by the Decision Support Service
redirectURI	01	uri	Specifies a URI where an interactive evaluation session will be redirected when the session is completed. This parameter SHALL NOT be populated in the \$evaluate interaction. It SHALL be populated by the Order Evaluation Requester when the parameters resource is passed to the interactive session.

Table 3.20.4.1.2-1: Message Parameters

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3.20.4.1.3 Expected Actions

- 1. The Order Evaluation Requester SHALL synchronously invoke the web page in a browser window via the URL specified in the endpoint parameter using an HTTP or HTTPS POST request.
- 685
 2. The request body SHALL be populated with a Parameters resource that copies appropriate values from the response body of the previous Evaluate Order request as described above. The Parameters resource SHALL also have the **redirectURI** parameter populated, and may include **answers** parameters for those questions that were already answered.
- 690 3. The Decision Support Servicer Actor shall interact with the user through this browser window to obtain answers to the questions.
 - 4. When the interactive session is complete, the Decision Support Service Actor SHALL return a redirect response using the URL specified in the **redirectURI** parameter.
 - a. The HTTP response code returned by the Decision Support Service Actor SHALL be 301 Moved Permanently.
 - b. The HTTP Location header shall be set to the **redirectURI** parameter concatenated with a query parameter named **evaluationURI**. The value of that query parameter shall be the URI where the evaluation response can be retrieved.
 - c. The form of the **evaluationURI** parameter should be [base]/Parameters/*identifier* where [base] is the base URL for the Decision Support Service Actor and *identifier* is a unique identifier for this evaluation result.

5. The Order Evaluation Requester retrieves the Parameters resource using an HTTP or HTTPS GET request. The resource is structured as described in Table 3.19.4.1.2-1 \$evaluate Message Parameters above.

705 **3.20.5 Security Considerations**

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Resources which are passed as parameters in this transaction may contain individually identifiable health information. This profile limits the required information to the service ordered, and the patient date of birth and gender, allowing date of birth to be specified with limited precision, restricting the quantity of PHI transmitted, and potentially needing to be stored

(e.g., audit logs) as a result of executing this transaction. Specific implementations of this profile may require more information be transmitted, or may further prohibit the transmission of certain details not otherwise required by this profile. The use of additional data elements can increase the attack surface of the interface specified within this transaction.

To secure these transactions, the ATNA Profile may be used to ensure that the information is encrypted, and that both sender and receiver are mutually authenticated.

The use of Questionnaire and QuestionnaireAnswer resources to provide additional information allows the Decision Support Service to request information that may include PHI. An Order Evaluation Requester Actor may pre-emptively supply answers to questions it knows may be asked for certain orders. Again, this can increase the attack surface of the interface described in this transaction.

There may be a short period of time where the Decision Support Service needs to store PHI to allow the Order Evaluation Requester to retrieve the response. Once the response has been retrieved, it can be discarded. Implementers must choose how they want to interact with the user to minimize the PHI that may need to be stored in this case.

725 The Order Evaluation Requester should ensure that the web URL is from a trusted source, and that the communication channel is protected. The ATNA Profile supports mutual authentication of the client and server, and encrypts the communication channel.

Volume 4 – National Extensions

730 *Add appropriate Country Section*

4 National Extensions

4.I National Extensions for US

4.I.1 Comment Submission

This national extension document was authored under the sponsorship and supervision of IHE
 735 USA, who welcome comments on this document and the IHE USA initiative. Comments should be directed to <u>http://www.ihe.net/PCC_Public_Comments</u>:

4.I.2 Guideline Appropriate Ordering (GAO)

The Guideline Appropriate Ordering Profile supports the CMS requirements for appropriate image ordering.

740 **4.I.2.1 Resource Constraints**

- 1. The codes for the service or services ordered in the Evaluation and Order resources SHALL come from appropriate terminologies as specified by Federal authorities for the service being performed.
- 2. The identifier of the ordering provider in the Practitioner and Evaluation resources SHALL be the National Provider Identifier or other such identifier as specified by Federal authorities.
 - 3. The identifier of the Decision Support Service SHALL be the identifier assigned by and/or registered with Federal authorities for use by that instance of the service.
 - 4. The identifier of the Clinical Guideline or guidelines in the Evaluation resource SHALL be the identifier assigned by and/or registered with Federal authorities for identification of those guidelines.
 - 5. The codes used to describe clinical data SHALL come from appropriate terminologies selected by Federal authorities for these uses.

4.I.2.2 Mapping Required Reporting Data

755 US legislation requires the following information be reported by the furnishing professional is described below¹:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

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760	(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);
	(II) whether the service ordered would not adhere to such criteria; or
	(III) whether such criteria was not applicable to the service ordered.
765	(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

The table below indicates where each of these required reporting data elements appears in the Basic resource that is returned as the Result or as an Alternative.

Required Information	Location
Information about which qualified clinical decision support mechanism	cmap:dss.Device.identifier
Applicable Appropriate Use Criteria	cmap:guideline
Adherence to applicable appropriate use criteria	code
National Provider Identifier	subject.source.identifier

Table 4.I.2.2-1: Required Reporting Data Locations