

Integrating the Healthcare Enterprise



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**IHE Patient Care Coordination
Technical Framework Supplement**

10

**Guideline Appropriate Ordering
(GAO)**

15

Draft for Public Comment

20 Date: June 1, 2015
Author: PCC Technical Committee
Email: pcc@ihe.net

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

Foreword

30 This is a supplement to the IHE 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.

35 This supplement is published on June 1, 2015 for public comment. Comments are invited and may be submitted at http://www.ihe.net/PCC_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by July 1, 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.

<i>Amend Section X.X by the following:</i>
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40 Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

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

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

50 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 IT Infrastructure Technical Framework can be found at: http://ihe.net/Resources/Technical_Frameworks.

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Introduction to this Supplement

- 115 This supplement updates the PCC Technical Framework Volumes 1, 2 and 3 to incorporate changes necessary to add the Guideline Accountable 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.
- 120

Open Issues and Questions

1. Is Authorize Order the right transaction name? What about Review Order? Is another name appropriate?

Closed Issues

- 125
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 [here](#) and was that FHIR® was the best candidate.

General Introduction

130 *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:

135

Actor	Definition
Authorization Requester	An actor that requests authorization or 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:

140

Transaction	Definition
PCC-Y Authorize Order	Evaluates an order against guidelines and/or policies to determine its appropriateness in a given context.

Volume 1 – Profiles

X Guideline Appropriate Ordering (GAO) Profile

145 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 (essentially an authorization) to be stored and transmitted, and the receiver of those results to verify that an order was evaluated with regard to appropriateness.

150 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 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
155 also identified a need for use of appropriateness criteria in cardiovascular imaging³.

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 http://ihe.net/Technical_Frameworks/.

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

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>

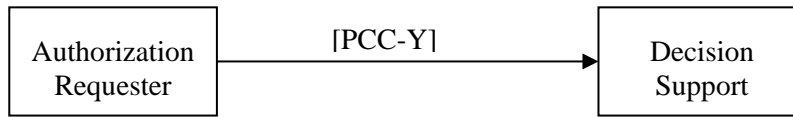


Figure X.1-1: GAO Actor Diagram

165 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”).

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

Actors	Transactions	Optionality	Reference
Authorization Requester	Authorize Order	R	PCC TF-2: 3.Y
Decision Support Service	Authorize Order	R	PCC TF-2: 3.Y

170

X.2 GAO Actor Options

Actor	Option	Reference
Authorization 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

175 The Conversational Interaction Option provides a mechanism by which the Decision Support Service can provide an interactive user interface through the web, and an Authorization Requester can receive the end result of that interactive session.

X.3 GAO Required Actor Groupings

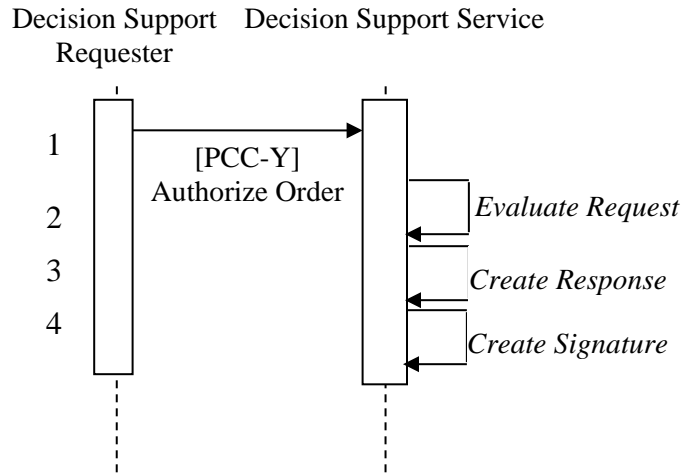
There are no required actor groupings for this profile.

X.4 GAO Overview

180 **X.4.1 Concepts**

X.4.2 Use Cases

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



185

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

Pre-conditions:

The Authorization 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.

190

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:

195

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

2. The Decision support service validates that the requested procedure is appropriate according to clinical guidelines and stores the result.

200

3. The Decision Support Service creates a response containing the provider identifier, procedure identifier, the decision support service identifier, identifiers for the relevant clinical guidelines, the result of the decision and confirmation of appropriateness and returns it to the Authorization Requester.

Post-conditions:

205

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.

X.5 GAO Security Considerations

X.5.1 Fraud

210 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.

X.5.1.1 Impersonation

215 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.

220 The asset at risk is money, where the payer ends up paying more for unnecessary services. Given 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.

225 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 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
230 eliminating the risk to the manufacturer's original certificate.

X.5.1.2 Repudiation

235 Because the authorization can represent that an order is eligible for payment, there are financial incentives to challenge whether or not an authorization is valid for a particular service. This profile enables the authorizing party or system to digitally sign an authorization. The digital signature signs the authorization identifier, the type of authorization given, the validity period of the authorization, 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 authorization to verify that the authorization was issued by the identified decision support service without having to query that service.

X.5.1.3 Replay

240 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

individual. Another form of replay is when an authorization is given, but it is not used until after
245 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 authorization 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
250 may be ordered together, yet multiple providers could perform different components of these
services under the same authorization. This is already the case for example, in Medicare, where a
single authorization can be used to authorize both the technical component (capturing an image),
and the professional component (interpreting the image).

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

255 **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 authorizations are positively reviewed are well
known, as would be the case for published guidelines. Thus, users of the system could be
260 incited financially to generate patient data which would be known to generate a positive
response. This sort of gaming cannot readily be prevented technologically, and is also fairly
likely to occur.

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
265 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
attack. Growing use of cloud services which are not necessarily designed for use in Healthcare
270 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.

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.

275 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.

280 **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.

285 If a secure communications channel cannot be created between two known 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.

290 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

295 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).

300 This profile should require that ordering providers accessing the Decision Support Service through this profile be authenticated by the Authorization 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 parties in the channel be known entities, and that users accessing services are authenticated.

305 **X.5.2.4 Availability**

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

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

315 **X.6 GAO Cross Profile Considerations**

When used with the Radiology Scheduled Workflow (SWF) Profile, this profile can be used to create content that can be passed from the Order Placer to the Order Filler, enabling the Order Placer to confirm that it has used decision support to determine that the imaging order is within clinical guidelines. That same content can be used by the Order Filler by grouping the Order Filler with the Content Consumer Actor of the DSG Profile to verify the signature.

320

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 __ (from the IHE Pharmacy Domain).

Volume 2 – Transactions

325 *Add Section 3.Y*

3.Y Authorize Order

3.Y.1 Scope

330 This transaction is used to evaluate an order to determine if it is acceptable according to guidelines. The Authorization 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 would be authorized according to guidelines.

3.Y.2 Actor Roles

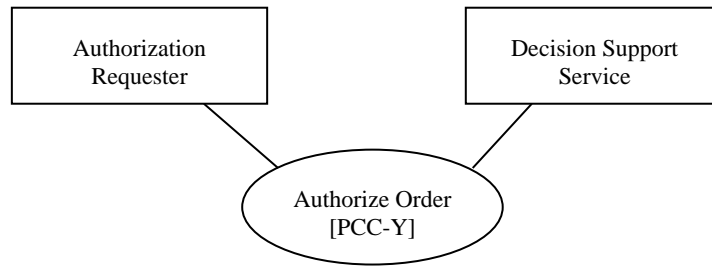


Figure 3.Y.2-1: Use Case Diagram

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Table 3.Y.2-1: Actor Roles

Actor:	Authorization Requester
Role:	The authorization requester provides clinical details necessary to make a determination whether the requested diagnostic or intervention is acceptable 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 acceptable based on those guidelines.

3.Y.3 Referenced Standards

HL7® Fast Healthcare Information Resources (FHIR®) DSTU 2.0 Draft for Ballot

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3.Y.4 Interaction Diagram

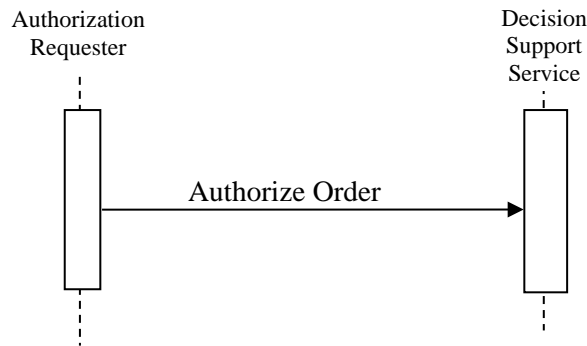


Figure 3.Y.4-1: Simple Authorization of an Order

345 The figure above illustrates a simple request/response message in which Authorization Requester proposes an order and the Decision Support Service evaluates it and returns an authorization response. In this sequence, the Authorization 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.

350

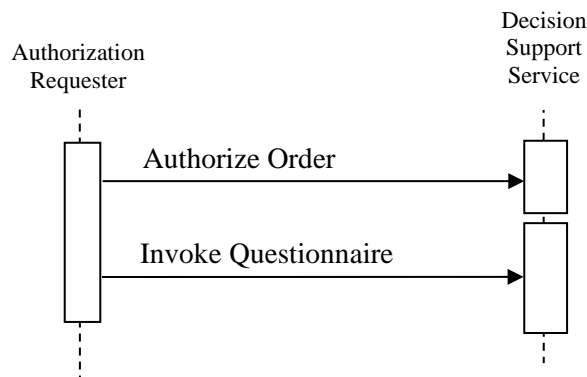


Figure 3.Y.4-2: Processing an Authorization with Questions

355 The figure above illustrates the 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 authorization response might be improved. The Authorization Requester can either

360 answer the questions directly, or it can make a request to the Decision Support Service to interact with the user to complete the authorization process.

3.Y.4.1 Authorize Order

365 The Authorize Order transaction is implemented through the FHIR® \$authorize 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.Y.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.

370 **3.Y.4.1.2 Message Semantics**

The message is a FHIR operation with the input and output parameters shown below in Table 3.Y.4.1.2-1. The name of the operation is \$authorize, and it is applied to Order resources. It is sent synchronously in JSON format from the Authorization Requester Actor to the Decision Support Service Actor using an HTTP or HTTPS POST request.

375 The URL for this operation is: [base]/Order/\$authorize

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

Table 3.Y.4.1.2-1: \$authorize Message Parameters

Parameter	Card.	Data Type	Description
Input Parameters			
order	1..1	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
Output Parameters			
order	1..1	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	1..1	Basic	A Basic resource indicating the status of the authorization produced by evaluating the order.
alternative	0..*	Basic	Basic resources indicating the status of authorizations produced by evaluating alternative orders suggested by the Decision Support Service Actor.
questions	0..*	Questionnaire	A reference to one or more Questionnaire resources, which, if completed might generate a different response from the decision support service.

Parameter	Card.	Data Type	Description
questionnaireURI	0..1	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.
redirectURI	0..1	uri	Specifies a URI where an interactive authorization session will be redirected when the session is completed. This parameter SHALL NOT be populated in the \$authorize interaction. It SHALL be populated by the authorization requester when the parameters resource is passed to the interactive session.

380 **3.Y.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.Y.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 \$authorize operation, and in the response returned from that operation.

Table 3.Y.4.1.2.1-1: Order Parameter Semantics

Attribute	Card.	Data Type	Description/Notes
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	1..1	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 authorization can verify that the order being placed was the same as an order that was authorized.
date	1..1	dateTime	The date associated with the order SHALL be provided so that the receiver of the authorization can verify that the order was produced within a reasonable time period for accepting the authorization according to local policies, and to enable the Decision Support Service to apply relevant guidelines.
subject	1..1	Patient<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 determine appropriateness.

Attribute	Card.	Data Type	Description/Notes
source	1..1	Provider<contained>	The identifier of the provider SHALL be provided in order for the receiver of the authorization to verify that the authorization given is associated with the correct order.
reason[x]	1..*	CodeableConcept Any<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 ⁴ , or other resources. This information must be supported and SHALL be provided.
detail	1..1	DiagnosticOrder<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	1..1	code	The patient gender SHALL be provided. This demographic is commonly used to determine appropriateness of orders.
birthDate	1..1	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.

⁴ 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
Provider Resource The provider resource is required to identify the provider placing 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).
DiagnosticOrder The diagnostic order resource is required to identify the service or services that were ordered, and to provide additional details that may be necessary to evaluate the order for appropriateness.			
clinicalNotes	0..1	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 ⁵ .
supporting Information	0..*	Observation<contained> Condition<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	1..1	CodeableConcept	The service being requested SHALL be provided. This is the service being evaluated against guidelines.
item.bodySite Codeable Concept	0..1	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	0..0	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.

3.Y.4.1.2.2 Answers

390 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.

395

⁵ Authorization Requester actors must demonstrate that they can populate this field.

Table 3.Y.4.1.2.2-1: Answers Parameter Semantics

Attribute	Card.	Data Type	Description/Notes
<p>QuestionnaireAnswers Resource 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 Authorization Requester Actor may pre-emptively provide answers to questions for orders it suspects may be necessary.</p>			
group.linkId	1..1	string	Each group in the QuestionnaireAnswers resource must be linked back to the group in the Questionnaire to which it corresponds.
question. linkId	1..1	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.

3.Y.4.1.2.3 Result

400 The **result** parameter is an output containing a Basic resource structured as defined in Table 3.Y.4.1.2.3-1 below. The basic resource identifies the Decision Support Service, the type of authorization provided, and the order that was subject of the authorization. It also identifies the guideline against which the order was evaluated.

405 **Table 3.Y.4.1.2.3-1: Result Parameter Semantics**

Attribute	Card.	Data Type	Description/Notes														
Basic Resource																	
identifier	0..1	Identifier	A business identifier associated with the authorization SHALL be provided unless the code is “incomplete” or “cannot be evaluated”. Note that this identifier may be associated with multiple authorizations.														
code	1..1	CodeableConcept	The code SHALL be provided. It must be selected from one of the following four values: <table border="0"> <tr> <td>Code</td> <td>Description</td> </tr> <tr> <td>within</td> <td>Order is within identified guidelines.</td> </tr> <tr> <td>outside</td> <td>Order is outside of identified guidelines.</td> </tr> <tr> <td>no guidelines</td> <td>No guidelines apply.</td> </tr> <tr> <td>incomplete</td> <td>Evaluation was not completed (e.g., because more information is necessary).</td> </tr> <tr> <td>cannot evaluate</td> <td>Cannot evaluate this order⁶.</td> </tr> <tr> <td>manual</td> <td>The authorization was issued through a manual process.</td> </tr> </table>	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 ⁶ .	manual	The authorization was issued through a manual process.
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 ⁶ .																
manual	The authorization was issued through a manual process.																
subject	0..1	Order	A reference to the order being evaluated SHALL be provided Unless the authorization was issued manually, in which case it is optional. This SHALL be a reference to the order in the parameters result ⁷ .														
gao:score	0..1	decimal	An optional value which can be used to record a score associated with the authorization process. The interpretation of this value may vary depending upon guidelines and Decision Support Service actors used. It is present to enable quality improvement efforts related to ordering.														
gao:period	0..1	Period	The period over which the authorization is valid SHALL be provided unless the authorization was issued manually, in which case it is optional.														
gao:item	1..*	Element	The services that are to be ordered SHALL be provided.														
gao:item.code	1..1	CodeableConcept	The service SHALL be identified by a code.														

⁶ Typically this would occur in the case where multiple items are ordered and multiple guidelines apply. The solution in this situation is for the Authorization requester to make a simpler request instead of trying to authorize multiple ordered services.

⁷ This element is also used in the Alternatives parameter with different constraints.

Attribute	Card.	Data Type	Description/Notes
gao:item. bodySite Codeable Concept	0..1	CodeableConcept	The body site associated by the service SHALL be provided if it is relevant to the authorization.
gao:guideline	0..*	uri	A reference to the guidelines or policies under which the authorization was created SHALL be provided unless the authorization was issued manually, in which case it is optional.
gao:device	0..1	Device	A reference to the Device resource describing the Decision Support Service Actor SHALL be provided unless the authorization was issued manually, in which case it is optional.
gao: practitioner	0..1	Identifier	An identifier representing the ordering practitioner SHALL be provided unless the authorization was issued manually, in which case it is optional.
gao:signature	0..1	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?

410 **3.Y.4.1.2.4 Alternative**

The **alternative** parameter is an output containing a Basic resource structured as defined in Table 3.Y.4.1.2.3-1 above. This parameter is like Result, but rather than evaluating the input order, it authorizes an alternative order constructed by the Decision Support Service. This enables the service to suggest and authorize alternative diagnostic tests instead of a proposed test that may be outside of guidelines, or simply less desirable according to some measure.

415 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 authorized in response to an authorization request. The order being referenced shall be to a contained resource because it is constructed by the Decision Support Service Actor.

420 **3.Y.4.1.2.5 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.

425

Table 3.Y.4.1.2.5-1: Questions Parameter Semantics

Attribute	Card.	Data Type	Description/Notes
Questionnaire Resource			
group.linkId	1..1	string	Each group in the Questionnaire resource SHALL have a link so that it can be referenced in a QuestionnaireAnswers resource.
question.linkId	1..1	string	Each question in the Questionnaire resource SHALL have a link so that it can be referenced in a QuestionnaireAnswers resource.
question.type	1..1	code	Each question SHALL specify the answer type. The answer type SHALL NOT be Attachment or Resource.

430 **3.Y.4.1.2.6 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 Interaction Option and the **questions** parameter is present in the response. See Section 3.Y.4.2

435 Invoke Questionnaire message below for more details on the use of the **questionnaireURI** parameter.

3.Y.4.1.3 Expected Actions

1. The Authorization Requester SHALL synchronously call the \$authorize 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.Y.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.
3. If none of the guidelines are applicable, the Decision Support Service Actor SHALL return a **result** parameter indicating that no applicable guidelines applied.
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 applicable against those guidelines.
- 450 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.
 - 455 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.

- 460
- 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 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.
- 465
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, 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 authorization for this service. Providing authorizations for alternative orders allows subsequent order management activities to potentially change the order without requiring a re-authorization.
- 470
- 475
7. If the authorization 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 authorization process is not yet finished.
- 480
8. If the authorization 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 Authorization Requester to decide whether or not to pursue a better result by providing that information.
- 485
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.
- 490
- d. 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.Y.4.2 Invoke Questionnaire

495 This message is used to invoke an interactive session in a way that the Authorization Requester can complete the process of obtaining an authorization.

3.Y.4.2.1 Trigger Events

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

500 3.Y.4.2.2 Message Semantics

The Authorization Requester Actor issues an HTTP (or HTTPS) POST request to the end point specified in the Questionnaire Resource. The body of the request is application/JSON containing the parameters found in the response to the Authorization Request. See Table 3.Y.4.1.2-1 \$authorize Message Parameters for the content of the Parameters resource.

505 3.Y.4.2.3 Expected Actions

1. The Authorization 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.
2. The request body SHALL be populated with a Parameters resource that copies the values from the response body of the previous Authorize Order request. The Parameters resource SHALL also have the **redirectURI** parameter populated.
3. The Decision Support Servicer Actor shall interact with the user through this browser window to obtain answers to the questions.
- 515 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.
 - 520 b. The HTTP Location header shall be set to the **redirectURI** parameter concatenated with a query parameter named **authorizationURI**. The value of that query parameter shall be the URI where the authorization response can be retrieved.
 - c. The form of the **authorizationURI** 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 authorization result.
- 525 5. The Authorization Requester retrieves the Parameters resource using an HTTP or HTTPS GET request. The resource is structured as described in Table 3.Y.4.1.2-1 \$authorize Message Parameters above.

530 **3.Y.5 Security Considerations**

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
535 (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
540 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 Authorization 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
545 this transaction.

When a Decision Support Service Actor implements the Conversational Interaction Option, there may be a short period of time, where it would need to store PHI to allow the Authorization 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
550 need to be stored in this case.

When interacting with a web browser control using the Conversational Interaction Option, the Authorization 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.
555

Volume 4 – National Extensions

Add appropriate Country Section

4 National Extensions

4.1 National Extensions for US

560 4.1.1 Comment Submission

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

4.1.2 Guideline Appropriate Ordering (GAO)

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

4.1.2.1 Resource Constraints

- 570 1. The codes for the service or services ordered in the Authorization 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 Authorization resources SHALL be the National Provider Identifier or other such identifier as specified by Federal authorities.
- 575 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 Authorization resource SHALL be the identifier assigned by and/or registered with Federal authorities for identification of those guidelines.
- 580 5. The codes used to describe clinical data SHALL come from appropriate terminologies selected by Federal authorities for these uses.