## FHIR 101 For the Policy Community

Viet Nguyen, MD Chief Standards Implementation Officer

March 30, 2023



International

## **HL7 International**

- A not-for-profit organization, founded in 1987
- ANSI-accredited standards development organization
- Dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information
- Three Product Families: FHIR, V3/CDA, V2.x



## **HL7's Global Reach**



International

## What are health care data standards?

In the context of health care, the term data standards encompasses *methods, protocols, terminologies, and specifications* for the *collection, exchange, storage, and retrieval of information* associated with health care applications, including medical records, medications, radiological images, payment and reimbursement, medical devices and monitoring systems, and administrative processes (Washington Publishing Company, 1998).



https://www.ncbi.nlm.nih.gov/books/NBK216088

## What do YOU mean by interoperability?

### Health IT Stack<sup>©</sup>





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## **Standards Stakeholders**





# How does policy drive standards development and adoption?

- Listening to stakeholder needs
- Direct support of standards development and adoption
- Setting of standards directly e.g. HIPAA, ONC Cures Act
- Adoption by agencies





International

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## Why are policies important to implementers?

- Legal and regulatory requirements and compliance
- Standards and guidelines for implementation for certification
- Privacy and security
- Data governance
- Consent management
- Collaboration and partnerships
- Technological infrastructure
- Education and training
- Continuous improvement



## Interoperability must move from a compliance activity to a strategic initiative.



## FHIR Timeline and Federal Regulations

CMS and ONC have identified FHIR as the foundational standard to support data exchange via secure application programming interfaces (APIs).



CMS identified FHIR in their final rules to establish a future where data flows freely and securely between payers, providers, and patients and to achieve truly coordinated care, improved health outcomes, and reduced costs.



## **FHIR 101**



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# The World Has Been Changed By Application Programming Interfaces (APIs)...



## What is an API and what is healthcare's API?



## What is FHIR?

# F – Fast H – Healthcare I – Interoperability R - Resources





## **Overview of FHIR**

- Consistent, simple to use content model resources
  - Controlled extensibility
- Supports all paradigms of exchange
  - Real-time APIs
  - Documents, Messages & Operations
- Designed with implementers in mind
- Freely available
- Detailed on-line, hyperlinked specification
- Freely available tooling, servers, libraries
- Massive supporting community



## **Benefits of FHIR**

#### **For Patients**

 Improved patient engagement, enabled through FHIR-enabled applications

#### **For Organizations**

- Major vendor commitment
- Faster deployment
- Standards based API to support internal application development
- Data standards to support analytics and population management

#### For Clinicians

- Access to a more complete patient record and improved decision-making tools, leading to:
  - Better decision making
  - More efficient diagnosis and treatment
  - Higher quality care

#### **For Implementers**

- Familiar tooling and technologies
- Predefined resources and APIs
- Validation services
- Active and supportive community
- Open source code libraries



## Scenario

55 y.o. AA male with hypertension and diabetes

#### **Encounter 1**

History: Patient is seen at and afterhours urgent care for a sore throat for 3 days. He has had a mild fever up to 101 Fahrenheit. He denies any other respiratory or gastrointestinal symptoms. Medications: metoprolol and glipizide. Allergies: none. Social History: non-smoker. Married. 3 adult children.

Vital signs: temperature 100.5 F, BP 110/75, RR 12, HR 70, O2 Sat 97% on room air On exam he has pus over his tonsils. His neck lymph nodes are enlarged. The rest of the exam is normal Lab: Rapid strep test is positive Assessment and Plan: Streptococcal sore throat. Patient is prescribed amoxicillin

#### **Encounter 2**

History: Patient returns with a rash over his chest that began after he started the amoxicillin. He admits that he has never taken amoxicillin before. He has no other respiratory symptoms. His fever and sore throat have resolved.

Vital signs are normal. Exam shows a raised rash over patient's chest and arms Assessment: penicillin allergy. Strep throat resolving Plan: Patient was switched to azithromycin

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## FHIR Essential Concepts

- Navigating the Specification
- FHIR Versioning
- Resources
- Profiles
- Operations
- Implementation Guides
- Key FHIR Technologies SMART on FHIR, CDS Hooks, Bulk FHIR, and CQL



## **FHIR Homepage**



This page is part of the FHIR Specification (v4.0.1: R4 - Mixed Normative and STU). This is the current published version. For a full list of available versions, see the Directory of published versions

#### 0 Welcome to FHIR®

FHIR is a standard for health care data exchange, published by  $HL7 \circledast$ .

#### First time here?

See the executive summary, the developer's introduction, clinical introduction, or architect's introduction, and then the FHIR overview / roadmap & Timelines. See also the open license (and don't miss the full Table of Contents and the Community Credits or you can search this specification).

#### **Technical Corrections:**





#### **Technical Corrections:**



## **Published vs Build Versions**



History

#### Publication (Version) History

This table provides a list of all the versions of FHIR (Fast Health Interoperability Resources) that are available. See also the directory of FHIR Implementation Guides.

The following versions of the FHIR Specification have been published:

Date	Version	Description	Links	
Current Vers	ions			
2019-10-30	4.0.1	FHIR Release #4: First Normative Content	Published Version	<b>₽ 4</b> 9999 9
(current)	(last commit)	Current Development build (about 30min behind change rapidly)	Build Version <sup>e incoherent and</sup>	
R5 Sequence	(Work in Progre	55)		
2020-08-20	4.5.0	FHIR Release #5: Preview #3		🛃 🖻 🔌 笒 🏈



HL7

## FHIR Getting Started



See the executive summary, the developer's introduction, clinical introduction, or architect's introduction, and then the FHIR overview / roadmap & Timelines. See also the open license (and don't miss the full Table of Contents and the Community Credits or you can search this specification).

**Technical Corrections:** 





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#### 1.9 Getting Started with FHIR

	FHIR Infrastructure 🖪 Work Group	Maturity Level: N/A	Standards Status: Informative	
--	----------------------------------	---------------------	-------------------------------	--

FHIR is a platform specification that defines a set of capabilities use across the healthcare process, in all jurisdictions, and in lots of different contexts. While the basics of the FHIR specification are relatively straight-forward (see the Overviews: General, Developers, Clinical, and Architects), it can still be difficult to know where to start when implementing a solution based on FHIR.

This page provides some guidance to help get new implementers started on their path to successful implementation. Beyond reading the overviews (previous paragraph), where should an implementer start? Generally, an implementer needs to resolve:



## **FHIR Documentation**



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#### **Technical Corrections:**



## **FHIR Documentation**

#### 1.1 Documentation Index

HL7

International

HIR Infrastructure 🗗 Work Group	Ma	turity Level: N/A	Standards Status: Informative
is page provides an index to the key commonly	used document	ation pages for FHIR.	
ramework	Exchanging I	Resources	Adopting & Using FHIR
Conformance Rules		API (HTTP) N	Profiling FHIR
Resource Life Cycles	<ul> <li>Searc</li> </ul>	h N (Search Param Registry)	FHIR Workflow
References between Resources	<ul> <li>Opera</li> </ul>	tions N	• Downloads - Schemas, Code, Tool
Compartments	<ul> <li>Async</li> </ul>	hronous Use	Managing Multiple FHIR Versions
Narrative	<ul> <li>Using</li> </ul>	GraphQL	Validating Resources
• Extensibility N	<ul> <li>Document</li> </ul>	S	Best Practices for Implementers
• Formats: N XML N, JSON N, & RDF	<ul> <li>Messaging</li> </ul>	I	Mapping Language (tutorial)
• Terminologies N (Code Systems, Value Sets)	Services		• Testing Implementations
• FHIRPath N	<ul> <li>Persistence</li> </ul>	e/Data bases	
Mappings to other standards	Base Types		Safety & Security
ersion Management	• Data Type	s (Base) N	Security, Security Labels & Signate
• Change Management & Versioning <b>N</b>	Metadata		Clinical Safety
			http://hl7.org/fhir/index.html

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## **FHIR Resources**

Home Getting Started	Documentation	Resources	Profiles Ex	xtensions	Operations	Terminologies	
Home					A resou	rce is an entity that:	
This page is part of the I versions, see the Directo			xed Normati	ive and STU	can ł	a known identity a URL by which it be addressed ains a set of structured data items	vailable
Welcome to	FHIR®					escribed by the definition of the	
• Welcome to		hange, published	by HL7®.		as de resor • has a	escribed by the definition of the urce type an identified version that changes if contents of the resource change	



## **FHIR Resources**

#### 1.2 Resource Index

FHIR Infrastructure 🖪 Work Group	Maturity Level: N/A	Standards Status: Informative
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This page is provided to help find resources quickly. There is also a more detailed classification, ontology, and description. For background to the layout on the layers in this page, see the Architect's Overview. See also the abstract Base Resources Resource and DomainResource.

egorized Alphabetical	R2 Layout By Maturity	Security Category By St	andards Status By Committe	
Conformance	Terminology	Security	Documents	Othe
CapabilityStatement	CodeSystem	Provenance 3	Composition 2	Basic 1
StructureDefinition	ValueSet	AuditEvent 3	<ul> <li>DocumentManifest 2</li> </ul>	• Binary N
ImplementationGuide 1	ConceptMap 3	Consent 2	DocumentReference 3	• Bundle N
SearchParameter 3	NamingSystem 1		CatalogEntry 0	• Linkage 0
<ul> <li>MessageDefinition 1</li> </ul>	• TerminologyCapabilities 0			MessageHeader 4
OperationDefinition				<ul> <li>OperationOutcom</li> </ul>
<ul> <li>CompartmentDefinition 1</li> </ul>				Parameters
<ul> <li>StructureMap 2</li> </ul>				<ul> <li>Subscription 3</li> </ul>
<ul> <li>GraphDefinition 1</li> </ul>				
• ExampleScenario 0				



## FHIR Resources – Alphabetical

#### 1.2 Resource Index

FHIR Infrastructure 🖪 Work Group	Maturity Level: N/A	Standards Status: Informative
----------------------------------	---------------------	-------------------------------

This page is provided to help find resources quickly. There is also a more detailed classification, ontology, and description. For background to the layout on the layers in this page, see the Architect's Overview. See also the abstract Base Resources Resource and DomainResource.

Categorized Alphabetica	R2 Layout	By Maturity	Security Category	By Standards Statu	IS By Committee
Aphabeted	R2 Edyout	by Huturity	Security category	by Standards State	by committee
Alphabetical					
A-D:	D-L:		M-P:		P-Z:
• Account 2	DeviceMe	tric 1	Measure 2		PractitionerRole 2
<ul> <li>ActivityDefinition 2</li> </ul>	DeviceRe	quest 1	MeasureRepo	ort 2	Procedure 3
AdverseEvent 0	DeviceUs	eStatement 0	Media 1		Provenance 3
AllergyIntolerance 3	<ul> <li>Diagnosti</li> </ul>	cReport 3	Medication 3		• Questionnaire 3
Appointment 3	Documen	tManifest 2	MedicationAct	Iministration 2	QuestionnaireResponse 3
• AppointmentResponse 3	Documen	tReference 3	MedicationDi	spense 2	RelatedPerson 2
• AuditEvent 3	EffectEvic	lenceSynthesis 0	MedicationKr	iowledge 0	RequestGroup 2
Basic 1	• Encounte	r 2	MedicationRe	quest 3	<ul> <li>ResearchDefinition 0</li> </ul>
Binary     N	Endpoint	2	MedicationSt	atomont 3	ResearchFlementDefinition



## FHIR Maturity Model

#### Draft

FMM0 = the artifact has been published on the current build. This level is synonymous with Draft.

#### STU

- FMM1 = FMM0 + the artifact produces no warnings during the build process and the responsible WG has indicated that they consider the artifact substantially complete and ready for implementation. For resources, profiles and implementation guides, the FHIR Management Group has approved the underlying resource/profile/IG proposal.
- FMM2 = FMM1 + the artifact has been tested and successfully supports interoperability among at least three independently developed systems leveraging most of the scope (e.g. at least 80% of the core data elements) using semi-realistic data and scenarios based on at least one of the declared scopes of the artifact (e.g. at a connectathon). These interoperability results must have been reported to and accepted by the FMG
- FMM3 = FMM2 + the artifact has been verified by the work group as meeting the Conformance Resource Quality Guidelines; has been subject to a round of formal balloting; has at least 10 distinct implementer comments recorded in the tracker drawn from at least 3 organizations resulting in at least one substantive change
- FMM4 = FMM3 + the artifact has been tested across its scope (see below), published in a formal publication (e.g. STU), and implemented in multiple prototype projects. As well, the responsible work group agrees the artifact is sufficiently stable to require implementer consultation for subsequent non-backward compatible changes.
- FMM5 = FMM4 + the artifact has been published in two formal publication release cycles at FMM1+ (i.e. STU level) and has been implemented in at least 5 independent production systems in more than one country
- Normative
  - FMM6 = FMM5 + the responsible work group and the FMG agree the material is ready to lock down and the artifact has passed HL7 normative ballot



## **FHIR Profiles**



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#### **Technical Corrections:**



## **FHIR Profiles**

#### 1.3 Profiles defined as part of FHIR

FHIR Infrastructure 🖪 Work Group	Maturity Level: N/A	Standards Status: Informative	
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This specification is a common platform standard that must be adapted to particular use cases. Some particular use cases are common or important enough to be described as a part of the specification itself. These are published as groups of Structure Definitions (profiles or extensions), which are often found in implementation guides, along with Value Sets, newly defined search parameters and examples that are all defined with a common purpose. Additional profiles and extensions may be registered on the HL7 FHIR registry at http://registry.fhir.org

Name	Description	Kind	FMM
General			
EHRS FM Record Lifecycle Event - Audit Event	Defines the elements to be supported within the AuditEvent resource in order to conform with the Electronic Health Record System Functional Model Record Lifecycle Event standard	profiles	
Clinical Reasoning Extensions	Defines common extensions used by the Clinical Reasoning Module.	extensions	
Common extensions for Coding data type	Defines "common" extensions for use with the DataElement data type	extensions	
Common extensions for ContactPoint data type	Defines "common" extensions for use with the ContactPoint data type	extensions	
Element-definition Extensions for use by FHIR Implementers	A set of extensions that constrain data elements, whether used in DataElements, StructureDefinitions or Questionnaires	extensions	
ISO 11179 Element Definition	A profile showing how to use ElementDefinition to express 11179 Data_Element and	extensions	



## **FHIR Extensions**

Home Getting Started Document	ation Resources P	rofiles Extensions	Operations	Terminologies	
Home					
This page is part of the FHIR Specific versions, see the Directory of publish		ed Normative and STL	<sup>))</sup> approa	ension is the FHIR ach to adding valid data ements to a resource.	available
0 Welcome to FHIR®				ble – US Core race	
HIR is a standard for health care dat	a exchange, published	by HL7®.	extens	ion on Patient resource	
First time here?					

**Technical Corrections:** 



## **FHIR Extensions**

#### 1.4 FHIR Core-defined Extension Registry

FHIR Infrastructure 🛃 Work Group	Maturity Level: N/A	Standards Status: Informative
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All extensions in this list are defined in this specification and have a base URI of <a href="http://hl7.org/fhir/StructureDefinition/">http://hl7.org/fhir/StructureDefinition/</a>. Additional extensions can be registered on the HL7 FHIR registry at <a href="http://hl7.org/fhir/registry">http://hl7.org/fhir/registry</a> .

Identity	Conf.	Туре	Context	FMM
capabilities	0*	code	CapabilityStatement.rest.security	1
oauth-uris	01	(complex)	CapabilityStatement.rest.security	1
11179-objectClass	01	Coding	ElementDefinition.mapping	1
11179-objectClassProperty	01	Coding	ElementDefinition.mapping	1
11179-permitted-value-conceptmap	01	canonical	StructureDefinition.snapshot.element.binding.valueSet, StructureDefinition.differential.element.binding.valueSet, Questionnaire.item.answerValueSet	1
11179-permitted-value-valueset       01       canonical       StructureDefinition.snapshot.element.binding.valueSet         StructureDefinition.differential.element.binding.valueSet       Questionnaire.item.answerValueSet				
DiagnosticReport-geneticsAnalysis	0*	(complex)	DiagnosticReport	1
DiagnosticReport-geneticsAssessedCondition	0*	Reference	DiagnosticReport	1



## **US Core Patient Profile**

#### This profile builds on Patient

Text Summary	<b>Differential View</b>		ntial View	Full View	All Views		
Name	Flags	Card.	Туре	Description & Cor	nstraints		
Patient		0*	Patient	Information about a	an individual or animal receiving health care services		
💿 us-core-race	S	01	(Complex)	US Core Race Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-race			
- 🌰 us-core-ethnicity	S	01	(Complex)	US Core ethnicity Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-ethnicity			
e us-core-birthsex	S	01	code	Extension URL: http://hl7.org Binding: Birth Sex	g/fhir/us/core/StructureDefinition/us-core-birthsex (required)		
🝅 identifier	S	1*	Identifier	An identifier for this patient			
🗔 system	S	11	uri	The namespace for	the identifier value		
value	S	11	string	The value that is ur	nique within the system.		
- 🧿 name	SI	1*	HumanName	A name associated with the patient <b>us-core-8:</b> Either Patient.name.given and/or Patient.name.family SHALL be present or a Data Absent Reason Extension SHALL be present.			
🛄 family	SI	01	string	Family name (often called 'Surname')			
given	SI	<mark>0</mark> *	string	Given names (not always 'first'). Includes middle names			
📇 telecom	S	0*	ContactPoint	A contact detail for the individual			



## **FHIR Operations**

<b>HL7</b> <sup>°</sup> FHIR <sup>°</sup> <sub>Release 4</sub>	HL7
Home Getting Started Documentation Resources Profiles Extensions Operations Terminologies	
Home	_
This page is part of the FHIR Specification (v4.0.1: R4 - Mixed Normative and STU) versions, see the Directory of published versions of the set of common interactions	available
0 Welcome to FHIR® read, update, search, etc.	
FHIR is a standard for health care data exchange, published by HL7®. <b>Control of typed resources</b> .	
<b>First time here?</b> See the executive summary, the developer's introduction, clinical introduction, or architect's introduction, and then the FHIR overview / roadmap & Timelines. See also the open license (and don't miss the full Table of Contents and the Community Credits or you can search this specification).	•

**Technical Corrections:** 


#### **FHIR Operations**

#### 1.5 Defined RESTful API Operations

FHIR Infrastructure 🖪 Work Group	Maturity Level: N/A	Standards Status: Informative
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The RESTful API defines a set of common interactions (read, update, search, etc.) performed on a repository of typed resources. For further information concerning how operations are defined and invoked, see Extended Operations on the RESTful API.

This is a full list of the operations defined by this specification:

Base Operations (All resource types)			
Validate a resource	[base]/[Resource]/\$validate   [base]/[Resource]/[id]/\$validate		
Access a list of profiles, tags, and security labels	[base]/\$meta   [base]/[Resource]/\$meta   [base]/[Resource]/[id]/\$meta		
Add profiles, tags, and security labels to a resource	[base]/[Resource]/[id]/\$meta-add		
Delete profiles, tags, and security labels for a resource	[base]/[Resource]/[id]/\$meta-delete		
Convert from one form to another	[base]/\$convert		
Execute a graphql statement	[base]/\$graphql   [base]/[Resource]/[id]/\$graphql		
Return a graph of resources	[base]/[Resource]/[id]/\$graph		
Operations Defined by Resource Types			
Apply         [base]/ActivityDefinition/\$apply   [base]/ActivityDefinition/[id]/\$apply			
Data Requirements	quirements [base]/ActivityDefinition/[id]/\$data-requirements		
Fetch a subset of the CapabilityStatement resource [hase1/CapabilityStatement/\$subset 1 [hase1/CapabilityStatement/[id1/\$subset			



#### Reference/Pilot Implementation RESTful Architecture Model



# **FHIR Terminologies**



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#### **Technical Corrections:**



http://hl7.org/fhir/index.html

### **FHIR Terminologies**

#### 4.3.0 Code Systems

Vocabulary 🛃 Work Group	Maturity Level: 3	Standards Status: Trial Use
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The following names (URIs) may be used in the *system* element of the Coding data type. If a URI is defined here, it SHALL be used in preference to any other identifying mechanisms. If a code system is not listed here, the correct URI may be determined by working through the following list, in order:

- the HL7 OID Registry
- the documentation associated with the code system
- consulting the owner of the code system
- asking on the HL7 vocabulary mailing list

See also the list of known identifier systems that can be used in the *system* element of the Identifier data type. Additional identifier systems may be registered on the HL7 FHIR registry at http://hl7.org/fhir/registry **Z**.

#### **Important Notes:**

- This list of names is incomplete and subject to change. Some values may be dropped, and others will likely be added in the coming months as HL7 institutes formal processes around URIs in vocabulary
- Note that some of the URNs in this list follow the URN specification in RFC 5141 🗹 for referring to standards published by ISO, such as urn:iso:std:iso:11073:10101. Where ISO standards define codes with meanings, and there is no entry in the list above, and they are not registered in the HL7 OID registry, the default URN for the code system is that defined by the RFC 5141.
- For several of the code systems in this list, multiple systems are given. This means that the variants identified are different code systems, not just



External Internal (FHIR) External (FHIR) HL7 v3 HL7 v2				
URI	Source	Comment	OID (for non-FHIR systems)	
Externally Published code systems		'		
http://snomed.info/sct	SNOMED CT (IHTSDO 🛃)	See Using SNOMED CT with FHIR	2.16.840.1.113883.6.96	
http://www.nlm.nih.gov/research/umls/rxnorm	RxNorm (US NLM 🗗	See Using RxNorm with FHIR	2.16.840.1.113883.6.88	
http://loinc.org	LOINC (LOINC.org	See Using LOINC with FHIR	2.16.840.1.113883.6.1	
http://unitsofmeasure.org	UCUM: (UnitsOfMeasure.org ) Case Sensitive Codes	See Using UCUM with FHIR	2.16.840.1.113883.6.8	
http://ncimeta.nci.nih.gov	NCI Metathesaurus	See Using NCI Metathesaurus with FHIR	2.16.840.1.113883.3.26.1.2	
http://www.ama-assn.org/go/cpt	AMA CPT codes 🗗	See Using CPT with FHIR	2.16.840.1.113883.6.12	
http://hl7.org/fhir/ndfrt	NDF-RT (National Drug File – Reference Terminology) 🗗	See Using NDF-RT with FHIR	2.16.840.1.113883.6.209	
http://fdasis.nlm.nih.gov	Unique Ingredient Identifier (UNII)	See Using UNII with FHIR	2.16.840.1.113883.4.9	
http://hl7.org/fhir/sid/ndc	NDC/NHRIC Codes	See Using NDC with FHIR	2.16.840.1.113883.6.69	
http://hl7.org/fhir/sid/cvx	CVX (Vaccine Administered)	See Using CVX with FHIR	2.16.840.1.113883.12.292	

### **FHIR Modules**



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#### 0 Welcome to FHIR®

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#### **Technical Corrections:**



http://hl7.org/fhir/index.html

# Levels

Foundation Base Docur		ocumentation, XML, JSON, RE	mentation, XML, JSON, REST API + Search, Data Types, Extensions		
vel 2 Supporting Imp	lementation, and bindin	g to external specifications			
Implementer Support	Security & Privacy	Conformance	Terminology	Linked Data	
Downloads, Common Use Cases, Testing	Security, Consent	StructureDefinition, CapabilityStatement, Profiling	CodeSystem, ValueSet, ConceptMap, Terminology Svc	RDF	
Administration	Patient,	Practitioner, Device, Organiz	zation, Location, Healthcar	re Service	
vel 4 Record-keeping	and Data Exchange for	the healthcare process			
Clinical	Diagnostics	Wedications	Workflow	<b>Financial</b>	
Clinical Allergy, Problem, etc.	Observation, Report, Request, etc.	Medications           Order, Dispense,           Administration,           Statement, etc.	Task, Subscription, etc.	Financial Claim, EligibilityRequest, etc.	
Allergy, Problem, etc.	Observation, Report, Request,	Order, Dispense, Administration, Statement, etc.	Task, Subscription,	Claim, EligibilityRequest,	



http://hl7.org/fhir/index.html

### SMART on FHIR

#### SMART on FHIR®® – Open Platform Architecture



http://hl7.org/fhir/smart-app-launch/1.0.0/



### FHIR Bulk Data Access



This page is part of the FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1) based on FHIR R4 2. This is the current published version in it's permanent home (it will always be available at this URL). For a full list of available versions, see the Directory of published versions 2 2

#### FHIR Bulk Data Access (Flat FHIR)

Providers and organizations accountable for managing the health of populations often need to efficiently access large volumes of information on a group of individuals. For example, a health system may want to periodically retrieve updated clinical data from an EHR to a research database, a provider may want to send clinical data on a roster of patients to their ACO to calculate quality measures, or an EHR may want to access claims data to close gaps in care. In most cases, access to these bulk-data exports is pre-authorized between the data holder and the data requester. The data exchange involves extracting a specific subset of fields from the source system, mapping the fields into a structured file format like CSV, and persisting the files in a server from which the requester can then download them into the target system. This multi-step process increases the cost of integration projects and can act as a counter-incentive to data liquidity.

Existing FHIR APIs work well for accessing small amounts of data, but large exports can require hundreds of thousands of requests. This



http://hl7.org/fhir/uv/bulkdata/

### **Clinical Quality Language CQL**



https://cql.hl7.org/index.html



# **Implementation Guides**



#### Why do we need Implementation Guides?





#### What is a FHIR Implementation Guide?

An implementation guide (IG) is a set of rules about how FHIR resources are used (or should be used) to solve a particular problem, with associated documentation to support and clarify the usage. Classically, FHIR implementation guides are published on the web after they are generated using the FHIR Implementation Guide Publisher.



### Major Components of an Implementation Guide

- Framework/Guidance
- Use cases and examples
- FHIR Artifacts e.g. profiles, operations, terminology
- Conformance language and CompatibilityStatement
- Some variation between guides



#### Business → Technical



### Reviewing an IG

- Workflow context
- Required resources, profiles, data elements, value sets, etc.
- Technical and exchange interactions
- Additional required technologies
- Dependencies on other IGs
- Conformance and CapabilityStatement



# **Example Scenarios**



#### Patient and Provider Access APIs (PDex)

International



PDex Information Sources/Flow

#### PAYER DATA EXCHANGE (PDex)

Internationa

Data Associated With Payers Meeting the Administrative/Financial and Clinical Requirements of the Interoperability Exchange



# Why should the policy community understand FHIR?



#### Structured vs Unstructured Data

<u>Question</u>. Are impacted payers required to **convert** large unstructured documents like portable document formats (**PDF**) to Fast Healthcare Interoperability Resources (FHIR) to support the clinical data exchange requirements of the Patient Access API? In other words, are impacted payers required to convert documents to FHIR to **identify clinical data elements** that may or may not be present on a PDF or fax?

**Response.** ...Patient Access API must meet the technical standards as finalized by HHS in the ONC 21st Century Cures Act final rule...CMS does not require payers to manually go through large files that cannot be parsed into data elements efficiently for the purposes of this API. The final rule did not require payers to include these large files as data available via the API.



#### **Authorization**

**Question:** Does the final rule allow payers impacted by the payer-to-payer data exchange requirements to accept another payer's requests for a payer-to-payer data exchange on behalf of a member? Can a health plan be considered the enrollee's personal representative for the purpose of payer-to-payer data exchange?

**Response**: ...final rule (CMS-9115-F) imposes a requirement for certain impacted payers to send, at a current or former enrollee's request (or at the request of a personal representative)... Per the ... (HIPAA) privacy regulations at 45 CFR § 164.502(g), a personal representative is someone authorized under state or other applicable law to act on behalf of the individual in making health care related decisions (such as a parent, guardian, or person with a medical power of attorney). ... However, a health plan cannot be considered an enrollee's personal representative



#### **Compliance and Testing**

<u>Question:</u> Does CMS require certification to determine if a payer's APIs comply with the requirements of the Interoperability and Patient Access final rule?

**<u>Response</u>**: No, CMS does not require that payers certify their APIs as part of the requirements... However, these impacted payers are required to conduct routine testing and monitoring, and update their systems as appropriate, to ensure the API functions properly, including conducting assessments to verify that the API is fully and successfully implementing privacy and security features such as those required to comply with HIPAA requirements...



https://www.cms.gov/files/document/faqs-interoperability-patient-access-and-cop-event-notifications-may-2021.pdf

### **Maintained Data**

**Question**. What is the requirement for impacted payers to maintain their data? Please clarify the intended meaning of the word "maintain."

**Response**. The Interoperability and Patient Access final rule (CMS-9115-F) defines "maintain" to mean the impacted payer has access to the data, control over the data, and authority to make the data available through the API (85 FR 25538). Payers are only required to make the data that they maintain in their systems available through the Patient Access API and for exchange with other payers. If a payer does not maintain clinical information for covered patients in its systems, the payer will not have to share clinical information through the Patient Access API or for exchange with other payers.



https://www.cms.gov/files/document/faqs-interoperability-patient-access-and-cop-event-notifications-may-2021.pdf

# How to Participate in the HL7 Community



### HL7.org





#### Confluence.HL7.org

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Clinical Interoperability Council

Community-Based Care and Privacy

Clinical Quality Information

Initiative

Conformance

Emergency Care

Specifications

Mobile Health

Patient Care

FHIR Infrastructure

**Financial Management** 

Human and Social Services

Implementable Technology

Infrastructure and Messaging

Learning Health Systems

Orders & Observations

Patient Administration

Devices

**Cross-Group Projects** 

Electronic Health Records

#### Confluence Spaces - People Glossaries

#### HL7

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- HL7 Essentials
- HL7.org
- F HL7 Work Groups & Projects
- HL7 Documentation & Help
- Project Scope Statements
- Project Proposals
- 2 Zoom
- Joint WGM Scheduler
- PAGE TREE
- HL7 Acceptable Use Policy
- HL7 Work Groups & Projects
- Participating in HL7
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# **Thank you!**

