PSS for Payer Coverage Decision Exchange

1. Project Name and ID

Enter the name of the project here: Payer Coverage Decision Exchange

Project ID: 1515

Complete this section for all "Direct to Normative" ballot projects and when a project proceeds from "Informative to Normative" or "STU to Normative".

Forward PSS to the TSC (via tscpm@HL7.org); this triggers American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission.

TSC Notification: Informative/STU to Normative
- or - Direct to Normative (no STU) (includes reaffirmations)

Identify ISO, IEC or ISO/IEC standard to be adopted in text box below

Enter info here if an ISO, IEC or ISO/IEC Standard is to be adopted as an American National Standard; Enter the designation of the standard(s) to be adopted:

Includes text from ISO, IEC or ISO/IEC standard: Check here if this standard includes excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption.

Select the unit of measure used in the standard; if no measurements are in the standard, select N/A

Select the unit of measure used in the standard; if no measurements are in the standard, select N/A

Investigative Project (aka PSS-Lite) Date:

Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition. Sections 1-Project Name, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3e-Project Objectives/Deliverables/Target Dates, 3i-Project Document Repository, 6b-[Realm, if known], and 6d-[applicable Approval Dates] are required for Investigative Project. Investigative Project specific instructions are highlighted in yellow. An investigative project must advance in two WGM cycles, requiring a full scope statement. Otherwise the project will be closed.

2. Sponsoring Group(s) / Project Team

2.a. Primary Sponsor/Work Group

Primary Sponsor/Work Group (1 And Only 1 Allowed) Financial Management

2.b. Co-sponsor Work Group(s)

Co-sponsor Work Group(s): (Enter co-sponsor approval dates in Section 6.d Project Approval Dates) Attachments

Indicate the level of involvement that the co-sponsor will have for this project:

X Request formal content review prior to ballot WGMs
X Request periodic project updates. Specify period WGMs

Other Involvement. Specify details here:

2.c. Project Team

All names should have confirmed their role in the project prior to submission to the TSC.

Project facilitator (1Mandatory) Robert Dieterle, Viet Nguyen

Other interested parties and their roles Viet Nguyen and Lloyd McKenzie (technical FHIR support)

Multi-disciplinary project team (recommended)
3. Project Definition

3.a. Project Scope

This PSS will use FHIR to exchange specific coverage/treatment decisions to another payer to allow for continued coverage of specific treatments without needing to repeat the review and authorization process that creates a burden for the provider, patient, and the payer. The decisions may be based on commercial guidelines that can be uniquely referenced or based on specific payer rules (may be difficult to define in a structured, rules based, resource or be limited by the proprietary nature of the payer’s evaluation process). In addition, the need exists to exchange the supporting documentation that was used to validate the necessity for coverage of specific treatments.

This PSS builds on existing or in process implementation guides for the automation of requests to a payer for coverage information (Coverage Requirements Discovery – CRD), access to payer information (Payer Data Exchange – PDex) and the Health Record Exchange Library/Framework (HRex).

This project will define patient driven/authorized exchange methods to meet the anticipated requirements for coverage portability.

This project will reference, where possible, the “standards” defined by the Health Record exchange (HRex) Library/Framework Implementation Guide which in turn will utilize prior work from Argonaut, US Core and QI Core effort for FHIR DSTU2, STU3, and R4 where appropriate. The following diagram depicts the anticipated scope of the HRex Exchange Library/Framework IG.

The ultimate goal is to support the portability of coverage by exchanging information between payers to define decision making and supporting documentation with regard to treatment for chronic illnesses without the need to burden the provider and/or patient or risk a discontinuity of care.

The project team plans to work with existing FHIR artifacts where possible. If changes are necessary, the project team will work with the responsible Work Group to review and implement (via tracker items or new PSS) any necessary enhancements to base FHIR resources, extensions, and/or profiles.
3.b. Project Need

Payers need a method of communicating the basis for specific coverage/treatment decisions (especially for chronic conditions) to another payer to allow for continued coverage of specific treatments without needing to repeat the review and authorization process that creates a burden for the provider, patient, and the payer. While this may not cover all situations, the ability to understand the basis for the decision (e.g. specific commercial clinical guidelines) and the relevant clinical information supporting the decision may allow the new payer to continue coverage for the existing services without additional burden to the provider or patient.

This PSS builds on existing or in process implementation guides for the automation of requests to a payer for coverage information (Coverage Requirements Discovery – CRD), access to payer information (Payer Data Exchange – PDex) and the Health Record Exchange Library/Framework (HRex).

Currently, no FHIR implementation guide exists to standardize the exchange of coverage decisions and supporting documentation. This implementation guide will provide a standard for adoption by payers for the definition, exchange, and evaluation of documentation supporting portability of coverage.

3.c. Security Risks

Will this project produce executable(s), for example, schemas, transforms, style sheets, executable program, etc. If so the project must review and document security risks. Refer to the Cookbook for Security Considerations for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment.

3.d. External Drivers

CMS NPRM

3.e. Project Objectives / Deliverables / Target Dates

<table>
<thead>
<tr>
<th>Work Product / Objective</th>
<th>Target Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard For Trial Use (First Ballot Cycle)</td>
<td>2019 September Ballot</td>
</tr>
<tr>
<td>Complete STU Reconciliation</td>
<td>2020 January</td>
</tr>
<tr>
<td>Request STU Publication</td>
<td>2020 January WGM</td>
</tr>
<tr>
<td>Submit for STU 2 Ballot (Second Ballot Cycle)</td>
<td>2021 May Ballot</td>
</tr>
<tr>
<td>Complete STU 2 Reconciliation</td>
<td>2021 Aug</td>
</tr>
<tr>
<td>Request STU 2 Publication</td>
<td>2021 Sept WGM</td>
</tr>
<tr>
<td>STU 2 Period</td>
<td>2021 Sept -2023 May</td>
</tr>
</tbody>
</table>
Submit for Normative Ballot | 2023 May Ballot
---|---
Complete Normative Reconciliation | 2023 Sept WGM
Submit Publication Request | 2023 Oct
Project End Date (all objectives have been met) | 2023 Dec

3.f. Common Names / Keywords / Aliases

- Da Vinci, Coverage Decision Exchange, Coverage Decisions

3.g. Lineage

- n/a

3.h. Project Dependencies

- Health Record Exchange Framework
- Payer Data Exchange

3.i. HL7-Managed Project Document Repository Location

Projects must adhere to the TSC’s guidelines (which were approved on 2016-04-04 and summarized in Appendix A).


Enter the SPECIFIC URL of the HL7-MANAGED SITE where supporting project documents, deliverables, ballot reconciliation work and other project information will be kept.

- [https://github.com/HL7/davinci-pcovex](https://github.com/HL7/davinci-pcovex)

3.j. Backwards Compatibility

Are the items being produced by this project backward compatible?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>X</th>
<th>N/A</th>
</tr>
</thead>
</table>

If you check ‘Yes’ please indicate the earliest prior release and/or version to which the compatibility applies:

For V3, are you using the current data types?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>X</th>
<th>N/A</th>
</tr>
</thead>
</table>

(Refer to TSC position statement on new projects using R2B for more information on the current V3 data types)

If you check no, please explain the reason:

If desired, enter additional information regarding Backwards Compatibility.

3.k. External Vocabularies
4. Products (check all that apply)

<table>
<thead>
<tr>
<th>Arden Syntax</th>
<th>V2 Messages – Administrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Information Modeling Initiative (CIMI)</td>
<td>V2 Messages - Clinical</td>
</tr>
<tr>
<td>Clinical Context Object Workgroup (CCOW)</td>
<td>V2 Messages - Departmental</td>
</tr>
<tr>
<td>Domain Analysis Model (DAM)</td>
<td>V2 Messages – Infrastructure</td>
</tr>
<tr>
<td>Electronic Health Record (EHR) Functional Profile</td>
<td>V3 Domain Information Model (DiM / DMIM)</td>
</tr>
<tr>
<td>FHIR Extensions</td>
<td>V3 Documents – Administrative (e.g. SPL)</td>
</tr>
<tr>
<td>FHIR Implementation Guide (enter FHIR product version below)</td>
<td>V3 Documents – Clinical (e.g. CDA)</td>
</tr>
<tr>
<td>FHIR Profiles (enter FHIR product version below)</td>
<td>V3 Documents - Knowledge</td>
</tr>
<tr>
<td>? FHIR Resources</td>
<td>V3 Foundation – RIM</td>
</tr>
<tr>
<td>Guidance (e.g. Companion Guide, Cookbook, etc)</td>
<td>V3 Foundation – Vocab Domains &amp; Value Sets</td>
</tr>
<tr>
<td>Logical Model</td>
<td>V3 Messages - Administrative</td>
</tr>
<tr>
<td>New/Modified/HL7 Policy/Procedure/Process</td>
<td>V3 Messages - Clinical</td>
</tr>
<tr>
<td>New Product Definition (please define below)</td>
<td>V3 Messages - Departmental</td>
</tr>
<tr>
<td>New Product Family (please define below)</td>
<td>V3 Messages - Infrastructure</td>
</tr>
<tr>
<td>Non Product Project - (Educ. Marketing, Elec. Services, etc.)</td>
<td>V3 Rules - GELLO</td>
</tr>
<tr>
<td>White Paper</td>
<td>V3 Services – Java Services (ITS Work Group)</td>
</tr>
<tr>
<td>Creating/Using a tool not listed in the HL7 Tool Inventory</td>
<td>V3 Services – Web Services (SOA)</td>
</tr>
</tbody>
</table>

If you checked New Product Definition or New Product Family, please define below:

For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?
R4, STU3, DSTU2

5. Project Intent (check all that apply)

<table>
<thead>
<tr>
<th>Create new standard</th>
<th>Supplement to a current standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revise current standard (see text box below)</td>
<td>X Implementation Guide (IG) will be created/modified</td>
</tr>
<tr>
<td>Reaffirmation of a standard</td>
<td>Project is adopting/endorsing an externally developed IG:</td>
</tr>
<tr>
<td>New/Modified HL7 Policy/Procedure/Process</td>
<td>Specify external organization in Sec. 6 below;</td>
</tr>
<tr>
<td></td>
<td>Externally developed IG is to be (select one):</td>
</tr>
<tr>
<td></td>
<td>Adopted - OR - ? External or Endorsed</td>
</tr>
<tr>
<td>White Paper (select one):</td>
<td>N/A (Project not directly related to an HL7 Standard)</td>
</tr>
<tr>
<td>Balloted Informative OR</td>
<td>Non-balloted WG White Paper</td>
</tr>
</tbody>
</table>

If revising a current standard, indicate the following:

- Name of the standard being revised:

- Date it was published (or request for publication, or ANSI designation date)

- Rationale for revision
5.a. Ballot Type (check all that apply)

<table>
<thead>
<tr>
<th>Comment (aka Comment-Only)</th>
<th>Joint Ballot (with other SDOs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informative</td>
<td>N/A (project won’t go through ballot)</td>
</tr>
<tr>
<td>X STU to Normative - OR -</td>
<td>X Normative (no STU)</td>
</tr>
</tbody>
</table>

If necessary, add any additional ballot information here. If artifacts will be jointly balloted with other SDOs, list the other groups.

5.b. Joint Copyright

Check this box if you will be pursuing a joint copyright. Note that when this box is checked, a Joint Copyright Letter of Agreement must be submitted to the TSC in order for the PSS to receive TSC approval.

Joint Copyrighted Material will be produced? | Yes | X | No

6. Project Logistics

6.a. External Project Collaboration

Include SDOs or other external entities you are collaborating with, including government agencies as well as any industry outreach. Indicate the nature and status of the Memorandum of Understanding (MOU) if applicable.

For projects that have some of their content already developed:

<table>
<thead>
<tr>
<th>How much content for this project is already developed?</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the content externally developed?</td>
<td>Y Da Vinci</td>
</tr>
<tr>
<td>Is this a hosted (externally funded) project? (not asking for amount just if funded)</td>
<td>X Yes No</td>
</tr>
</tbody>
</table>

6.b. Realm

<table>
<thead>
<tr>
<th>Universal - OR -</th>
<th>X Realm Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Check here if this standard balloted or was previously approved as realm specific standard</td>
</tr>
<tr>
<td>U.S.</td>
<td>Includes vocabulary and profiles that are specific to the US healthcare system</td>
</tr>
<tr>
<td>Support US Healthcare workflows</td>
<td></td>
</tr>
</tbody>
</table>

6.c. Stakeholders / Vendors / Providers

This section must be completed for projects containing items expected to be ANSI approved, as it is an ANSI requirement for all ballots

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Vendors</th>
<th>Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Clinical and Public Health Laboratories</td>
<td>Pharmaceutical</td>
<td>X Clinical and Public Health Laboratories</td>
</tr>
<tr>
<td>Immunization Registries</td>
<td>X</td>
<td>EHR, PHR</td>
</tr>
<tr>
<td>------------------------</td>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>X Quality Reporting Agencies</td>
<td>Equipment</td>
<td>Local and State Departments of Health</td>
</tr>
<tr>
<td>X Regulatory Agency</td>
<td>X</td>
<td>Health Care IT</td>
</tr>
<tr>
<td>Standards Development Organizations (SDOs)</td>
<td>X</td>
<td>Clinical Decision Support Systems</td>
</tr>
<tr>
<td>X Payors</td>
<td>X</td>
<td>Lab</td>
</tr>
<tr>
<td>X Other (specify in text box below)</td>
<td>HIS</td>
<td>N/A</td>
</tr>
<tr>
<td>N/A Other (specify below)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Other: Federal Healthcare Agencies (e.g. CMS), Providers (e.g. Physicians)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6.d. Project Approval Dates

Click here to go to HL7 Project Scope Statement Instructions#Appendix A for more information regarding this section. Approvals are by simple majority vote of the approving body.

<table>
<thead>
<tr>
<th>Sponsoring Work Group Approval Date:</th>
<th>FM Approval Date - Original</th>
<th>2019-03-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FM R4 Only Approval Date</td>
<td>2020-04-21</td>
</tr>
</tbody>
</table>

**Administrative review – in parallel with Work Group Approval**

<table>
<thead>
<tr>
<th>Co-Sponsor Group Approval Date</th>
<th>Attachments</th>
<th>2019-03-12</th>
</tr>
</thead>
</table>

**Family Management Group Approval Date(s)**

<table>
<thead>
<tr>
<th>CIMI Projects: CIMI Management Group</th>
<th>CIMI MG Approval Date</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDA Projects: CDA Management Group</td>
<td>CDA MG Approval Date</td>
<td>N/A</td>
</tr>
<tr>
<td>FHIR Projects: FHIR Management Group</td>
<td>FMG Approval Date</td>
<td>2019-03-20</td>
</tr>
<tr>
<td>V2/Publishing Projects: V2 Management Group</td>
<td>V2 MG Approval Date</td>
<td>N/A</td>
</tr>
<tr>
<td>US Realm Projects: US Realm Steering Committee Approval (Email WG approved PSS to: <a href="mailto:tscpm@HL7.org">tscpm@HL7.org</a>)</td>
<td>USRSC Approval Date</td>
<td>2019-03-26</td>
</tr>
<tr>
<td>Affiliate Specific Projects: Affiliate Approval Date</td>
<td>Affiliate Approval Date</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Submit PSS to Steering Division after all of the above approvals are received**

<table>
<thead>
<tr>
<th>Steering Division (of Primary Sponsor WG) Approval Date:</th>
<th>SD Approval Date CCYY-MM-DD</th>
<th>2019-03-26</th>
</tr>
</thead>
</table>

**Last PBS Metrics Score:**

<table>
<thead>
<tr>
<th>X</th>
<th>Green</th>
<th>Yellow</th>
<th>Red</th>
</tr>
</thead>
</table>

**PBS Metrics Reviewed?** (required for SD Approval if not green)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**ARB and Steering Division approval may be in parallel**

<table>
<thead>
<tr>
<th>Architectural Review Board Approval Date:</th>
<th>ARB Approval Date</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>(required for externally developed content)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TSC Approval**

If applicable, TSC has received a Joint Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

**Technical Steering Committee Approval Date:**

(Email SD WG approved PSS to: tscpm@HL7.org)

<table>
<thead>
<tr>
<th>TSC Approval Date</th>
<th></th>
</tr>
</thead>
</table>