Project Scope Statement
2015 Version
Release 1

HL7 Project Management Office
Project Services Work Group

Point of Contact Name and Email
David Hamill (pmo@hl7.org)

Co-Chairs of Project Services Work Group:
http://www.hl7.org/Special/committees/projectServices/leadership.cfm

Publication Date: January, 2015

URL to download document:
http://www.hl7.org/permalink/?ProjectScopeStatement

For prior versions of this document refer to:
http://www.hl7.org/Special/committees/projectServices/docs.cfm

The objective of this document is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products. It’s intended for projects to produce standards or Implementation Guides as well as infrastructure projects.
## Template Usage Information:

- Replace **Highlighted Courier New** text with appropriate content.
- To use Track Changes, turn off “protection” by clicking on Tools > Unprotect Document; in Word 2010, select Review>Track Changes
- For assistance in completing each section, refer to Appendix A.
- Information on the Project Approval Process is documented in Appendix B.
- For FAQs (Frequently Asked Questions), refer to Appendix C
- Submit template change requests to PMO@HL7.org

### 1. Project Name and ID

<table>
<thead>
<tr>
<th>Consumer Mobile Health Application Functional Framework</th>
<th>Project ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ TSC Notification Informative/DSTU to Normative</td>
<td></td>
</tr>
</tbody>
</table>

### 2. Sponsoring Group(s) / Project Team

<table>
<thead>
<tr>
<th>Primary Sponsor/Work Group (1 Mandatory)</th>
<th>Mobile Health Work Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-Sponsor Work Group(s)</td>
<td>EHR Work Group</td>
</tr>
<tr>
<td>Co-Sponsor Group Approval Date</td>
<td>Co-Sponsor Approval Date</td>
</tr>
<tr>
<td>Indicate the level of involvement that the co-sponsor will have for this project:</td>
<td>CCYY-MM-DD</td>
</tr>
<tr>
<td>☒ Request formal content review prior to ballot</td>
<td>Monthly update on EHR Work Group calls.</td>
</tr>
<tr>
<td>☐ Request periodic project updates. Specify period:</td>
<td>Encourage participation by EHR Work Group members who are not also members of the Mobile Health Work Group</td>
</tr>
<tr>
<td>☐ Other Involvement. Specify details here:</td>
<td>In addition, while not formal sponsors, both the Security and Devices Work Groups have agreed to provide input to this project.</td>
</tr>
</tbody>
</table>

**Project Team:**

**Project facilitator (1 Mandatory)**

| Tim McKay (Tim.A.Mckay@kp.org) |

**Other interested parties and their roles**

- **Multi-disciplinary project team (recommended)**
  - Modeling facilitator: Gora Datta
  - Publishing facilitator: Harry Rhodes (Harry.Rhodes@AHIMA.org)
  - Vocabulary facilitator: Sandra Stuart (Sandra.Stuart@kp.org)
  - Domain expert rep: Gora Datta, Tim McKay
  - Business requirement analyst: Tim McKay
  - Conformance facilitator (for IG projects): Gora Datta
  - Other facilitators (SOA, etc):

**Implementers (2 Mandatory for DSTU projects)**

*FHIRE Project Note: The implementer requirement will be handled by the “balloting” project. Therefore work groups do not fill out the above field.*
3. Project Definition

3.a. Project Scope

This project will define security, privacy and data standards for secure mobile health applications (apps). The intent is to provide industry guidance and common methods to enable the development of mobile health smartphone apps targeted to consumers/citizens that use protected health information (PHI) and personally identifiable information (PII). These standards will not address the content of such apps, but will provide a framework for security, privacy and trusted integration of data generated from apps into Personal Health Record (PHR) and Electronic Health Record (EHR) systems as well as into other types of data repositories (e.g., personal data stores, population care systems).

This project will reuse conformance criteria already available within the HL7 PHR-S and EHR-S Functional Models, augmenting with new conformance criteria specific to mobile platforms (e.g., use of geolocation services, accelerometers, cameras, microphones).

In particular, standards will address the following areas:
- Privacy policy, terms of use, and in-app disclaimers
- User, device, and cross-system authentication
- Authorization to content and features
- Proxy designations
- Use of location services, camera, accelerometers and other smartphone services
- Security of data at rest (local and cloud)
- Security of data in transit (wired and wireless)
- Minimum data standards for device generated and device transmitted information
- Record system reliability; record authenticity (it is what it represents to be)
- Data provenance
- Audit
- Standards related to discontinuation of use of an app

3.b. Project Need

Industry is in need of privacy and data standards in order to create consumer smartphone health apps which are secure, private, and that allow for data generated from and through these apps to be used in other health care contexts (e.g., personal data tracking, integration into a person’s record of care, clinical decision making). While the HL7 PHR-S FM expresses many of these functional requirements, it is not possible to use the PHR-S FM as-is to create mobile application standards. Mobile apps are generally not comprehensive in scope and, as such, mobile app standards cannot be extracted as PHR system profiles as it is impossible for most apps to adhere to all the SHALL statements within the PHR-S FM.

3.c. Success Criteria
### 3.d. Project Risks

This product intends to use the Sparx Systems ‘Enterprise Architect’ Profile Designer Tool for documentation and publishing and is dependent on personnel with EA expertise to be available to work on the project.

<table>
<thead>
<tr>
<th>Risk Description</th>
<th>Risk Type</th>
<th>Likelihood</th>
<th>Impact</th>
<th>Risk To HL7</th>
<th>Mitigation Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product intends to use the Sparx Systems ‘Enterprise Architect’ Profile Designer Tool for documentation and publishing and is dependent on personnel with EA expertise to be available to work on the project.</td>
<td>Requirements</td>
<td>High</td>
<td>Critical</td>
<td>Internal to HL7</td>
<td>Have at least two people on the project team trained to use the EA Profile Designer Tool. Rely on ad-hoc consulting with current implementers within the EHR Work Group for troubleshooting and support.</td>
</tr>
</tbody>
</table>

### 3.e. Security Risks

Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks.

<table>
<thead>
<tr>
<th>Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks.</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

### 3.f. External Drivers

No external drivers are known at this time.

### 3.g. Project Objectives / Deliverables / Target Dates

<table>
<thead>
<tr>
<th>Objective</th>
<th>Target Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit Framework for Comment Only Ballot(First Ballot Cycle)</td>
<td>2015 September Ballot</td>
</tr>
<tr>
<td>Complete consideration of comments</td>
<td>2016 January WGM</td>
</tr>
<tr>
<td>Submit for DSTU Ballot (1)</td>
<td>2016 May Ballot</td>
</tr>
<tr>
<td>DSTU Period - 12 months; complete reconciliation of comments</td>
<td>2017 May WGM</td>
</tr>
<tr>
<td>Submit for Normative Ballot</td>
<td>2017 May</td>
</tr>
<tr>
<td>Complete Normative Reconciliation</td>
<td>2017 Sep WGM</td>
</tr>
<tr>
<td>Submit Publication Request</td>
<td>2017 October</td>
</tr>
<tr>
<td>Receive ANSI Approval</td>
<td>2018 January</td>
</tr>
<tr>
<td>Project End Date (all objectives have been met)*</td>
<td>2018 January</td>
</tr>
</tbody>
</table>

*consideration will be given to beginning new project for V2 of the framework dependent on the continued evolution of consumer mobile devices and applications

### 3.h. Common Names / Keywords / Aliases

Mobile Health Framework; Consumer Health Mobile Framework

### 3.i. Lineage

While this is a new product, it will draw conformance criteria from both the EHR-S FM Release 2 and the PHR-S FM Release 1.

### 3.j. Project Requirements
3.k. Project Dependencies

None

3.l. Project Document Repository Location

TBD

3.m. Backwards Compatibility

Are the items being produced by this project backward compatible? □ Yes □ No □ Unknown □ N/A

For V3, are you using the current data types? □ Yes □ No □ N/A
(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:

3.n. External Vocabularies

Will this project include/reference external vocabularies? □ Yes □ No □ Unknown □ N/A
If yes, please list the vocabularies:

4. Products

Non Product Project- (Educ. Marketing, Elec. Services, etc.) □ V3 Domain Information Model (DIM / DMIM)
□ Arden Syntax □ V3 Documents – Administrative (e.g., SPL)
□ Clinical Context Object Workgroup (CCOW) □ V3 Documents – Clinical (e.g. CDA)
□ Domain Analysis Model (DAM) □ V3 Documents – Knowledge
□ Electronic Health Record (EHR) Functional Profile □ V3 Foundation – RIM
□ Logical Model □ V3 Foundation – Vocab Domains & Value Sets
□ V2 Messages – Administrative □ V3 Messages – Administrative
□ V2 Messages - Clinical □ V3 Messages - Clinical
□ V2 Messages - Departmental □ V3 Messages - Departmental
□ V2 Messages – Infrastructure □ V3 Messages - Infrastructure
□ FHIR Resources □ V3 Rules - GELLO
□ FHIR Profiles □ V3 Services – Java Services (ITS Work Group)
□ New/Modified/HL7 Policy/Procedure/Process □ V3 Services – Web Services (SOA)
□ New Product Definition □ N/A (Project not directly related to an HL7 Standard)
□ New Product Family

This is a variation/extension of the EHR-S and PHR-S functional models.

5. Project Intent (check all that apply)

Create new standard □ Supplement to a current standard
□ Revise current standard (see text box below) □ Implementation Guide (IG) will be created/modified
□ Reaffirmation of a standard □ Project is adopting/endorsing an externally developed IG:
□ New/Modified HL7 Policy/Procedure/Process Specify external organization in Sec. 6 below;
□ Withdraw an Informative Document Externally developed IG is to be (select one):
□ N/A (Project not directly related to an HL7 Standard) □ Adopted - OR - □ Endorsed

This project will create artifacts which are conceptually related to the PHR-S FM but directly address the needs of consumer mobile applications.

5.a. Ballot Type (check all that apply)

Create new standard □ Supplement to a current standard
□ Revise current standard (see text box below) □ Implementation Guide (IG) will be created/modified
□ Reaffirmation of a standard □ Project is adopting/endorsing an externally developed IG:
□ New/Modified HL7 Policy/Procedure/Process Specify external organization in Sec. 6 below;
□ Withdraw an Informative Document Externally developed IG is to be (select one):
□ N/A (Project not directly related to an HL7 Standard) □ Adopted - OR - □ Endorsed

This project will create artifacts which are conceptually related to the PHR-S FM but directly address the needs of consumer mobile applications.
Intent is to produce an artifact for comment only balloting in 2015 and to move to a DSTU ballot by mid-2016.

### 5.b. Joint Copyright

*Click here to go to Appendix A for more information regarding this section*

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**

### 6. Project Logistics

#### 6.a. External Project Collaboration

*Click here to go to Appendix A for more information regarding this section and FHIR project instructions.*

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>Assuming 30% to 50% of material will be derivative from existing conformance criteria from the PHR-S FM and EHR-S FM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this a hosted (externally funded) project? (not asking for amount just if funded)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### 6.b. Realm

*Click here to go to Appendix A for guidelines regarding choosing Universal or Realm Specific.*

- **Universal**
- **Realm Specific**

#### 6.c. Project Approval Dates

*Click here to go to Appendix A for more information regarding this section.*

<table>
<thead>
<tr>
<th>Affiliate/US Realm Task Force Approval Date (for US Realm Specific Projects)</th>
<th>USRTF Approval Date CCYY-MM-DD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsoring Work Group Approval Date</td>
<td>WG Approval Date CCYY-MM-DD</td>
</tr>
<tr>
<td>Steering Division Approval Date</td>
<td>SD Approval Date CCYY-MM-DD</td>
</tr>
<tr>
<td>PBS Metrics and Work Group Health Reviewed? (required for SD Approval)</td>
<td>Yes</td>
</tr>
<tr>
<td>FHIRR Project: FHIRR Management Group Approval Date</td>
<td>FMG Approval Date CCYY-MM-DD</td>
</tr>
</tbody>
</table>

**Technical Steering Committee Approval Date**

TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties.

**Yes** | **No**

#### 6.d. Stakeholders / Vendors / Providers

*Click here to go to Appendix A for more information regarding this section*

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>Immunization Registries</td>
<td>EHR, PHR</td>
<td>Emergency Services</td>
</tr>
<tr>
<td>Quality Reporting Agencies</td>
<td>Equipment</td>
<td>Local and State Departments of Health</td>
</tr>
<tr>
<td>Regulatory Agency</td>
<td>Health Care IT</td>
<td>Medical Imaging Service</td>
</tr>
<tr>
<td>Standards Development Organizations (SDOs)</td>
<td>Clinical Decision Support Systems</td>
<td>Healthcare Institutions (hospitals, long term care, home care, mental health)</td>
</tr>
</tbody>
</table>

**PSS Consumer Mobile Health Standards Framework 20150213-1 rdg.docx**

**2015 Release**

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6.e. Synchronization With Other SDOs / Profilers

Check all SDO / Profilers which your project deliverable(s) are associated with.

- ASC X12
- AHIP
- ASTM
- BioPharma Association (SAFE)
- CEN/TC 251
- CHCF
- CLSI
- ASC X12
- CHA
- LOINC
- DICOM
- GS1
- IEEE
- IHE
- IHTSDO
- ISO
- N/A
- NCPDP
- NAACCR
- Object Management Group (OMG)
- The Health Story Project
- Other (specify below)

Click here to go to Appendix A for more information regarding this section.

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