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My Health Record FHIR Gateway Operations Requirements and Guidelines

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Note: This document must be read in conjunction with the Portal Operator Registration Agreement

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1 Introduction

1.1 Purpose

The purpose of this document is to define the operations requirements and guidelines for applications (apps) connecting with the My Health Record system APIs via the My Health Record FHIR Gateway, using interaction models #1 or #4 (refer to Appendix A for details).

For the purpose of this document:

- registered portal operators using My Health Record APIs are collectively referred to as "developers".
- The Agency is referred to as the System Operator (SO) for the purposes of the My Health Record Act 2012 (Cth).
- References to "User" may to refer to a Registered Healthcare Recipient, Authorised Representative or Nominated Representative who may use the portal.

1.2 Intended audience

The intended audience for this document includes:

- registered portal operators (which includes mobile application developers) and
- the System Operator (which includes Accenture and the Gateway Operator).

1.3 Scope

These requirements apply to consumer apps that connect to the My Health Record system.

This document does not address the My Health Record business-to-business (B2B) web-services. Developers interested in using these services will need to complete a separate process including conformance with a different set of requirements, specifications, and the submission of specific B2B web-services forms.

Information about connecting to the B2B web-services can be obtained by emailing: help@digitalhealth.gov.au.

1.4 Types of applications

The following types of apps can connect to the My Health Record APIs and are referenced throughout this document:

1 **Mobile applications** are developed to run natively on a specific mobile device or platform (e.g. iOS, Android).

2 **Web applications** are powered by a web browser (e.g. Chrome, Firefox, Safari etc.) through the internet. Web applications are typically built using HTML, CSS, and JavaScript and are served through a mobile or desktop browser. Web applications can be built to look and feel just like a native application but will always run through a visible browser.

3 **Hybrid applications** are usually coded in HTML, CSS and JavaScript. They are run through an invisible browser which has been packaged into a native application. This enables the application to have the look, feel and functionality of a native application. Hybrid applications allow developers to minimise development time as minimal work is required to target various mobile operating systems. An additional benefit of using a hybrid application framework includes allowing developers to access Native API calls which can be used to enable binary security mechanisms from the device itself. Hybrid Applications can also be distributed through native application stores (allowing for additional vetting).

4 **Progressive web applications** can appear and behave as native applications on mobile devices but do not require installation of the application on the device.

The type of app you develop, your target audience, and your intentions for transmitting and storing data will determine the model for interacting with the My Health Record system. For example, an app may connect directly to the My Health Record system via the My Health Record FHIR Gateway, or via an intermediary server managed by the app developer. Refer to Appendix A for interaction model diagrams.

1.5 Requirement keywords

The following normative verbs in these requirements should be read as follows.

SHALL	When appearing in a conformance requirement, the verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicates an option that is recommended against.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.

2 Operations requirements

The following requirements apply to all interaction models and developers connecting with the My Health Record FHIR Gateway as defined in Section 1.1 and Appendix A, unless otherwise stated.

Table 1 - OPS-DEV-001

Requirement	OPS-DEV-001
Action	Formally apply to participate in the My Health Record system and access the My Health Record test environment.
Description	Developers **SHALL** formally apply to the System Operator to participate in the My Health Record system and access the My Health Record test environment by submitting a *Portal Operator Registration Form*, as provided by the System Operator.
Additional information	The intent of this requirement is for the System Operator to collect all necessary information from a developer regarding their organisation and proposed app as input into an assessment of the suitability for connection to the My Health Record system and access to the My Health Record test environment. This information includes (but is not limited to) the purpose of the app, intended app users, requested APIs for use in the test environment, interaction model and appointment of a minimum of one and maximum of three Operator Officers.

Table 2 - OPS-DEV-002

Requirement	OPS-DEV-002
Action	Formally apply to access the My Health Record production environment.
Description	Developers **SHALL** formally apply to the System Operator to access the My Health Record production environment by submitting a *Production Environment Access Request form* and a *Portal Operator Registration Agreement*, as provided by the System Operator.
Additional information	The intent of this requirement is for the System Operator to collect all necessary information from the developer regarding their organisation and app, including (but not limited to) the requested APIs, contact persons for production incident management purposes, details of customer support channels, and declaration of conformance to the mandatory requirements and API specifications. The details provided on the *Production Environment Access Request form* will be used to assess the developer's app for suitability to access the My Health Record production environment. An executed *Portal Operator Registration Agreement* is a mandatory requirement for the developer's app to access the My Health Record production environment.

Table 3 - OPS-DEV-003

Requirement	OPS-DEV-003
Action	Complete Notice of Connection (NOC) testing.
Description	Developers **SHALL** satisfy the requirements for My Health Record NOC testing. The NOC test sub-requirements are: • Developers **SHALL** perform their own thorough product testing. • Developers **SHALL** perform all test cases provided by the System Operator, using only the test data provided by the System Operator, in the My Health Record Test Environment (this is referred to as "self-assessment"). • Developers **SHALL** provide the test case results to the System Operator. The format of the test case results and mechanism for providing the test case results to the System Operator will be determined and communicated to the developer by the System Operator. • Developers **SHALL** satisfactorily pass the self-assessment, as determined by the System Operator based on the provided test case results, before progressing to the virtual session. • Developers **SHALL** attend a virtual session with the System Operator to test the connectivity of the app in the My Health Record test environment. The agenda of the virtual session and developer participation requirements will differ depending on the type of connection with the My Health Record system. The agenda and developer participation requirements will be determined and communicated to the developer by the System Operator. • Developers **SHALL** satisfactorily pass the test cases executed during the virtual session, as determined by the System Operator.
Additional information	The intent of this requirement is to ensure that the app can successfully connect with the My Health Record system, before the developer is eligible to apply for access to the My Health Record production environment.

Table 4 - OPS-DEV-004

Requirement	OPS-DEV-004
Action	Satisfy the requirements for the Conformance and Compliance Declaration (CCD).
Description	Developers **SHALL** satisfy the requirements for My Health Record CCD. The CCD sub-requirements are: • Developers **SHALL** submit a completed *Production Environment Access Request form* and a *Portal Operator Registration Agreement*, including a declaration that the app conforms to the mandatory requirements and API specifications. • Developers **SHALL** pass an assessment performed by the System Operator of the app's suitability for connecting with the My Health Record system.
Additional information	The intent of this requirement is to ensure that developers accept responsibility for the app's conformance to applicable My Health Record requirements and specifications.

Table 5 -OPS-DEV-005

Requirement	OPS-DEV-005
Action	Re-complete Notice of Connection (NOC) testing, and the Conformance and Compliance Declaration (CCD).
Description	Developers **SHALL** re-complete NOC testing and CCD process for the following app changes or updates: • Technical, design, clinical safety/usability, security or privacy/policy impacts that materially affect the way the app interacts with the My Health Record system. • Fixes that address issues reported by the System Operator.
Additional information	The intent of this requirement is to ensure that connectivity testing and re-declaration is completed in the event of app changes or updates, and that the System Operator can track app versions in the Production Environment. Further information about managing app changes/upgrades and notifying the System Operator is available in *My Health Record – Managing Your App in Production* [MHRMYAIP].

Table 6 - OPS-DEV-006

Requirement	OPS-DEV-006
Action	Maintain app with updated System Operator mandatory conformance requirements and API specifications[1] in accordance with the System Operator's rights under the Portal Operator Registration Agreement.
Description	Developers **SHALL** maintain their app against System Operator My Health Record conformance requirements and API specifications to ensure compliance with those conformance requirements and specifications. When changes to mandatory conformance requirements and API specifications are made, the System Operator will notify developers in writing (Notice). Developers **SHALL** review, assess and update their app to comply with those changed requirements and specifications within a reasonable time from the date of the System Operator's Notice.
Additional information	The intent of this requirement is to ensure compliance with updated mandatory conformance requirements and API specifications. We will make all conformance requirements and API specifications available via the Implementer Hub at: https://implementer.digitalhealth.gov.au.

[1] These requirements and specifications are published on the Implementer Hub at: https://implementer.digitalhealth.gov.au Alternatively, contact help@digitalhealth.gov.au to obtain these resources.

Table 7 - OPS-DEV-007

Requirement	OPS-DEV-007
Action	Adopt reasonable incident management processes.
Description	Developers **SHALL** be able to demonstrate to the satisfaction of the System Operator they have incident management processes in place to identify, log, analyse, and resolve incidents as they occur and to minimise the possibility of a re-occurrence.
Additional information	The intent of this requirement is to ensure that the System Operator can call on the developer to demonstrate they can manage app related incidents as they arise.

Table 8 - OPS-DEV-008

Requirement	OPS-DEV-008
Action	Notify the My Health Record System Operator of errors or issues.
Description	Developers **SHALL** notify the System Operator as soon as possible, and no later than two business days, if there is a My Health Record system-related error or defect in their app that will, or has the potential to, impact on the operation, security, integrity, clinical safety or reputation of the My Health Record system.
Additional information	The intent of this requirement is to ensure that the System Operator is made aware of errors or issues in a timely manner so that the error or issue can be suitably addressed.

Table 9 - OPS-DEV-009

Requirement	OPS-DEV-009
Action	Work co-operatively with the My Health Record System Operator for issues or errors.
Description	Developers **SHALL** work with the System Operator in a reasonable timeframe to address issues or errors with their app. This may include supporting the System Operator with any requests (e.g. providing app transaction logs).
Additional information	The intent of this requirement is to ensure that any errors or issues can be addressed promptly.

Table 10 - OPS-DEV-010

Requirement	OPS-DEV-010
Action	Work co-operatively with the My Health Record System Operator for ongoing monitoring and auditing.
Description	Developers **SHALL** provide reasonable assistance to the System Operator in relation to conformance monitoring, audits, reviews, and quality analysis of their app.
Additional information	The intent of this requirement is to ensure that the developer and System Operator work co-operatively to maintain the safety, quality, and integrity of the My Health Record system data.

Table 11 - OPS-DEV-011

Requirement	OPS-DEV-011
Action	Provide business hours support to the System Operator.
Description	Developers **SHALL** provide at least two business hours points of contact (Monday-Friday, not including public holidays) that have the authority and are able to resolve, or coordinate the resolution of, any technical, security or operational issues or errors affecting the My Health Record system.
Additional information	The intent of this requirement is to ensure that the System Operator can contact the developer during business hours and have any issues or errors investigated or resolved in a reasonable timeframe. The details of the points of contact can be communicated to the System Operator via the *Production Environment Access Request form*, as provided by the System Operator.

Table 12 - OPS-DEV-012

Requirement	OPS-DEV-012
Action	Provide after-hours support to the My Health Record System Operator.
Description	Developers **SHALL** provide at least two after-hours (i.e. 24/7) points of contact that have the authority and are able to resolve, or coordinate the resolution of, any technical, security or operational issues or errors affecting the My Health Record system.
Additional information	The intent of this requirement is to ensure that the System Operator can contact the developer after hours and have any issues or errors investigated or resolved in a reasonable timeframe. The details of the points of contact can be communicated to the System Operator via the *Production Environment Access Request form*, as provided by the System Operator.

Table 13 - OPS-DEV-013

Requirement	OPS-DEV-013
Action	Provide customer support to app users.
Description	Developers **SHALL** provide during Australian business hours (Monday-Friday, not including public holidays) support services to their customers (i.e. app users). The support mechanism is at the discretion of the developer but must satisfy the System Operator that it is fit-for-purpose and meets the needs of app users.
Additional information	The intent of this requirement is to ensure developers provide support services to enable their customers (i.e. app users) to report issues such as app defects, or the display of false or otherwise inappropriate information in their My Health Record. The customer support details provided in the Production Environment Access Request Form will be published on the My Health Record website and provided to the My Health Record Help Line to help direct app users to app support channels if required. The details of the customer support services are to be communicated to the System Operator via the *Production Environment Access Request form*, as provided by the System Operator.

Table 14 - OPS-DEV-014

Requirement	OPS-DEV-014
Action	Notify the My Health Record System Operator of changes.
Description	Developers **SHALL** notify the System Operator of: • significant changes or upgrades impacting the way their app interacts with the My Health Record system (see also requirement OPS-DEV-005) • material change in the developer's organisational legal structure • changes to nominated contact persons • changes to nominated Operator Officers.
Additional information	The intent of this requirement is to enable the System Operator to have the latest information about a developer and app to support communications, management of apps in the My Health Record production environment and ongoing monitoring and assessment of conformance. Changes to the legal structure and contact persons are covered in Rule 50 of the My Health Records Rule 2026 [MHRR2026]. It is mandatory to notify the SO in writing within 2 business days if there is a change in contact detail for an operator officer, change in operator officer and any material change (Rule 50). My Health Records Rules 2026 - Federal Register of Legislation

Table 15 - OPS-DEV-017

Requirement	OPS-DEV-017
Action	Deprecation strategy for application version control.
Description	Developers **SHALL** develop a deprecation strategy to limit the number of native versions of their app that are made available for installation, and to phase out faulty apps.

Additional information	The intent of this requirement is to ensure users are interacting with the My Health Record on safe and functional apps, utilising supported APIs.

Table 16 - OPS-DEV-018

Requirement	OPS-DEV-018
Action	Capability to require latest version of the app.
Description	Developers **SHALL** develop technical controls into their app to ensure the capability exists to force users, when required, to download and use the latest version of the app.
Additional information	The intent of this requirement is to ensure that app users use the latest version that may address clinical usability or security issues, or later versions of the APIs, by implementing either: • a background auto-update process, or • logon prevention until the user updates the software.

Table 17 - OPS-DEV-019

Requirement	OPS-DEV-019
Action	Capability to prevent use of deprecated version/s of the app.
Description	Developers **SHALL** develop the capability into their app to ensure users are prevented from logon until the user updates the app, either: • when requested by the System Operator; or • proactively by the developer for outdated apps, or apps with security vulnerabilities.
Additional information	The intent of this requirement is to ensure that users are prevented from using previous versions of the app when required by the System Operator (e.g. to address security vulnerabilities).

Table 18 - OPS-DEV-020

Requirement	OPS-DEV-020
Action	Notify the System Operator of deprecated apps.
Description	A developer **SHALL** advise the System Operator of newly deprecated app versions.
Additional information	The intent of this requirement is to provide notice to the System Operator of deprecated app versions.

Table 19 - OPS-DEV-021

Requirement	OPS-DEV-021
Action	Notify the System Operator of scheduled outages.
Description	Developers **SHALL** notify the System Operator of scheduled outages in which the app will be unavailable due to maintenance or other work no less than three days before the scheduled outage. The notice **SHALL** specify the reasons for the scheduled outage; when the scheduled outage will start and end.
Additional information	The intent of this requirement is to ensure that the System Operator is made aware of scheduled outages in a timely manner.

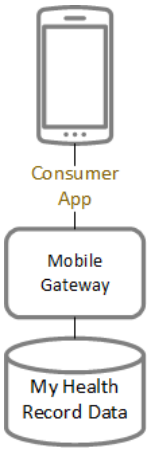
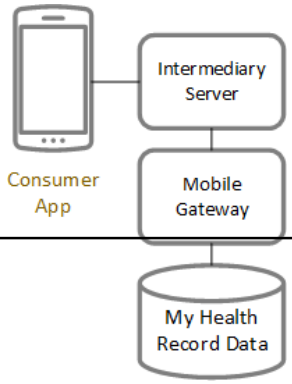
Table 20 - OPS-DEV-022

Requirement	OPS-DEV-022
Action	Notify the System Operator of a data breach.
Description	Developers **MUST** notify the System Operator, immediately if they become aware that there are reasonable grounds to suspect that there may have been a data breach in relation to any personal information held in the My Health Record system. (Section 75 of the *My Health Records Act 2012*) My Health Records Act 2012 - Federal Register of Legislation
Additional information	The intent of this requirement is to ensure that the System Operator is made aware of data breaches in a timely manner so that the error or issue can be suitably addressed.

Appendix A Interaction models

The following tables describe the two available interaction models for an application to connect with the My Health Record system, and vary based on the type of app, app end users and intended plans for accessing, using and storing My Health Record data.

Table 21 - Interaction models

Model	Description
#1 Consumer/Self-Care 	Consumer mobile app connects with the My Health Record system via the My Health Record FHIR Gateway.
#4 Consumer Connection via Platform 	Consumer mobile app connects with the My Health Record system via an intermediary server (managed by the Mobile Application Developer), which orchestrates the flow of data between the mobile app, My Health Record FHIR Gateway, or an end server (either managed by the Mobile Application Developer or third party). **Note:** It is possible that the data accessed via the intermediary server may be presented to the end user in a web app (e.g. portal accessible via a web browser).

Acronyms

Acronym	Description
API	application programming interface
CCD	conformance and compliance declaration
CIS	clinical information system
FHIR	Fast Health Interoperability Resources
NOC	notice of connection
SO	System Operator

Glossary

Term	Meaning
Accenture	Accenture is the business area responsible for providing and managing the My Health Record system on behalf of the System Operator.
Application programming interface (API)	An application programming interface (API) is a particular set of rules and specifications that software programs can follow to communicate with each other. It serves as an interface between different software programs and facilitates their interaction, similar to the way the user interface facilitates interaction between humans and computers.
application (app)	For the purposes of this document, a type of software that can connect to the My Health Record APIs. The types of applications that can connect to the My Health Record APIs are: • **Mobile applications** are developed to run natively on a specific mobile device or platform (e.g. iOS, Android). • **Web applications** are powered by a web browser (e.g. Chrome, Firefox, Safari etc.) through the internet. Web applications are typically built using HTML, CSS and JavaScript and served through a mobile or desktop browser. Web applications can be built to look and feel just like a native application but will always runs through a visible browser. • **Hybrid applications** are usually coded in HTML, CSS and JavaScript. They are run through an invisible browser which has been packaged into a native application. This enables the application to have the look, feel and functionality of a native application. Hybrid applications allow developers to minimise development time as minimal work is required to target various mobile operating systems. An additional benefit of using a hybrid application framework includes allowing developers to access Native API calls which can be used to enable binary security mechanisms from the device itself. Hybrid Applications can also be distributed through native application stores (allowing for additional vetting). • **Progressive web applications** can appear and behave as native applications on mobile devices, but do not require installation of the application on the device.
Conformance and compliance declaration	Process for vendors to self-declare conformance to the My Health Record interoperability requirements, guidelines, conformance profiles and specifications.
Clinical information system	A system that deals with the collection, storage, retrieval, communication and optimal use of health-related data, information, and knowledge. A clinical information system may provide access to information contained in an electronic health record, but it may also provide other functions such as workflow, order entry, and results reporting.
Developer	An organisation that develops a software product, or a provider of e-health services.

Gateway Operator	The business area responsible for providing and managing the My Health Record system on behalf of the System Operator.
Healthcare Recipient	Healthcare recipient has the same meaning as in the My Health Records Act 2012 (Cth).
interaction models	Describes how an application connects with the My Health Record system. Refer to Appendix A.
My Health Record system	Has the same meaning as in the My Health Records Act 2012 (Cth).
Notice of connection	A notice issued by the My Health Record system operator indicating that a system is ready to connect to the My Health Record system. Notice of Connection Testing is a test to ensure connectivity with the My Health Record system, using test cases and test data provided by the System Operator and executing a test in the My Health Record Test Environment.
Operator Officer	Operator Officer has the same meaning as in the My Health Records Rule 2016.
Portal	An electronic interface that facilitates access to the System by Representatives and Registered Healthcare Recipients and has the functionality set out in the Portal Operator Registration Agreement (PORA)
Production Environment Access Request (PEAR) form	Form for app developers to apply for Production Environment access by providing the specific details of their app and declaring that the app conforms to the mandatory conformance requirements.
Portal Operator Registration Agreement (PORA)	The conditions that the System Operator imposes on the registration of a Registered Portal Operator.
Registered portal operator (RPO)	Registered Portal Operator means “registered portal operator”, as defined in the My Health Records Act 2012 (Cth).

Term	Meaning
Registered Portal Operator	A legal entity that provides an electronic interface that facilitates access to the My Health Record system. Software vendors can be registered as portal operators subject to satisfying eligibility criteria.
System Operator	The System Operator is presently the Australian Digital Health Agency. It is responsible for establishing and operating the My Health Record system.
Representative	Representative means a Nominated Representative or an Authorised Representative.
System Operator	System Operator has the same meaning as in the My Health Records Act 2012 (Cth).

References

[MHRMYAIP] Australian Digital Health Agency. *My Health Record – Managing Your App in Productio*n, Available as part of the My Health Record Mobile Developer Welcome Pack: My Health Record Mobile Developer Welcome Pack v1.0 | Digital Health Implementer Hub

[MHRR2016] *My Health Records Rule 2016*, https://www.legislation.gov.au/Details/F2016C00607