



Australian Government
Australian Digital Health Agency



My Health Record FHIR Gateway Operations Requirements and Guidelines

13 March 2020 v1.1

Approved for external use

Document ID: DH-3087:2020

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au



Acknowledgements

Council of Australian Governments

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

Disclaimer

The Australian Digital Health Agency (“the Agency”) makes the information and other material (“Information”) in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

Copyright © 2020 Australian Digital Health Agency

This document contains information which is protected by copyright. All Rights Reserved. No part of this work may be reproduced or used in any form or by any means – graphic, electronic, or mechanical, including photocopying, recording, taping, or information storage and retrieval systems – without the permission of the Australian Digital Health Agency. All copies of this document must include the copyright and other information contained on this page.

OFFICIAL

Document information

Key information

Owner Director, System Management

Contact for enquiries Australian Digital Health Agency Help Centre

Phone [1300 901 001](tel:1300901001)

Email help@digitalhealth.gov.au

Product or document version history

Product or document version	Date	Release comments
1.1	13/03/2020	Final version for release

Table of contents

1	Introduction	5
1.1	Purpose	5
1.2	Intended audience	5
1.3	Scope.....	5
1.4	Types of applications	5
1.5	Requirement keywords.....	6
2	Operations requirements.....	7
	Appendix A Interaction models.....	15
	Acronyms	16
	Glossary.....	17
	References.....	19

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).

1.2 Intended audience

The intended audience for this document includes:

- mobile application developers
- registered portal operators
- the System Operator
- the National Infrastructure Operator (NIO).

For the purposes of this document, Registered Portal Operators and mobile application developers using My Health Record APIs are collectively referred to as “developers”.

1.3 Scope

These requirements are limited to consumer apps with view-only connections 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 <i>Portal Operator Registration Form</i> , as provided by the System Operator.
Additional information	<p>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.</p> <p>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.</p>

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 <i>Production Environment Access Request form</i> and a <i>Portal Operator Registration Agreement</i> , as provided by the System Operator.
Additional information	<p>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 <i>Production Environment Access Request form</i> will be used to assess the developer's app for suitability to access the My Health Record production environment. An executed <i>Portal Operator Registration Agreement</i> is a mandatory requirement for the developer's app to access the My Health Record production environment.</p>

Table 3 - OPS-DEV-003

Requirement	OPS-DEV-003
Action	Complete Notice of Connection (NOC) testing.
Description	<p>Developers SHALL satisfy the requirements for My Health Record NOC testing. The NOC test sub-requirements are:</p> <ul style="list-style-type: none"> • 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 My Health Record production environment access.

Table 4 - OPS-DEV-004

Requirement	OPS-DEV-004
Action	Satisfy the requirements for the Conformance and Compliance Declaration (CCD).
Description	<p>Developers SHALL satisfy the requirements for My Health Record CCD. The CCD sub-requirements are:</p> <ul style="list-style-type: none"> • Developers SHALL submit a completed <i>Production Environment Access Request form</i> and a <i>Portal Operator Registration Agreement</i>, 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	<p>Developers SHALL re-complete NOC testing and CCD process for the following app changes or updates:</p> <ul style="list-style-type: none"> • 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 <i>My Health Record – Managing Your App in Production</i> [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	<p>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.</p> <p>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 12 months from the date of the System Operator’s Notice.</p>
Additional information	<p>The intent of this requirement is to ensure compliance with updated mandatory conformance requirements and API specifications.</p> <p>We will make all conformance requirements and API specifications available via the Developer site at: https://developer.digitalhealth.gov.au.</p>

¹ These requirements and specifications are published on the Developer site at: <https://developer.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 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 <i>Production Environment Access Request form</i> , 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 <i>Production Environment Access Request form</i> , 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 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.
Additional information	<p>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.</p> <p>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.</p> <p>The details of the customer support services are to be communicated to the System Operator via the <i>Production Environment Access Request form</i>, as provided by the System Operator.</p>

Table 14 - OPS-DEV-014

Requirement	OPS-DEV-014
Action	Notify the My Health Record System Operator of changes.
Description	<p>Developers SHALL notify the System Operator of:</p> <ul style="list-style-type: none"> • 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	<p>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 55 of the <i>My Health Records Rule 2016</i> [MHRR2016].</p>

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

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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 apps.

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.

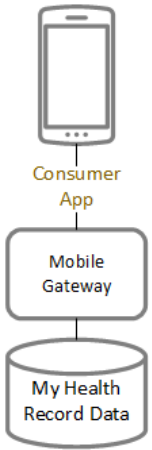
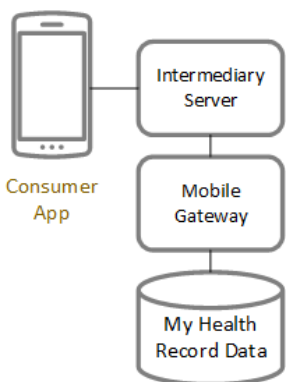
Table 20 - OPS-DEV-022

Requirement	OPS-DEV-022
Action	Notify the System Operator of a data breach.
Description	Developers SHALL notify the System Operator, as soon as possible, and no later than three days, 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.
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
<p>#1 Consumer/Self-Care</p> 	<p>Consumer mobile app connects with the My Health Record system via the My Health Record FHIR Gateway.</p>
<p>#4 Consumer Connection via Platform</p> 	<p>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).</p> <p>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).</p>

Acronyms

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

Glossary

Term	Meaning
application programming interface	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 application types are listed in Section 1.4.
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.
interaction models	Describes how an application connects with the My Health Record system. Refer to Appendix A.
National Infrastructure Operator	The business area responsible for providing and managing the My Health Record system on behalf of the System Operator.
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	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	An Operator Officer is someone who represents a repository or portal operator for the purposes of liaison and communication with the system operator, and who is responsible for maintaining the professional and business details of the operator and operator officer on the My Health Record system.
portal	An electronic interface that facilitates access to the My Health Record system. Portals do not store health information for the purposes of the My Health Record system, although a portal may store other information such as security credentials and logs of access. Portals can allow access to the My Health Record system by individuals or people acting on their behalf such as representatives, contracted service providers or third parties who are acting with the consent of individuals.

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.

References

[MHRMYAIP] Australian Digital Health Agency. *My Health Record – Managing Your App in Production*
(Contact help@digitalhealth.gov.au to obtain this resource.)

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