



My Health Record

Software Vendor Guide to the Connection Process

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OFFICIAL

Document information

Key information

Owner	Director Enterprise Operations
Contact for enquiries	Australian Digital Health Agency Help Centre
	Phone 1300 901 001
	Email help@digitalhealth.gov.au

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1 Welcome to the My Health Record system

Thank you for your interest in developing software to access the My Health Record system.

This document describes the steps required in preparing a Clinical Information System (CIS) or software used by a Contracted Service Provider (CSP) for connection to the My Health Record system (previously known as PCEHR or Personally Controlled Electronic Health Record).

On 1 July 2015, the approach for conformance and compliance of systems transacting with the My Health Record system, moved to an industry-enabled model. A self-declaration approach applies for My Health Record conformance profiles and specifications. In addition, an evidence verification applies to the My Health Record Connecting Systems Security conformance profile. The vendor's product adherence to conformance will consist of declarations based on each respective profile conformance requirements and specifications.

This document provides an overview of the process required to connect your software to the My Health Record system production environment. Table 1 describes the type of access available, based on the access channel used to connect to the My Health Record system.

Table 1 – Access channel matrix

Access channel	View access	Upload access
B2B Gateway	Supported	Supported
B2B CIS to NPP Service	Supported	Not Supported

For further information, please consult the Australian Digital Health Agency (the Agency) website at: www.digitalhealth.gov.au.

1.1 The welcome pack

Once you have registered for access to the My Health Record system community, download The Welcome Pack. See step 3 Table 4 - Required vendor actions for further details.

The welcome pack contains:

- Guide to the My Health Record system connection process (this document)
- Software vendor product details form
- Conformance vendor declaration form
- Instructions for completing the conformance declaration form
- My Health Record system vendor contacts list
- Managing your B2B software in production

If you have feedback on this kit, please email myhealthrecord.operations@digitalhealth.gov.au with the subject line: *My Health Record Welcome Pack*.

1.2 Onboarding stage

When completed, return the Software Vendor Product Details Form to help@digitalhealth.gov.au and the Application to Request a National Authentication Service

for Health (NASH) Public Key Infrastructure (PKI) Test Certificate to the Services Australia
Developer Liaison Team at Developerliaison@servicesaustralia.gov.au

2 Pre-requisites for access to the My Health Record system

Depending on the type of software you are developing and access channel you are going to use, the pre-requisites in Table 2 will apply.

Table 2 - Pre-requisites matrix

Access channel	Type of software	
	CIS	CSP
B2B Gateway (View and upload access)	<ul style="list-style-type: none">• Connection to the HI Service• HPI-I and HPI-O• NASH PKI test certificates	<ul style="list-style-type: none">• Connection to the HI Service• HPI-I• NASH PKI test certificates of CSP organisation
B2B CIS to NPP Service (View access only)	<ul style="list-style-type: none">• HPI-O and HPI-I• NASH PKI test certificate	Not Supported

2.1 Healthcare Identifiers (HI) Service

The Australian state and territory governments have developed a national HI Service, which uniquely identifies healthcare providers and individuals who seek to be involved in healthcare in Australia. Services Australia is the operator of the HI Service. The HI Service gives individuals and healthcare providers confidence that the right health information is associated with the right individual at the point of care.

To connect to the My Health Record system, a CIS must be able to verify data through the HI Service. This ability, whether it exists within the software itself, or is provided through another integrated system, is a pre-requisite for connection to the My Health Record system. It is important that you understand how your product will interact and connect to the HI Service as part of interacting with the My Health Record system.

Other than for CIS software connecting via CIS to NPP Service, you will need to apply for access to the HI Service, see step 3 Table 4 - Required vendor actions.

For more information on the HI Service, including information on developing software to connect to the HI Service, go to the Services Australia website for health professionals and developers (software vendors):

<http://www.medicareaustralia.gov.au/provider/vendors/healthcare-identifiers-developers/index.jsp>

Note: The HI Service is not required for clinical software connecting to My Health Record using the B2B CIS to NPP Service.

2.2 Test HPI-I, HPI-O or CSP NASH PKI certificates

To gain access to the My Health Record Software Vendor Test (SVT) environment, you must obtain the following test certificates and healthcare identifiers:

- NASH PKI certificate
- HPI-O
- HPI-I

The type of test certificates and healthcare identifiers required depend on your software type and the access channel you are using. Refer to Table 2 for more information.

NASH PKI test certificates will allow you to develop and test the workflow of your product by facilitating:

- authentication to the test environment for the My Health Record system (healthcare providers utilise NASH PKI organisation certificates to authenticate in the production environment); and
- testing the sending and receiving of secure messages.

The test certificates cannot be used in production and cannot be linked for use with the HI Service or any other online program. Software vendors are bound by the terms and conditions of the licence agreed to when applying for a NASH PKI test kit.

The NASH PKI test kit contains the following certificates:

- an active test NASH PKI organisation certificate for Healthcare Provider Organisations for two test organisations
- a revoked test NASH PKI certificate for Healthcare Provider Organisations for a test organisation, if requested, and
- an active test NASH PKI certificate for Supporting Organisations for a test organisation, if requested.

Test organisation names will vary in different test kits. Any healthcare identifiers embedded in the certificates are test healthcare identifiers only. Test certificates are valid for two years.

Software developers can request NASH PKI test kits by emailing Services Australia Developer Liaison team at developerliaison@servicesaustralia.gov.au:

For further information please see here:

<https://developer.digitalhealth.gov.au/resources/services/national-authentication-nash>

Note: A processing time of approximately two weeks is required.

You will also need to contact CO.HI.Vendor.Operations@servicesaustralia.gov.au and ask to have your test provider's HPI-I linked to your test organisation's HPI-O. To facilitate this, the team will require both the HPI-I and HPI-O numbers. For more information see step 5 Table 4 - Required vendor actions.

3 Testing

There are three types of testing required to validate your software product for connection to the My Health Record system. These are:

- Notice of Connection (NOC) testing. Testing your software using test cases and test data, provided by the System Operator, and observed by Gateway Operator.
- Evidence verification for My Health Record Connecting Systems Security Conformance Profile. Testing your software using conformance test specification and provide test evidence results to the Agency for evidence verification. See section 3.3 for more information.
- Conformance self-assessment. Your own internal self-assessment testing then preparation for the Conformance Vendor Declaration form.

All software products must successfully pass these testing requirements before gaining access to the My Health Record production system.

Note that the Vendor Product Details form must be completed and submitted prior to the commencement of NOC testing. See step 4 Table 4 - Required vendor actions for further details.

3.1 My Health Record Notice of Connection (NOC)

All software products need to pass NOC testing. NOC testing confirms that your software product performs according to the specified standards and conformance points defined in the technical and logical service specification documents. These documents are referenced within each implementation guide available on the Agency website:

<https://www.digitalhealth.gov.au/implementation-resources>

Once you have submitted the *Software Vendor Product Details Form* to help@digitalhealth.gov.au, Gateway Operator will send you a test pack, which includes the services nominated for use during the NOC process. Gateway Operator will observe NOC testing and when completed successfully, they will issue the Agency with a *My Health Record Declaration of Notice of Connection* for the specific version of your product that has been tested.

3.1.1 My Health Record Conformance Vendor Declaration Form

Upon completion of both NOC and conformance testing, you must complete the Conformance Vendor Declaration Form (for instructions, see: Instructions for completing the Conformance Vendor Declaration Form). By completing the Conformance Vendor Declaration Form, you are declaring conformance against the conformance profiles and specifications.

3.1.2 Vendor Deed Poll

Attached to the *My Health Record Conformance Vendor Declaration Form* is a *Vendor Deed Poll* that outlines several operational obligations to which you must agree when connecting a software product to the My Health Record system. The deed poll requires a signature from an authorised delegate of your organisation. The signature on the deed poll must be witnessed.

The System Operator has a responsibility to perform regular quality assurance analysis of the data and transactions submitted by products that connect to the My Health Record system (Operative Provision 9 in deed poll). If required, your organisation may be requested to assist with any product-specific analysis undertaken. The System Operator will keep your organisation informed of any findings related to your product(s).

Please email the completed *Conformance Vendor Declaration Form* to:
help@digitalhealth.gov.au

3.2 CIS or CSP software connecting via the B2B Gateway

If you are developing a CIS product for connection to the My Health Record system via the B2B Gateway, you may also want to consider developing and testing your product for use by a CSP. To be eligible for use by a CSP, CIS software requires a change to the transaction header. One option may be to control the CSP functionality through the product's configuration management.

For software to gain approval for use as a CIS or CSP product, it must pass a full set of NOC and CCD, CIS or CSP test cases. If a product is already approved for connection as one of these system types and additional approval is being sought (for example, change to support both CIS and CSP), then supplementary test cases per service must be passed.

Specification references for CSP testing are available from:
<https://developer.digitalhealth.gov.au/resources/my-health-record-b2b-gateway-services-v2-0>

For more information please see here:
<https://developer.digitalhealth.gov.au/resources/services/my-health-record/my-health-record-b2b-gateway>

The key Logical Service Specifications (LSS) and Technical Service Specifications (TSS) for the B2B Gateway are:

- Document Exchange Service LSS/TSS
- Record Access Service LSS/TSS
- View Service LSS/TSS
- Registration Service LSS/TSS.

3.3 Conformance testing

Conformance testing supports the safe and secure implementation and use of the My Health Record system as part of the Conformance Vendor Declaration process. The Conformance Vendor Declaration process requires that your software conforms to all applicable conformance profiles and the specifications they reference, and the conformance requirements for My Health Record Connecting Systems (Specifications), prior to your software being granted connection to the My Health Record system. Furthermore, you are required to maintain compliance following connection of your product to the production environment.

All technical specifications are available on the Digital Health Developer Portal:
<https://developer.digitalhealth.gov.au>

You verify conformance of your software product by conducting self-assessment testing using the conformance test specifications that are also available from the Developer Portal,

in conjunction with the Clinical Package Validator tool. Depending on the required assessment, you are required to either retain or provide evidence of the tests performed during self-assessment testing.

3.3.1 MHR Connecting Systems Security Conformance Profile

Figure 1 summarises the necessary steps for a software developer to obtain conformance to security profile which enables the software product to connect into My Health Record system.

Figure 1 – Connecting systems security conformance process



Table 3 provides a description of vendor actions required for each step of the vendor conformance process. The step numbers correlate to the numbers within the process flow described in Figure 22.

Table 3 - Vendor actions for security conformance

Process activity	Description/Action
Access and review all artefacts in Developer Portal	<ul style="list-style-type: none"> MHR Connecting Systems Security Conformance Profile is a prerequisite to a software product being connected to the My Health Record system. All documentation is published on the Agency's Developer Portal.
Complete pre-conformance testing	<ul style="list-style-type: none"> Execute software pre-conformance testing based on the security profile conformance test specification. Collect relevant test evidence (e.g., screenshot, recording) based on MHR Connecting Systems – Security Conformance Profile Conformance Test Specification. Complete an MHR Software Vendor Product Details form and make sure to update your software to the latest software version. Schedule a mini-NOC (Notice of Connection) with relevant vendor e.g., Deloitte. The mini-NOC applies to software which are already connected to My Health Record and are submitting only to meet MHR Connecting Systems Security Conformance Profile requirements. Arrange and secure either a penetration test, vulnerability test or both with an accredited third-party security organisation (if applicable). If

	the security organisation is not a member of CREST, please send a request to the Agency.
Submit Conformance Assessment documents to the Agency	<ul style="list-style-type: none"> • Send an email to help@digitalhealth.gov.au with the following information. <ul style="list-style-type: none"> ○ Completed MHR Software Vendor Product Details form and ensure that the software version has been incremented. ○ Request access to Agency's secure collaboration platform (e.g., GOVTEAMS), if not already granted. • Upload the following documents for Conformance Assessment. <ul style="list-style-type: none"> • A completed My Health Record Connecting Systems – Security Conformance Profile Conformance Test Specification. • Collected test evidence to support My Health Record Connecting Systems - Security Conformance Profile Conformance Test Specification. Penetration testing, vulnerability testing or both test reports, where applicable.
Submit Conformance Vendor Declaration to the Agency	<p>Submit the following documents for Conformance Declaration.</p> <ul style="list-style-type: none"> • My Health Record Software Vendor Welcome Pack - Conformance Vendor Declaration Form • My Health Record Connecting Systems Security Conformance Profile – Test Completion Report. This document is provided by the Agency upon successful assessment completion.

3.4 CIS software connecting via the B2B CIS to NPP Service

Specification references for CIS software connecting via the B2B CIS to NPP Service are available from:

<https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-2876-2019>

The key service specifications for the B2B CIS to NPP Service are:

- CIS to NPP Technical Service Specification
- National Provider Portal (NPP) CIS to NPP Implementation Guide.

3.5 Product authorisation

The System Operator will authorise a specific version of your software product to access the My Health Record system when the following occur:

- your software product is approved for connection to the HI system, with testing observed by Services Australia
- your software product passes your internal conformance testing
- your software product passes the relevant connectivity tests (NOC)
- you complete the *Conformance Vendor Declaration Form*.

3.6 Notification of environment availability

Services Australia will issue notifications to My Health Record software vendors when the SVT or the production environments experience an outage. The email address is sourced directly from the Health Systems Developer Portal (the portal) and each My Health Record software vendor organisation is responsible for keeping their own details up to date.

The authorised officer from the organisation will need to log in to the portal and edit the main, group and/or technical contacts via the 'Organisation details' tab.

The portal is accessed via the following URL -

<https://healthsoftware.humanservices.gov.au/claiming/ext-vnd>

The SVT environment is supported during business hours (8:30am to 5:00pm) Monday to Friday, Eastern Standard Time, excluding ACT public holidays.

4 Vendor conformance process

4.1 Vendor conformance process overview

Figure 2 summarises the steps necessary to test your product prior to connecting to the My Health Record system. Section 4.2 describes these steps in more detail.

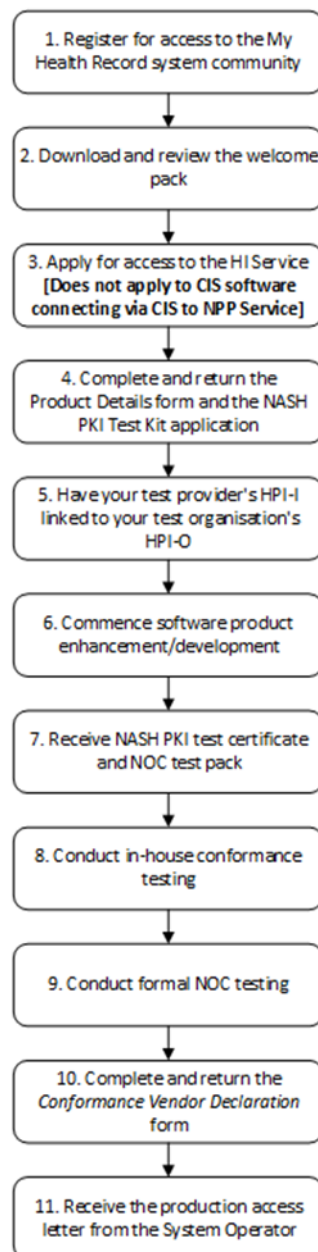


Figure 22 - Vendor conformance process

4.2 Vendor conformance process description

Table 4 provides a description of vendor actions required for each step of the vendor conformance process. The step numbers correlate to the numbers within the process flow described in Figure 2.

Note: The My Health Record system was previously known as the Personally Controlled Electronic Health Record (PCEHR). There are some conformance and specification documents that may reference PCEHR but these will be updated to My Health Record over time.

Table 4 - Required vendor actions

Step		Vendor action	Result
1.	Register to join the My Health Record Developer Community	<ul style="list-style-type: none">• Create an account at: https://developer.digitalhealth.gov.au/user/register• Enter your personal information• Accept the terms of use• Complete the registration process• Read the latest versions of recommended documents presented after registration:<ul style="list-style-type: none">○ <i>Specifications Standards Plan</i>○ <i>Specifications Delivery Roadmap</i> <i>Standards Analysis Supporting Document</i>	<ul style="list-style-type: none">• You now have access to all the documentation required for commencing the Conformance Vendor Declaration process• You may read or download the requirements as required

Step		Vendor action	Result
2.	Download and review the My Health Record Welcome Pack	<ul style="list-style-type: none"> Download the welcome pack from the Software Vendor Support page: https://developer.digitalhealth.gov.au/resources/services/my-health-record-mhr/my-health-record-b2b-gateway Read the welcome pack, which contains: <ul style="list-style-type: none"> <i>Guide to the My Health Record system connection process (this document)</i> <i>Software vendor product details form</i> <i>Conformance vendor declaration form</i> <i>Instructions for completing the conformance declaration form</i> <i>My Health Record system vendor contacts list</i> <i>Managing your B2B software in production</i> 	<ul style="list-style-type: none"> You have an overview of the stages required to gain software connection to the My Health Record system
3.	<p>Apply for access to the HI Service</p> <p>Note: This step does not apply to CIS software connecting via the B2B CIS to NPP Service</p>	<ul style="list-style-type: none"> If not previously registered with the HI Service, apply for access directly through the Health Systems Developer Portal. https://healthsoftware.humanservices.gov.au/claiming/ext-vnd/ 	<ul style="list-style-type: none"> HI Service access granted

Step		Vendor action	Result
4.	Complete and return the Vendor Product Details form and NASH application	<ul style="list-style-type: none"> Complete the Vendor Product Details form (contained in the Welcome Pack and return to help@digitalhealth.gov.au Complete the Application to Request a NASH PKI test certificate kit form and return to Developerliaison@servicesaustralia.gov.au. 	<ul style="list-style-type: none"> Developer Liaison Team issues the NASH PKI test certificate kit Gateway Operator selects the appropriate test cases based on the product details supplied Access to the SVT environment
5.	Have your test provider's HPI-I linked to your test organisation's HPI-O	<ul style="list-style-type: none"> Contact Developer Liaison Team at: Developerliaison@servicesaustralia.gov.au and ask to have your test provider's HPI-I linked to your test organisation's HPI-O <p>Note: Developer Liaison Team requires both the HPI-I and HPI-O numbers.</p>	<ul style="list-style-type: none"> Test HPI-I and HPI-O linked

Step		Vendor action	Result
6.	Commence software product development/enhancement	<ul style="list-style-type: none"> Develop software product based on technical specifications obtained through the Agency website 	<ul style="list-style-type: none"> Product is developed / enhanced to include My Health Record functions System Operator provides technical support for software design, development and testing You may contact the System Operator via email or phone for assistance with this process: email: help@digitalhealth.gov.au phone: 1300 901 001
7.	Receive NASH PKI test certificate kit and NOC test pack	<ul style="list-style-type: none"> Receive the NASH PKI test certificate Kit Receive the established NOC test cases and test data for the My Health Record functions included in your software from Gateway Operator Obtain relevant Conformance Vendor Declaration testing materials and instructions from the System Operator at: http://developer.digitalhealth.gov.au After submitting your self-assessment, the Gateway operator will reach out to arrange formal NOC testing 	<ul style="list-style-type: none"> Test certificates allow NOC and conformance testing within SVT Conformance testing may begin NOC testing may begin Gateway Operator will provide technical support for NOC testing

Step		Vendor action	Result
8.	Conduct in-house conformance testing	<ul style="list-style-type: none"> • Conduct in-house conformance testing based on: <ul style="list-style-type: none"> ○ the conformance profiles and the specifications they reference; and ○ the conformance requirements for software products connecting to the My Health Record system • It is recommended that you: <ul style="list-style-type: none"> ○ utilise conformance test specifications; and/or ○ use the Clinical Package Validator test tool in combination with The Information Quality Rules (IQ Rules) tool • Retain a copy of all conformance testing results • For MHR Connecting Systems Security Conformance Profile, see section 3.3.1. 	<ul style="list-style-type: none"> • Vendor has a history of successfully completed test cases and results <p>Note: The System Operator may wish to view these results as part of quality assurance activities that may be undertaken in the future.</p>
9.	Conduct formal NOC testing	<ul style="list-style-type: none"> • Conduct formal NOC testing observed by Gateway Operator. 	<ul style="list-style-type: none"> • Gateway Operator observes the formal testing and extracts log files and screen shots for verification of test case results

Step		Vendor action	Result
10.	Complete and return the <i>Conformance Vendor Declaration Form</i>	<ul style="list-style-type: none"> Complete the <i>Conformance Vendor Declaration Form</i> Attach the Security Conformance Profile Test Completion report. Email the form and Security Profile Test Completion report to the Agency help centre at: help@digitalhealth.gov.au 	<ul style="list-style-type: none"> You declare that your software product complies with all applicable My Health Record technical specifications and conformance points and has undergone the necessary internal testing
11.	Receive the My Health Record production system access	<ul style="list-style-type: none"> If requested, supply test evidence to the System Operator Receive the production access letter 	<ul style="list-style-type: none"> System Operator completes technical changes to enable your software to access the My Health Record system Healthcare providers may now use your software to access the My Health Record system Your software product is added to the Digital Health register of conformant software.

5 Support contacts

5.1 Registration

If you require assistance with the process of registration for My Health Record testing, please contact Developer Liaison Team on:

Email: Developerliaison@servicesaustralia.gov.au

Phone: 1300 550 115

5.2 Development

If you require assistance with developing your software for conformance testing, please contact the System Operator:

Email: help@digitalhealth.gov.au

Phone: 1300 901 001

5.3 Testing and non-urgent production issues

If you require technical assistance during the testing phase or you have production issues, please contact OTS:

Email: myhealthrecord.otshelpdesk@servicesaustralia.gov.au

Phone: 1300 550 115

5.4 Production Issues

Report functional or system availability issues via the following contacts:

Business Hours: OTS - 1300 550 115 or myhealthrecord.otshelpdesk@servicesaustralia.gov.au

After Hours: My Health Record Incident Support - 1800 723 471 (select option 2)

Glossary

Term	Description
Access Channel	Services in My Health Record system that enable users to access My Health Record. Examples include: Provider (<i>National Provider Portal</i>) and CIS (<i>B2B Gateway</i> and <i>B2B CIS to NPP Service</i>).
B2B	Business-to-Business
B2B CIS to NPP Service	An access channel which enables clinical information systems and healthcare providers to authenticate, authorise and gain access to a patient's My Health Record via the National Provider Portal.
B2B Gateway	An access channel by which external systems, such as clinical information systems and registered repositories, interact with the My Health Record system.
CIS	Clinical Information System
Connections Team	The Connections team at the Australian Digital Health Agency supports software vendors in developing products that connect to the My Health Record system, offering expert guidance on technical specifications.
CSP	Contracted Service Provider (under Section 5, My Health Record Act 2012). An entity contracted to a healthcare provider organisation to provide: <ul style="list-style-type: none"> information technology services relating to the My Health Record system; or health information management services relating to the My Health Record system
Declaration	Statement from the vendor declaring required information and conformance to requirements
Gateway Operator	The gateway operator operates and manages the My Health Record B2B and FHIR gateway.
HI	Healthcare Identifiers
HPI-I	Healthcare Provider Identifier—Individual (HPI-I)—allocated to individual healthcare providers (for example general practitioners) involved in providing patient care.
HPI-O	Healthcare Provider Identifier—Organisation (HPI-O)—allocated to healthcare organisations (for example a hospital or medical clinic) where healthcare is provided.
My Health Record	The system that is used for the operation of functions under the My Health Records Act by the System Operator.
NASH	National Authentication Service for Health
NOC	Notice of Connection
NPP	National Provider Portal. A web portal that allows provider-only access to view a consumer's My Health Record.
OTS	Online Technical Support. Vendor support helpdesk operated by Services Australia for HI and vendor support services.

Term	Description
PCEHR	Personally Controlled Electronic Health Record (Former name of My Health Record)
PKI	Public Key Infrastructure
SVT	Software Vendor Test. A pre-production environment for testing software that will connect to the My Health Record System.
System Operator	The System Operator is presently the Australian Digital Health Agency. It is responsible for establishing and operating the My Health Record system.