nehta

PCEHR Participation Guide

A System Guide for Software Development

Version 1.3 — 25 September 2012

Final

National E-Health Transition Authority

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Version History

Date	Version	Name	Comments/type of review
25 Sept 2012	1.3	NEHTA	Approved for publication

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Preface

Purpose

The purpose of this document is to provide sufficient information to allow software developers, such as third party software vendors or software development teams engaged within healthcare provider organisations, to consider options and plan for implementation of the required functionality and integration components to interact with the PCEHR system.

The three desired outcomes to support this purpose are;

1. Software developers will acquire sufficient introductory knowledge to understand PCEHR and the PCEHR System and its context within the e-Health environment
2. Software developers will understand what options are available to participate within the PCEHR System
3. Software developers will understand next steps to participation.

This is a living document, and subsequent versions may show updates, inclusions or exclusions to these events as more information becomes available.

Intended Audience

The primary audience for this document are the product managers and project planners from healthcare organisations who have the in-house capability and the third party software vendors who will consider the development of software products to connect to the PCEHR System.

There is an assumption that the decision to invest in the development of software products to interact with the PCEHR System has already been made.

The secondary audience are those healthcare provider organisations who wish to gain an understanding of the options for participation within the PCEHR System.

Scope

The scope of this document is to describe the indicative options to build and implement the functionality for connecting systems to access and interact with the PCEHR system – specifically for Clinical Information Systems, Registered Consumer Portals, Registered Provider Portals, Registered Repositories and Contracted Service Provider systems.

The document also

- Provides the initial steps to gain accreditation for their product(s) and will guide the reader in the requirements to register and obtain the PCEHR Welcome Pack.
- Provides direction to a range of conceptual, design and technical documents that provide background and guidance for development of software and systems to interact with the PCEHR System.

Standards

In September-November 2011, NEHTA collaboratively developed and published the PCEHR Specifications and Standards Plan[1]. This plan outlined how NEHTA would collaboratively develop, deliver, and support PCEHR System Specifications, and how

[1] PCEHR Specifications & Standards Plan: http://www.nehta.gov.au/ehealth-implementation/pcehr-standards

NEHTA would contribute to the ongoing development, maintenance and revision of relevant Australian and International Standards associated with the PCEHR System through Standards Australia's IT-014 work plan.

Standards are best utilised through complete adoption. Where a partial match or extensions are required, a profile is adapted for use. Lastly, where no applicable standard is available, a new standards publication will be developed in collaboration with the Standards Australia and IT14 community.

The PCEHR System has its foundation in relevant national and international standards. At the start of PCEHR System design, an extensive review of standards and specifications was conducted and a recommended underlying set identified. Following PCEHR System specification development, a standards review of the PCEHR System has validated the standards that underpin the system.

Document Roadmap

This is the first draft of a living document and represents the information that is current and known at the time of writing. Over time it will be updated as more information becomes available and so that it will align with final PCEHR legislation, technical specifications and the operational model.

This document has been developed through consultation with a number of software vendors and representatives of healthcare provider organisations through the Tiger team process. Further versions of this document will continue to consider feedback from software developers, implementers and healthcare provider organisations. Updates will be available on https://vendors.nehta.gov.au

Document Map

This guide is one of a number of related documents being produced as part of the PCEHR program Standards Foundation and Architecture work stream.

Figure 1 below shows how this document relates to other documents being produced by NEHTA as part of the national PCEHR program.

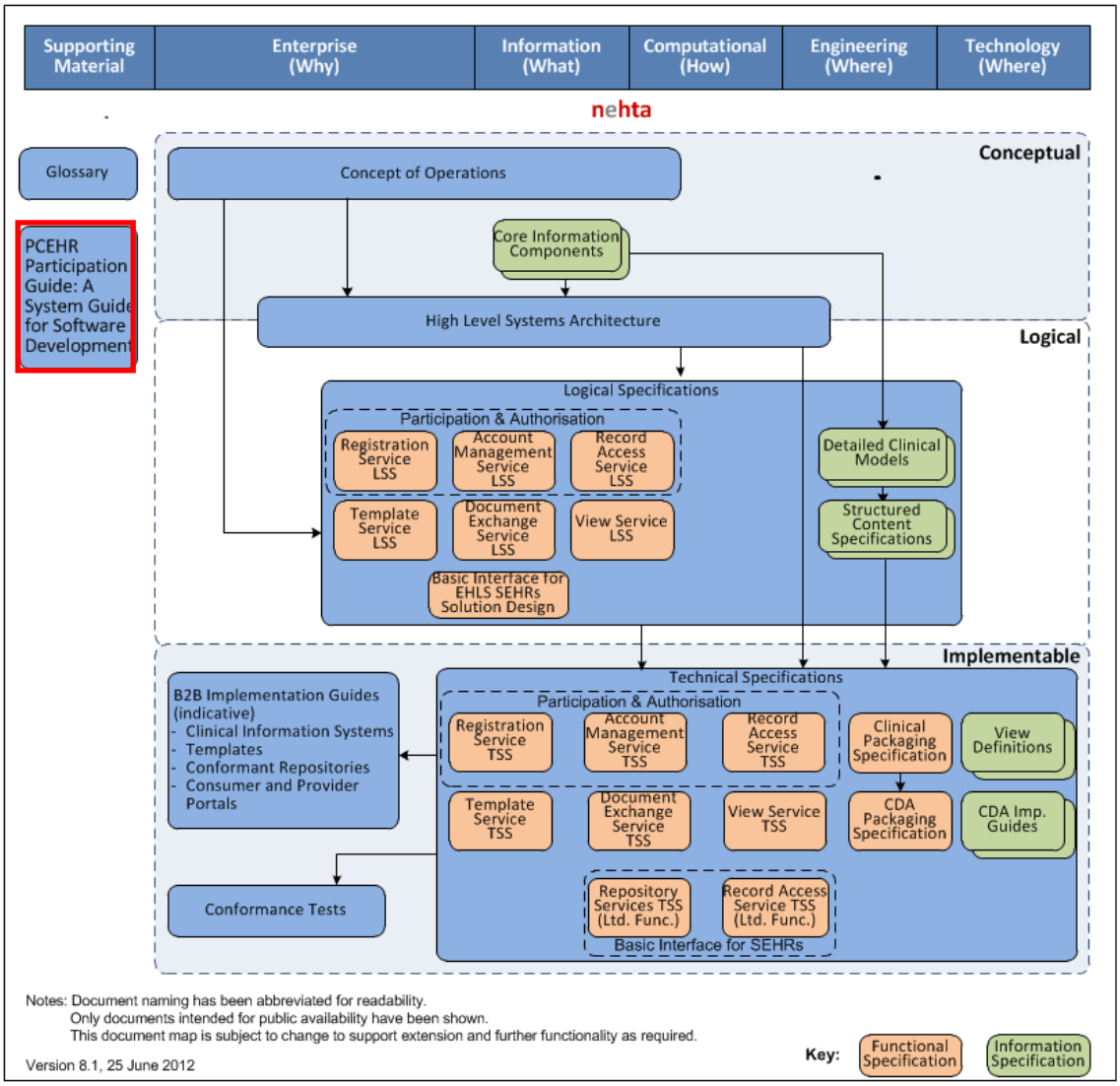

Figure 1: Document Map

Please note, while not listed within the Document Map itself, the conformance tests referenced are a set of documents as follows – they form an integral part of the PCEHR software product build;

Compliance, Conformance and Accreditation reference documents

- PCEHR CIS Conformance – Vendors Guide V1.2
- Conformance Test Specification PCEHR (CIS) V1.3
- Conformance Test Specifications for CDA Rendering V1.1
- Conformance Test Specification PCEHR (Conformance Profile) V1.0
- Conformance Test Specifications for CDA Packaging V1.2
- Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements V1.4
- Clinical Information Systems Connecting to the PCEHR System – Conformance Assessment Scheme
- PCEHR Conformance Profile for Electronic Referral Clinical Documents V1.3

- PCEHR Conformance Profile for Discharge Summary Clinical Documents V1.4
- PCEHR Conformance Profile for Event Summary Clinical Documents V1.2
- PCEHR Conformance Profile for Shared Health Summary Clinical Documents V1.4
- PCEHR Conformance Profile for Specialist Letter Clinical Documents V1.3

Acronyms and Terminology

This document includes acronyms and specialised terms that may be unfamiliar to some readers. Please refer to the Glossary for an explanation of these terms.

Please note that the Glossary in this document refers to the same definitions that can be found in the Glossary document as shown in Figure 1. It is not yet publicly available and the release date is not yet known.

Questions and Feedback

Feedback from the review of this draft document should be provided by email to pcehr@nehta.gov.au

1 Participation with PCEHR

1.1 Introduction

e-Health is important to the future of healthcare in Australia. For consumers and healthcare providers alike, it will enhance the way healthcare is delivered. The Personally Controlled Electronic Health Record (PCEHR) System is the next step in using eHealth to enhance the healthcare system. The PCEHR System enables the secure sharing of health information between a consumer's healthcare providers, while enabling the consumer to control who can access their PCEHR.

Software developers will build the software and systems (products) suited to the business practices and workflows of healthcare providers and healthcare provider organisations with the capability to interact (participate) with the PCEHR System. A prime objective of this document is to provide software development organisations with an understanding of the different possibilities or options for building product(s) for this interaction.

There are two primary steps required to gain an accredited product that can access and interact with the PCEHR System;

1. Software development, and
2. Testing of software under Compliance, Conformance & Accreditation (CCA) framework.

This is illustrated in Figure 2 below – please note that there is no requirement to start the accreditation process before the development process and vice-versa. But, the software must be completed as a pre-requisite to testing and accreditation.

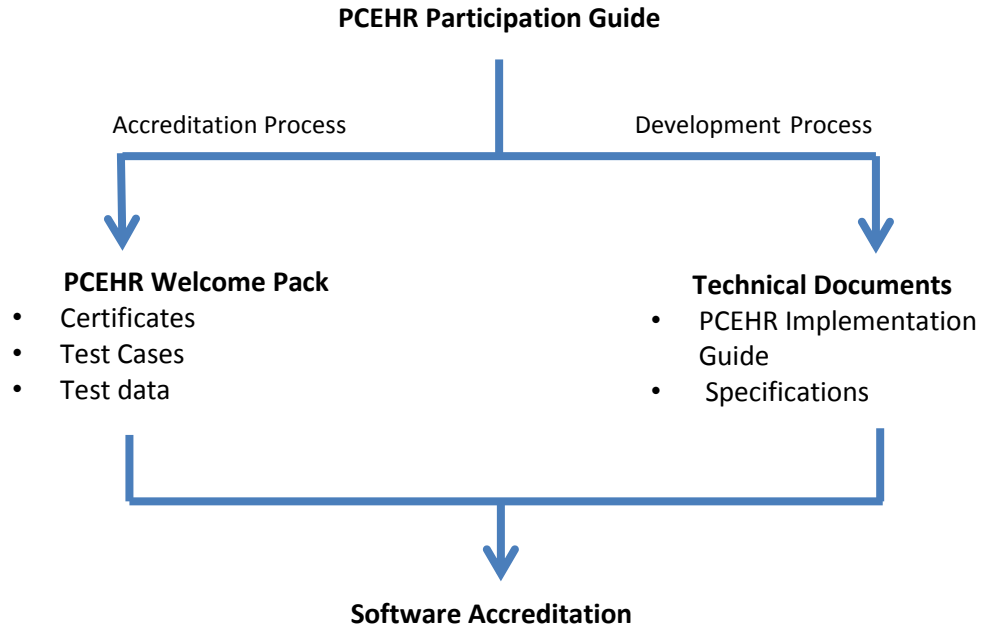

Figure 2: Participation Guide positioning with other PCEHR collateral for software development.

Section 2 of this document describes the steps required to receive the PCEHR Welcome Pack. This will take the developer through the steps to accreditation.

Section 3 of this document takes the developer through the options for product development and is intended to be an entry point for the software development process.

1.2 The PCEHR System

1.2.1 What is PCEHR?

The national PCEHR System[2] places the consumer at the centre of their own healthcare information management (as shown in Figure 3) by enabling access to important health information by each consumer and their healthcare providers when and where it is needed. With the consumer's permission, key pieces of their health information may be viewed by participating healthcare providers across different locations and healthcare settings. Consumers can choose whether or not to have a PCEHR. If they choose to participate, they will be able to set their own access controls to the health information in their PCEHR.

In order to deliver this vision, the PCEHR System will provide the necessary national infrastructure and standards-based specifications to enable secure access to a consumer's health information drawn from multiple sources. Suppliers of eHealth systems will be provided with PCEHR design and technical specifications to help organisations enhance their products and services to become conformant with the relevant standards and specifications necessary for interaction with the PCEHR system.

Figure 3: Consumer at the centre of their healthcare in the PCEHR system

Consumers and healthcare providers will be able to safely and securely interact with the PCEHR System to submit, exchange and view health related information. The PCEHR System will provide core services that will allow authorised participants to search for and view clinical documents.

The core principles of the PCEHR System are:

- **The consumer is at the centre of their care**
- **The consumer's consent is required for inclusion of information**
- **The consumer controls access to the information**
- **The PCEHR System facilitates interchange of information**
- **There is only one PCEHR System**

[2] A high level overview of the PCEHR system is described in the *Concept of Operations: Relating to the introduction of a Personally Controlled Electronic Health Record System* available from the Department of Health and Ageing's information portal website http://www.yourhealth.gov.au .

1.2.2 What happens to information in PCEHR?

The PCEHR System will have the capability to store health information entered by the consumer and access health related information, with the consent of the consumer, from the National Repositories and Registered Repositories.

Clinical documents such as event summaries, shared health summaries and discharge summaries will be contributed by participating organisations and providers and stored within the National Repositories. Other clinical documents such as test result reports may be available via the PCEHR System from registered and accredited repositories. These documents will be available to healthcare providers and clinical systems through the consumer's PCEHR. Figure 4 shows the high level information flow.

Note: Clinical documents can be uploaded to a consumer's PCEHR unless a consumer asks for them not to be uploaded or where express consent has been given if the document relates to existing laws that have been prescribed under the PCEHR regulations. Although the onus is on the consumer to exercise this option, healthcare providers should be conscious of whether a clinical document may or may not be suitable for uploading or is likely to be sensitive to the consumer concerned.

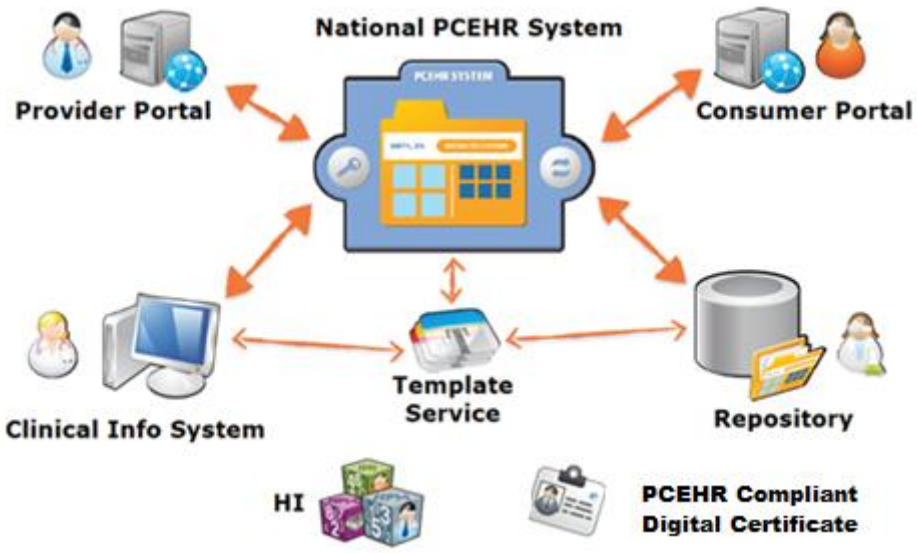

Figure 4: Interfaces and information flow

1.3 Accessing the PCEHR System

Consumers will be able to access their PCEHR online via the National Consumer Portal and will be able to access and manage the access to health information stored in their PCEHR. Over time it may be possible for consumers to access their PCEHR using independently operated Registered Consumer Portals.

Healthcare providers will be able to access and view a consumer PCEHR through the National Provider Portal. It is intended that they will alternatively utilise registered provider portals and clinical information systems built by software vendors, or software and systems developed in-house, to interact with the PCEHR system. This will enable healthcare providers to access a consumer's PCEHR and share clinical documents by providing the documents to the National Repositories or storing the documents in a registered repository accessible through a consumer's PCEHR.

Note: Healthcare providers will also need to carefully plan and implement a range of change and adoption activities to facilitate the participation of the organisation with the PCEHR System. The PCEHR is designed to leverage and supplement existing workflows and a range of support and training material is being developed to assist healthcare provider organisations in the transition process. This is out of

scope of this document but readers are asked to reference Change and Adoption material at https://vendors.nehta.gov.au

1.4 PCEHR System Roles

PCEHR recognises that the participating products can fulfil a number of different types of 'roles' and that these roles will be determined by the set of functionality that the product performs. The PCEHR System recognises five different role types - each is defined by the type of interactions it performs. These roles are; Clinical Information System, Registered Consumer Portal, Registered Provider Portal, Registered Repositories and Contracted Service Provider.

The PCEHR System itself does not concern itself with the build of the product; it looks to the connecting interface and is concerned with the behaviours and interactions of the software product when a session is executed. Because the software product itself must conform to certain requirements and standards, these interfaces are known as registered interfaces. Further, because the specific roles above transact through registered interfaces, the association means registered interfaces are also known and recognised by the role type.

It needs to be noted that the PCEHR concept of 'role' does not necessarily mean 'product'. From the local system perspective (be it GP, hospital or other healthcare provider organisation), there are only two roles and those are

- Consumer based – allowing access for the consumer through a Consumer Portal (National or Registered), or
- Healthcare provider based – providing access for the clinician and provider organisation through a system that uses some or all of the available functionality offered through the services available at the B2B gateway.

The interactions between the PCEHR System B2B interface and the healthcare provider organisations system interface are the result of messages that are defined by the services. These services are the Records Access, Registration, Account Management, View, Document Exchange and Template services (see section 3.1).

All systems connecting to the PCEHR using registered interfaces will need to undertake the PCEHR Compliance Conformance and Accreditation (CCA) process. This objective of the CCA process is to assure that connecting systems meet interoperability, clinical safety, information security and privacy protection requirements.

The explanation of these roles is provided at a high level below. Section 3 provides more detail of the operations of these roles so that a determination of product choice can be made by the software development organisation.

1.4.1 Clinical Information Systems

Over time access to the PCEHR System will be accessible from a range of clinical information systems such as GP desktop systems, hospital local clinical systems and aged care systems. The role of Clinical Information System has the most potential for interaction with the PCEHR System because clinicians will be able to access a consumer's clinical information during the course of treatment and clinical documents that are produced through clinical workflow could be uploaded to the consumer's PCEHR.

See Section 3.2: Clinical Information Systems

1.4.2 Registered Consumer Portal

The National Consumer Portal allows consumers to create their own PCEHR, and then to access and manage their PCEHR record settings for healthcare provider and healthcare provider organisation access, nominated and authorised representatives and the addition of additional health information such as advanced care directive custodian information. If a software product enables this functionality, then it is playing the role of being a consumer portal. Because it must conform to the CCA

requirements for conformance then this product is known as a registered consumer portal. It is envisaged that independent software products can play this role to enable assisted registration, for example.

See Section 3.3: Registered Consumer Portal

1.4.3 Registered Provider Portal

The National Provider Portal only allows healthcare providers to access, search and view consumer records. A software product that operates outside the PCEHR system and offers similar functions to the National Provider Portal has the potential to be a registered provider portal. As with the consumer portal, it must comply with CCA requirements and would be known as a registered provider portal.

See Section 3.4: Registered Provider Portal

1.4.4 Registered Repository

Over time locally stored information may become accessible to other users of the PCEHR System through Registered Repositories. The PCEHR System infrastructure, standards and specifications are designed to allow for safe and secure sharing of information stored within Registered Repositories with other authorised healthcare providers.

See Section 3.5: Registered Repositories

1.4.5 Contracted Service Provider

Third-party providers of health software offered as a service (SaaS) or hosted systems may be developed over time providing access to the PCEHR System on behalf of healthcare providers and healthcare provider organisations. The service offering could range from registered portal access through to a fully integrated clinical information system (CIS) and registered repository functionality.

See Section 3.6: Contracted Service Providers

2 PCEHR Accreditation Process

This section provides high level details on the software accreditation process and requirements, for more information refer to the 'PCEHR Health Record System: Proposals for Regulations and Rules' available at:

http://yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/pcehr-legals-regs-rules

2.1 Registration Steps

The following steps to register are sequential, the software development organisation will need to follow the below steps in order to complete registration. Please Note: There is a complimentary process required to gain access to the HI Service. This access is a pre-requisite for gaining PCEHR System access. Software developers will need to establish connectivity to the HI Service test environment to conduct PCEHR NOC and CCA testing. Please see –

http://www.medicareaustralia.gov.au/provider/vendors/healthcare-identifiers-developers/developing-software-for-the-hi-service.jsp

2.1.1 Expression of Interest

Software developers interested in connecting to the PCEHR System can lodge an expression of interest on the vendor portal;

https://ehealth.gov.au

Interested parties will need to create a user identity to access this site. Once this is done, the required form can be found under the "PCEHR Software Vendor Testing (SWVT)" option. SWVT is the acronym for the Software Vendor Test environment.

2.1.2 License Agreement

The Licence Agreement will be sent by the OTS Helpdesk once the software developer expresses interest. Software vendors need to read and accept the terms and conditions of the Licence Agreement 'For Accreditation in Connection and Conformance for PCEHR' to access the software vendor test environment.

Software developers will also need to complete and submit an application for the test certificate required to access the SWVT environment.

Both completed forms should be sent to the following address;

pcehr.otshelpdesk@humanservices.gov.au

2.1.3 Vendor Product Details Form

Following acceptance of the License Agreement, software vendors must complete the PCEHR Notice of Connection (NOC) - Vendor Product Details Form and submit to the On-line Technical Services (OTS) Helpdesk to request registration for NOC testing.

The Vendor product Details Form will be sent to the applicant upon agreement to the terms and conditions of the License Agreement. The completed form should also be sent to:

pcehr.otshelpdesk@humanservices.gov.au

2.2 PCEHR Welcome Pack

Following successful completion of the registration process above, software vendors will be provided with a PCEHR Welcome Pack that will give them access to the test material to complete the NOC and CCA process.

The PCEHR Welcome Pack contains the following items:

- Test data for Notice of Connection (NOC) testing
- Test cases specific to the PCEHR interface functionality selected for implementation
- Sample CDA packages
- HPI-I and HPI-O digital test certificates for authentication in the test environment
- Software Vendor Test environment URL
- CCA material specific to the chosen PCEHR role and clinical document(s)

2.3 Achieving Accreditation

An important concept for vendors to understand is the dependency relationships that exist between NOC and CCA testing for HI Service and PCEHR B2B before a software product can connect to the PCEHR System.

The following diagram (figure 5) demonstrates that ideally NOC testing for both HI and PCEHR should either be completed or well progressed before moving to CCA testing, and that both need to be successfully completed before access is granted. This is elaborated on in more detail in sections 2.3.1 and 2.3.2.

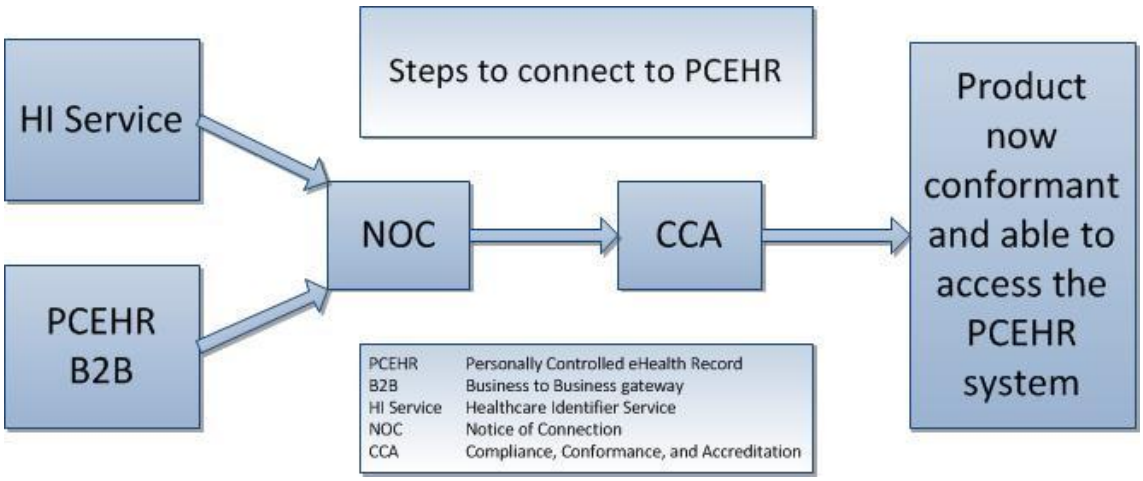

Figure 5: Steps Indicative of Dependencies to Connect to PCEHR

2.3.1 PCEHR Notice of Connection

The candidate software undergoes a connectivity test to verify that it will connect successfully. In this series of tests, the web-services are assessed in terms of the expected behaviour and interaction between the PCEHR System and the PCEHR role as represented by the software product.

Candidate software is required to be self-assessed by the software developer using the tests and the test data sent out in the Welcome Pack. The results are then reviewed by the NOC testers who will then conduct an observed test with the software developer running through exactly the same tests, and using such

evidence as payload, log files and screenshots to assess that the software has successfully completed the requirements for connection.

To complete the PCEHR NOC, the software under test must be able to verify data through the HI Service. This connection to the HI Service, whether it exists within the software under test or is an independent system, must be established as a pre-requisite. While it is not mandatory to have successfully completed the HI Service NOC before the PCEHR NOC testing, it is recommended so that issues can be isolated to root cause more easily. As a minimum, self-assessment of the HI Service NOC should be completed or progressed to the point whereby the software developer is certain that the connectivity is working as per requirements.

The healthcare organisation is responsible for applying to access the PCEHR online channels by registering and agreeing to conditions to gain access to the PCEHR System.

2.3.2 Conformance Testing

The Compliance, Conformance and Accreditation (CCA) process provides the software developer with points of conformance that must be incorporated into the vendor's software before the System Operator can allow the software to connect to the PCEHR System. These conformance points are indirectly tested during the Notice of Connection testing as they contribute to the behaviour and/or interaction of the web-services.

Over and above that there are a series of conformance tests that specifically look at the software product in the clinical setting, measuring the ability to safely fit into the clinical workflow, and form, author, send/receive and display clinical documents. As with NOC testing, the tests are supplied with the Welcome Pack and software developers are asked to complete them by self-assessment first before they are repeated and assessed through observed testing.

CCA testing can commence at any stage that the software developer wishes, but it is strongly advised that NOC testing is completed. At a minimum connectivity to the HI Service and PCEHR test environments is required for the PCEHR CIS conformance testing. There is no dependency between CCA testing for HI Service and PCEHR other than that both are required to be completed before production access approval is granted.

Once all the above tests are successfully completed software developers can apply to the System Operator to have these conformant products and versions recorded in the Register of Conformity that healthcare organisations consult to acquire products that are suitable for use to access the PCEHR.

2.3.3 Access Approval

Upon successful completion of the NOC and CCA testing the software developer will be issued with test results in the form of an official report. The software developer will then need to complete Declarations for NOC and Conformance for submission to the System Operator. Once processed the software developer will receive Product Access approval that will allow the software product to access the PCEHR System. The National Infrastructure Operator (NIO – who run the PCEHR System) will also be notified so that a healthcare provider who uses the product can gain access.

3 PCEHR System Interface Roles

3.1 Mapping B2B Services to Roles

All the technical design and specifications requirements needed to successfully develop a solution to interact with the PCEHR System (see Section 2.1) are available on the vendor portal. The specific documents required are as follows,

- PCEHR Implementation Guide
- Logical Service Specifications (LSS) for
    - Record Access
    - Registration
    - Account Management
    - View
    - Document Exchange
    - Template
- Technical Service Specifications for the same services as above.

Figure 6 demonstrates how the services map to the roles. All of the services displayed in this diagram must utilise the B2B Gateway for all interactions. Section 3 expands on the service to role relationship.

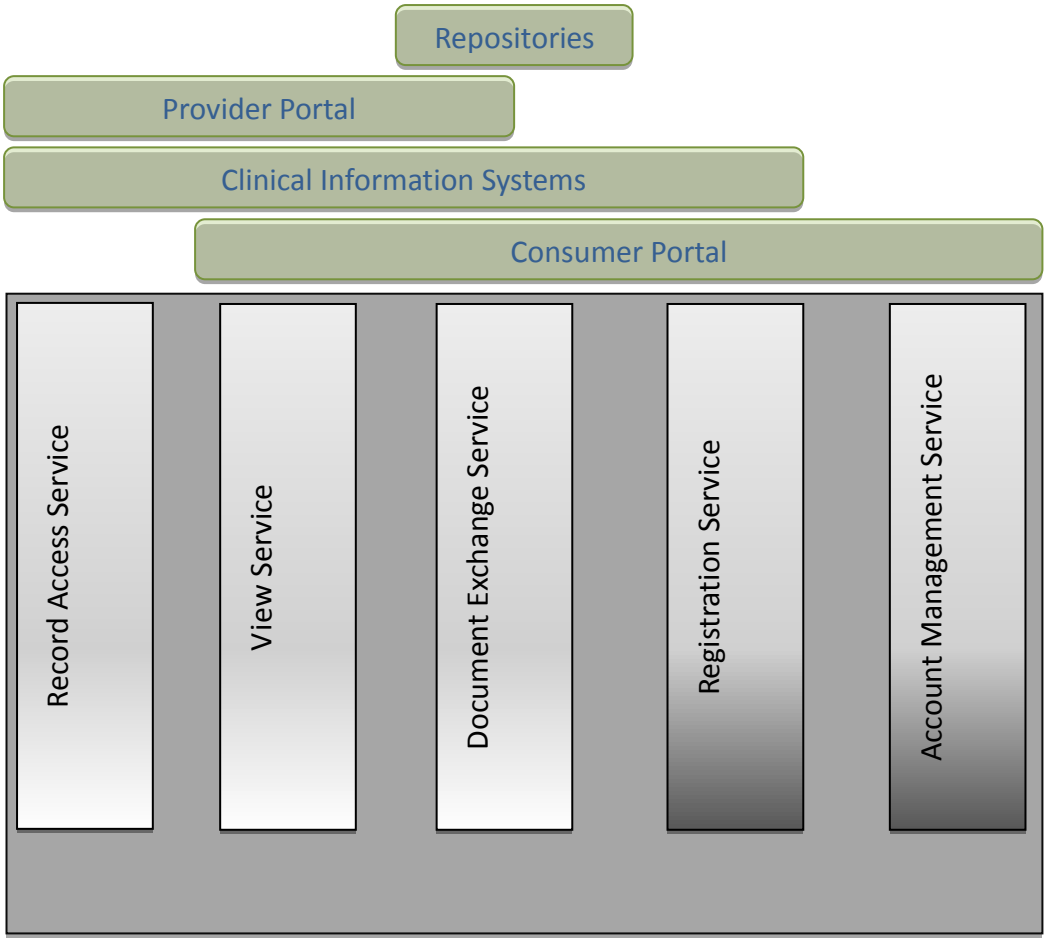

Figure 6: Mapping services to PCEHR recognised role type

The PCEHR System uses the Template Service to ensure that the structure of different types of clinical documents stored within the PCEHR System are consistent with an agreed common set of definitions. Information can only be shared via the PCEHR System if it has an approved template and the data is valid for the data validation rules within the template. These validation rules (XML schema for CDA documents; Schematron rules) can be used to automatically validate the conformance of clinical documents with their respective specifications. For example, a Shared Health Summary can only be loaded into the PCEHR System if it meets the data validation rules within the template.

The Template Service differs from the above listed B2B services because access to it does not need to go through the B2B gateway. In fact, a healthcare provider organisation using a CIS only needs to access this service to get a template to use or to update an existing one.

Operators of a registered Repository will likewise need to use the template validation rules to validate the data and documents being uploaded into PCEHR. As with the CIS, the decision to access the Template Service through the B2B gateway is optional.

All technical documentation can be accessed on the vendor portal -

https://vendors.nehta.gov.au

3.2 Clinical Information Systems

3.2.1 Overview

The Clinical Information System interaction with the PCEHR at its most integrated level provides the list of functions described in Table 1 below. This provides the healthcare provider with the ability to view all information that they are authorised to access, and to create and upload clinical documents.

The CIS Registered Interface will facilitate the following interactions with the PCEHR system:

- Locally authenticate a provider's identity in line with the standards of the National E-Health Authentication Framework (NEAF).
- Associate the account with an HPI-O and HPI-I and the related credentials.
- Allow the healthcare provider to access healthcare information which has been sourced from various records within the PCEHR and assembled by the View Service.
- Request a document, and allow the healthcare provider to view clinical documents (according to minimum user software requirements).
- Upload clinical documents to the National Repository.
- Remove a document from an individual's PCEHR where authorised.
- Gain authorisation to access a document to allow it to be shown in an individual's PCEHR.

Table 1: CIS Functions

The functions are the result of a number of services being built into the local clinical system. Figure 7 demonstrates a number of the above functions from a logical services view.

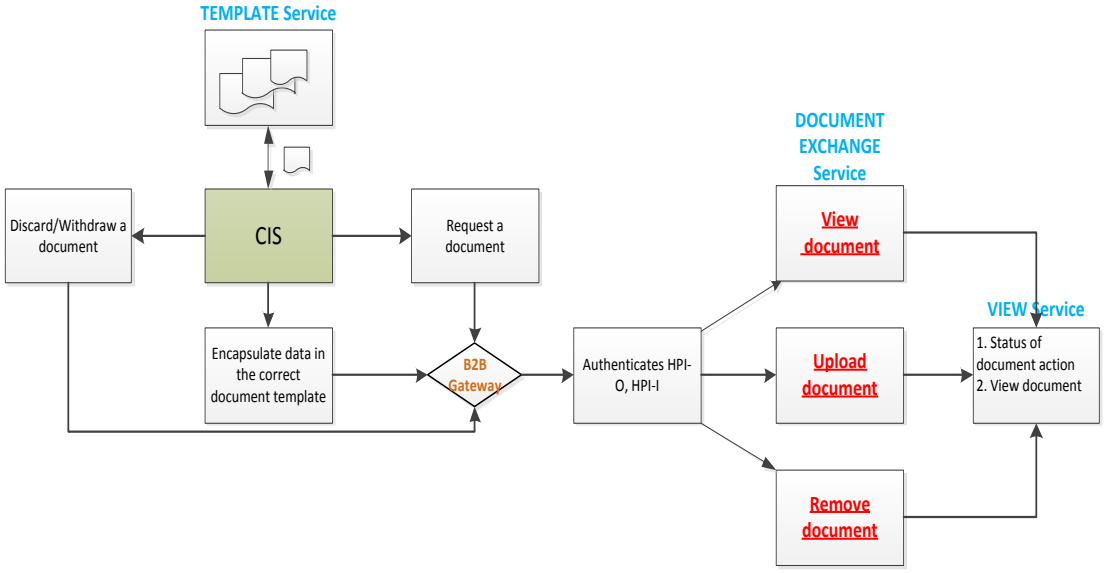

Figure 7: Logical view of integrated CIS services

3.2.2 Functions

Service	Operation	Outcome
Record Access Service	1. Verify PCEHR 2. Access a PCEHR for the first time 3. Subsequent access 4. Emergency access	A clinician can verify the existence of a consumer's PCEHR. If this is the first time the System will link the HPI-O to the consumer's record, the Organisation will be added to the provider list and it will stay there unless the access is revoked. The RAC and LDAC are captured and transmitted – access and limited access to clinicians is controlled. Emergency access can be achieved by over-riding the RAC code.
Document Exchange Service	1. Search document 2. Retrieve document 3. Submit document 4. Remove document 5. Manage document	Clinician is able to search and retrieve documents. During the course of consultation, the clinician is able (if he/she is the original document author) to edit existing downloaded documents and these can be uploaded as a new version. New documents available through the template service can be filled and uploaded. Documents can also be removed.
View Service	1. Retrieve document list 2. Retrieve Health Record Overview 3. Retrieve audit view 4. Retrieve change history 5. Retrieve individual details 6. Retrieve Medicare information 7. Retrieve authorised representatives listing	The clinician is able to view the requested information. Rendering of this information on the users' desktop is required to conform to the CCA Rendering Guidelines.
Template Service	1. Search templates 2. Retrieve templates	CIS software is required to validate the conformance of clinical documents with their respective specifications. The template packages from the Template Service provide the validation rules.

Table 2: CIS Services

3.3 Registered Consumer Portal

3.3.1 Overview

The National Consumer Portal interaction provides the list of functions described in Table 3 below. This gives the consumer the ability to manage the access and settings and view all information contained in their PCEHR, as well as consumer entered notes and shared health summaries. The option of B2B Integration for Registered Consumer Portal Providers (who are seeking tighter integration with the PCEHR System) is currently under development. The desired end point would be to make available all of the functionality in Table 6, but this may be dependent on any policy/privacy and clinical safety reviews to ensure alignment with relevant legislation and other requirements.

The Consumer Portal Registered Interface will facilitate the following interactions with the PCEHR System: • Authenticate an individual's identity and associate an account with an IHI and PCEHR. • Manage individual's preferences, contact settings and access rights. • View audit logs. • Manage representative status – nominate a representative and link and manage PCEHRs for which they are nominated. • Enter consumer only notes, advanced care directive custodian information and consumer-entered health summaries.

Table 3: Consumer Portal Functions

Figure 8 demonstrates the above functions from a logical services view. These functions are the result of a number of services being built into the local system.

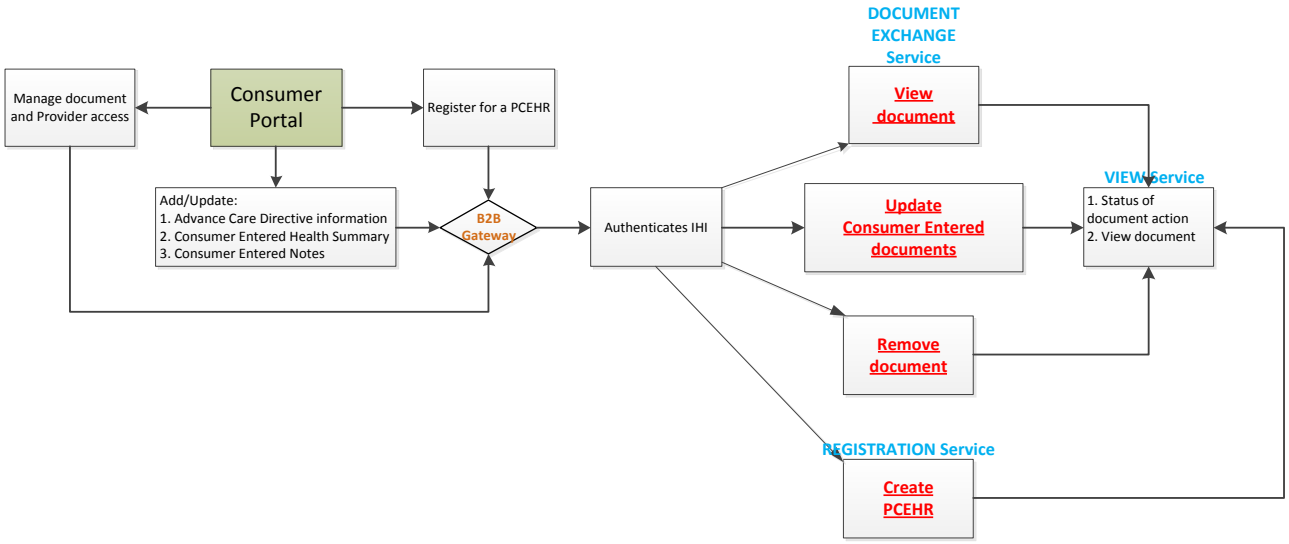

Figure 8: Logical view Consumer Portal services

3.3.2 Functions

Service	Operation	Outcome
Registration Service	1. Register 2. Retrieve terms and conditions 3. Accept terms and conditions 4. Link to PCEHR 5. Deactivate 6. Reactivate	The consumer is able to register with PCEHR using their personal IHI and the two become linked if the consumer accepts the Terms and Conditions. The consumer can deactivate their PCEHR and subsequently reactivate.
Account Management Service	1. Set Privacy settings 2. View Privacy settings 3. Set RAC 4. Set LDAC 5. Appoint Nominated Representative 6. Accept Nominated Representative 7. Update Nominated Representative 8. Remove Nominated Representative 9. Get Nominated Representatives 10. Create Authorised Representative 11. Remove Authorised Representative 12. Get Authorised Representatives 13. Create Notification Preference 14. Update Notification Preference 15. Remove Notification Preference 16. Get Notification Preferences 17. Set PCEHR Contact Details	The consumer can set access for clinicians and/or healthcare organisations. Similarly, the access can be refused. The use of the RAC code allows or blocks all access, whereas the use of the LDAC is applied to specific documents as selected by the consumer. The consumer can make this code available at the time of consultation to allow access. *Please note that the access settings applied by the consumer affect the access for the Healthcare Provider. Settings here can override the Record Access service.* Nominated and authorised representatives can be set up, the list of representatives viewed and representatives removed. Nominated representatives can be appointed by one consumer but need to be accepted by the nominated person. Authorised representatives can only be created at a Medicare office where proof of necessary documentation can be sighted. Authorised representatives can only be removed by the Medicare operator after sighting the required documentation. Consumers can create, edit (update), view and remove notification preferences. Consumers can insert contact details.

Service	Operation	Outcome
Document Exchange Service	1. Search document 2. Retrieve document 3. Manage document 4. Remove document	Consumer is able to search and retrieve documents. Certain document types can be edited (onscreen, document creation happens within the system) and/or removed.
View Service	1. Retrieve document list 2. Retrieve Health Record Overview 3. Retrieve audit view 4. Retrieve change history 5. Retrieve individual details 6. Retrieve Medicare information 7. Retrieve representatives listing	Consumer is able to view requested information. Rendering of this information on the users' desktop is required to conform to the CCA Rendering Guidelines.

Table 4: Consumer Portal Services

3.3.3 Options

3.3.3.1 Simple Redirection link to National Consumer Portal

This is considered to be the initial entry option, which is a "button on their Web Site" that redirects the consumer to the australia.gov.au web site where they may login and access their PCEHR.

There are anticipated to be no additional compliance obligations on organisations that wish to offer such a facility from their Web Site.

This option does not require any specific interface to be built nor does it call any PCEHR System services from the local clinical system. There is no change to the CIS software.

The consumer will have full access to the National Consumer portal functions in a web browser.

There are no conformance tests relating to this option, and it does not require a Notice of Connection.

This option does not require any change to the local system software that would require conformance testing.

3.3.3.2 Single Sign-on

This option is still under development but it is proposed that organisations that provide authenticated web sites may wish to offer their members the ability to access the PCEHR System via their site without the need to re-authenticate.

In this situation, the authenticated web site is fulfilling the same role as the australia.gov.au site within the National PCEHR Portal Infrastructure by providing authentication and credential management services.

Technically, the third-party portal account and the PCEHR Consumer Portal Identity are associated through the use of a locally created consumer identifier, and will connect in a similar manner to the australia.gov.au web site and the PCEHR National Consumer Portal Identity.

This option will require changes to the local system software that will require conformance testing.

3.3.3.3 B2B Integration

This option is still under development but it is expected that the Registered Consumer Portal mirror that of the National Consumer Portal. The implementation of this option will be dependent on the development of

- Software conformance scheme – similar to that described in 2.3.2, the implementation of the software will require the necessary levels of conformance testing before being able to connect to the B2B gateway.
- Terms and Conditions – these will require compliance and conformance with the non-functional stipulations of participation, with high consideration for:
    - Privacy
    - Security
    - Clinical safety

3.4 Registered Provider Portal

3.4.1 Overview

The National Provider Portal interaction provides the list of functions described in Table 5 below. This allows the healthcare provider with the ability to access and view all information that is authorised to them in a consumer's PCEHR. The option of B2B Integration for Registered Provider Portal Providers (who are seeking tighter integration with the PCEHR System) is currently under development. The desired end point would be to make available all of the functionality in Table 8, but this may be dependent on any policy/privacy and clinical safety reviews to ensure alignment with relevant legislation and other requirements.

The Provider Portal Registered Interface will facilitate the following interactions with the PCEHR System: • Locally authenticate a provider's identity in line with the standards of the National E-Health Authentication Framework (NEAF). • Associate the account with an HPI-O and HPI-I and the related credentials. • Allow the healthcare provider to perform Individual Search. The Individual search result will be sensitive to the individual access control for the healthcare provider. • Allow the healthcare provider to access healthcare information which has been sourced from various records within the PCEHR and assembled by the View Service. • Allow the healthcare provider to view clinical documents (according to minimum software requirements of the local clinical system).

Table 5: Provider Portal Functions

Figure 9 demonstrates the above functions from a logical services view. The functions are the result of a number of services being built into the local system (see Appendix B, B2B Interface Services).

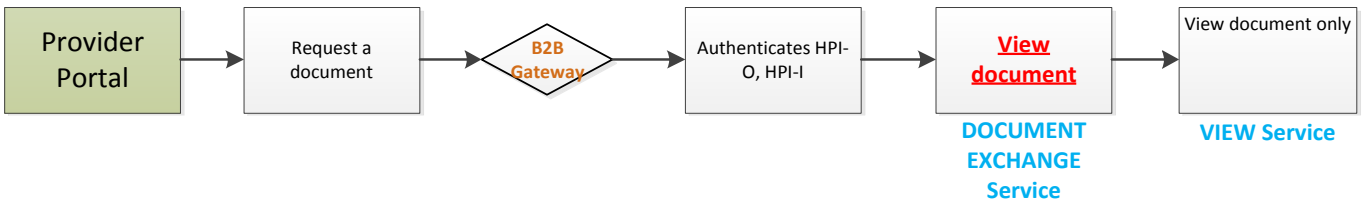

Figure 9: Logical view of integrated Provider Portal services.

3.4.2 Functions

Service	Operation	Outcome
Record Access Service	1. Verify PCEHR 2. Access a PCEHR for the first time 3. Subsequent access 4. Emergency access	A clinician can verify the existence of a consumer's PCEHR. If this is the first time the System will link the HPI-O to the consumer's record, add the organisation to the Provider Access List for that record and it will stay there unless the access is revoked. Emergency access can be achieved by over-riding the RAC code.
Document Exchange Service	1. Search document 2. Retrieve document	Clinician is able to search and retrieve documents.
View Service	1. Retrieve document list 2. Retrieve Health record Overview 3. Retrieve audit view 4. Retrieve change history 5. Retrieve individual details 6. Retrieve Medicare information 7. Retrieve authorised representatives listing	The clinician is able to view the requested information. Note that providers cannot see nominated representatives. Rendering of this information on the users' desktop is required to conform to the CCA Rendering Guidelines.

Table 6: Provider Portal Services

3.4.3 Options

The Registered Provider Portal provides access to any consumer's PCEHR and is, as a result, the subject of stringent security protocols.

Accessing the PCHER System using a Registered Provider Portal will be less functional than access via a fully integrated Clinical Information System in that it does not allow the uploading of clinical documents.

Some large healthcare provider organisations may wish to offer their healthcare providers ready access to the National Provider Portal in advance of implementing 'PCEHR Ready' Clinical Information Systems.

The following sections describe the options for establishing a Registered provider portal.

3.4.3.1 Simple Redirection link to National Provider portal

Using a simple redirection link (e.g. launching a browser from the local Clinical Information System or a new browser window from an existing session), the healthcare provider may be directed to the National Provider Portal.

Access would need to be gained via the normal National Provider Portal method, using NASH individual certificate on a secured access Token.

Having gained access, the healthcare provider would need to enter the details of the consumer to search for their PCEHR.

This option does not require any change to the local system software that would require conformance testing.

3.4.3.2 Single Sign On - Organisational Assertion

This option is still under development but it is proposed that it would allow a healthcare provider who is logged in and authenticated to a local clinical system or portal to link to the National Provider Portal without the need for the healthcare provider to authenticate a second time. The portal would authenticate itself and connect securely to the PCEHR System.

This approach is supported by Single Sign On to the National Provider Portal.

Under this scenario, the healthcare provider organisation would operate a SAML Identity Provider Service. They would authenticate to the National Provider Portal using their Organisational NASH Compliant Digital Certificate and assert the identity of the healthcare provider (End User). Using this method, it may be possible to pass the IHI for the PCEHR that is required, thereby avoiding the re-entry of the consumer's details and enhancing overall system security by ensuring that only the PCEHR of each locally identified consumer is available.

This option will require changes to the local system software that will require conformance testing.

3.4.3.3 B2B Integration

This option is still under development but it is expected that the Registered Provider Portal will have the capability to implement functions as defined in Table 6 above.

3.5 Registered Repository

3.5.1 Overview

The Registered Repository interaction at its most integrated level provides the list of functions described in Table 7 below. This gives the healthcare provider the ability to view all information that they are authorised to access, and to create and upload documents that are the result of a consumer's consultation about their healthcare.

The Registered Repository Interface will facilitate the following interactions with the PCEHR System:

- Locally authenticate a provider's identity in line with the standards of the National E-Health Authentication Framework (NEAF).
- Make a document available to an individual's PCEHR by requesting the document be registered or indexed.
- Send the document to an individual's PCEHR, on demand or on request from PCEHR System.
- Enable a document to be de-registered on request from the document source (request the PCEHR System to remove the index of the document).
- Validate documents against templates (using the template service or the template portal).

Additionally, a Registered Repository will:

- Store documents on behalf of one or more healthcare provider organisations.
- Maintain version control for replacement documents.
- Maintain audit and access logs and ensure documents are able to be traced to the document source.

Table 7: Registered Repository functions

*Acc*essing information from a registered repository is seamless to the requestor. It is an action controlled by the PCEHR System. Documents stored within Registered Repositories are indexed so that the PCEHR System can 'find' them.

The Registered Repositories can be a central point of storage for a number of healthcare providers and healthcare provider organisations who elect to use software offered as a service or third-party hosted system in preference to creating Registered Repositories at their own site. Note that documents cannot be uploaded to Registered Repositories through the PCEHR B2B gateway. The PCEHR B2B gateway only allows for existing (stored) documents to be accessed by a third party requestor and does not allow for any changes to be made to the original documents.

3.5.2 Functions

Service	Operation	Outcome
Document Exchange Service	1. Document registration 2. Retrieve document 3. Document de-registration	Registered documents are uploaded, are registered with the PCEHR System and appear against a PCEHR. A clinician who has access to the document can request to view and the System will retrieve the document. The document author can deregister the document – it is not deleted but is no longer accessible.
Template Service	1. Search templates 2. Retrieve templates	Registered repository providers must be able to validate conformance of clinical documents using the validation rules within the template packages.

Table 8: Registered Repository services

3.5.3 Options

Third-party providers of health software offered as a service (SaaS) or hosted systems may be developed over time providing access to the PCEHR System on behalf of healthcare providers and healthcare provider organisations. The service offering could range from portal access through to Contracted Service Providers.

3.5.3.1 Validate and upload low level documents

Registered Repositories may utilise the lower level conformant templates (CDA level 1a), and possibly a limited number of templates. This requires less validation testing than fully structured documents, and may simplify system development.

3.5.3.2 Validate and Upload higher conformance level documents

Registered Repositories will store higher levels of conformant documents (CDA level 1b and above) and validate against more complex content in the documents. The Registered Repositories may choose one, common, level of conformance across all content or may store a range of templates and documents with a range of conformant content levels.

3.5.3.3 Validate documents dynamically using templates from template Service

Registered Repositories may download the templates from the Template Portal, and load them into the Registered Repositories. The templates available to validate a document will be limited to the templates that have been published by the Template Service and made available on the template portal. The more integrated option would give the Registered Repositories a dynamic link to the Template Service, in which case the required template to be used to validate a document can be found and requested at the time the document is to be validated.

3.5.3.4 Store Registered Documents (defined templates) from one or several CISs, and/or one or several Portals

Registered Repositories may have the capability to receive and validate documents from more than one document source. This requires rigour in document attribution, quality control and error management.

3.6 Contracted Service Providers

3.6.1 Overview

The Contracted Service Provider is a third party supplier of health software services, including hosting and management to a healthcare provider or healthcare provider organisation, as described in Table 9 below.

The Registered Interface for a Contracted Service Provider will facilitate the following interactions with the PCEHR system: • Any or all of the functions of the other PCEHR System roles. • Additional rules and obligations on a Contracted Service Provider which involves management and governance that are specified on the medicareaustralia.gov.au website.

Table 9: CSP Functions

3.6.2 Functions

A software developer or vendor supplying services to healthcare providers and/or healthcare provider organisations as a Contracted Service Provider could offer interaction with the PCEHR System links in ways that are equivalent to the various roles and options discussed in this document.

3.6.3 Options

Third-party providers of health software offered as a service (SaaS) or hosted systems may be developed over time providing access to the PCEHR System on behalf of healthcare providers and healthcare provider organisations. The service offering could range from portal access through to a fully integrated clinical information system (CIS) and Registered Repositories functionality.

Appendix A Glossary

This Glossary covers only terms and acronyms used in this document. A complete PCEHR Glossary is available as part of the PCEHR Concept of Operations[3].

A.1 Acronyms

Acronym	Explanation
B2B	Business to business
CCA	Compliance, Conformance and Accreditation
CDA	Clinical Document Architecture
CIS	Clinical Information System
CSP	Contracted Service Provider
GP	General Practitioner
HPI-I	Healthcare Provider Identifier – Individual
HPI-O	Healthcare Provider Identifier – Organisation
IHI	Individual Healthcare Identifier
IT	Information Technology
LDAC	Limited Document Access Code
LSS	Logical Service Specification
NOC	Notice of Connection
PCEHR	Personally Controlled Electronic Health Record
RAC	PCEHR Record Access Code
RRP	Registered Repositories Provider
SaaS	Software as a Service
SAML	Security Assertion Markup Language
TSS	Technical Service Specifications

[3] A high level overview of the PCEHR system is described in the *Concept of Operations: Relating to the introduction of a Personally Controlled Electronic Health Record System* available from the Department of Health and Ageing's information portal website http://www.yourhealth.gov.au .

A.2 Specialised Terminology

Term	Explanation
Accreditation	End result of CCA testing.
Assisted Registration	Consumer registration undertaken through a healthcare provider organisation.
Clinical Information System	An Information System used to help support clinical activity.
Consumer	A user of the healthcare system. Has been referred to as 'individual' and 'patient'.
Health Record Overview	A view intended to provide a summary of an individual's PCEHR. It presents information from the Shared Health Summary and also indicates if other related information from other clinical documents is available.
PCEHR Registered interface	The interface on the local system that meets the standards, specifications and technology requirements to interact with the PCEHR System.
Personally Controlled eHealth Record	The consumer's specific personally controlled health information, as available online.
Registered Consumer Portal	A Registered Consumer Portal is a nationally operated portal to allow consumers to access their own PCEHR.
Registered Provider Portal	A provider portal complements existing local health record systems by providing an alternative form of access to the PCEHR for healthcare providers.
Registered Repositories	Repositories that conform to the appropriate PCEHR standards and specifications required to ensure interoperability, privacy, integrity and long term availability of the healthcare information it holds.
Service	A Service encapsulates the collaboration which occurs between two or more parties to achieve a goal. Each participant in the service may offer multiple Service Interfaces.
Software Developer	An organisation or company which builds software and systems. A software developer may also be a software implementer and software vendor.
Software Vendor	An organisation or company which sells software and systems. A software vendor may also be a software implementer and software developer.
Web Single Sign on	Single access control allowing a user authenticated on a local system to gain access to another system without further authentication.