Concept of Operations:
Relating to the introduction of a
Personally Controlled Electronic
Health Record System
Minister’s introduction

Australia has taken another step towards a national personally controlled electronic health record (PCEHR) system – an eHealth initiative that will help bring Australia’s healthcare into the 21st century.

I am pleased to present the Concept of Operations: Relating to the introduction of a personally controlled electronic health record system (PCEHR Concept of Operations). It is a significant enabling component of the Government’s national health reform agenda and a milestone achievement for e-health that will guide the PCEHR program delivery, including the development of key national IT infrastructure and connections.

The release of the PCEHR Concept of Operations is made possible by the support, feedback and submissions received by the Department of Health and Ageing during the public consultation process for the draft PCEHR Concept of Operations, which commenced in April 2011. I would like to thank the Australian community including individuals, healthcare providers, consumer and advocacy groups, the ICT industry and government organisations for their contribution and interest in the PCEHR program.

Where appropriate, the PCEHR Concept of Operations has been adapted to address issues raised during the public consultation process. The accompanying report, Analysis of Key Themes from the Public Consultation Process, provides information on major discussion themes raised during the public consultation phase, the steps being taken to progress these themes and consequential changes made to the PCEHR Concept of Operations.

From July 2012, all Australians who choose to can register for a PCEHR. As the PCEHR system matures, Australians who use a PCEHR will be able to see their important health information in one consolidated view. They will be able to share this information with trusted healthcare practitioners, who in turn will be able to access their patient’s PCEHR to support the delivery of high quality healthcare regardless of where and when it is needed.

Since April 2011, there have been significant milestones achieved for the PCEHR program, including the appointment of the National Infrastructure Partner, the National Change and Adoption Partner and the Benefits and Evaluation Partner.

As part of the PCEHR program, e-health lead implementation sites have been established around Australia to deploy components of electronic health record systems, providing valuable learning to inform the implementation of the national PCEHR system.

Together with investments in telehealth, the National Health Identifier Service and the National Broadband Network, electronic health records will improve accessibility to health services and information, which over time will significantly enhance health outcomes.

I look forward to sharing more information about Australia’s progression towards a national PCEHR system in the near future.

The Hon Nicola Roxon MP
Australian Government Minister for Health and Ageing
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Document information

Purpose

The purpose of this document is to provide an overview of the Personally Controlled Electronic Health Record (PCEHR) System and how it will work.

This version of the Concept of Operations is based on the framework for a national electronic health record system agreed by the Australian Health Ministers Conference in April 2010. It has been updated following public consultation on an April 2011 draft of this document, ongoing consultations with stakeholders (see Appendix A) and lessons learned from local and international efforts (see Appendix B). A summary of the key changes is given in Appendix C.

The Concept of Operations will be periodically updated as the development of the PCEHR System progresses. This version of the Concept of Operations will set the basis for the construction of the PCEHR System by the national infrastructure partner to be engaged to build the core components of the PCEHR System.

This version of the Concept of Operations contains a moderate level of detail about the PCEHR System. This is intentional as it provides readers with a single document that describes the many elements of the PCEHR System in sufficient detail to inform stakeholders.

What is not in scope

This document contains a high level overview of the PCEHR System approach and design. While it summarises a number of aspects of the PCEHR System, other documents cover different aspects of the system in more detail, as follows:

- **Requirements and Design**: More detailed documents are available covering different aspects of the system design, including the Business Requirements, Business Scenarios and Use Cases and High Level System Architecture. Additional documents are also in development, including Detailed Requirements, Operational Framework and a Data Quality Framework.
- **Legislation and Governance**: A Legislation Issues Paper [DOHA2011b] has been released to the community. Outcomes of consultation will inform the draft legislation. The Department of Health and Ageing is also developing the proposed governance model.
- **Change and Adoption**: A Change and Adoption Partner has been appointed. It is anticipated that more information around change and adoption will be available in time.
- **Benefits and Evaluation**: A Benefits Evaluation Partner has been appointed and it is anticipated that more information around benefits evaluation will be available in time.

Intended audience

This document is primarily aimed at readers wishing to understand the PCEHR System in a moderate level of detail. It is written for a wide range of readers who already have a general knowledge about the current Australian eHealth agenda. This includes individuals, healthcare providers, ICT industry and other interested parties.

Many parts of this document are also suitable for readers new to the area of eHealth. Readers interested in more general material should refer to the following websites:

- Videos explaining the PCEHR System: [http://www.youtube.com/watch?v=3IOoUMwSGMI](http://www.youtube.com/watch?v=3IOoUMwSGMI)
Additional material can be found at:
- NEHTA: www.nehta.gov.au

How to read this document

In order to describe something as significant as the PCEHR System, the Concept of Operations is by necessity a large document. Readers may prefer to focus on different sections of the document:

- Readers interested in a summary of the PCEHR System should read the overview (Section 1).
- Readers interested in scope and core functionality around participation, information management, privacy and security should read Sections 2, 3, 4 and 5.
- Readers wanting technical information describing each of the PCEHR System components should read Section 6.
- Readers interested in operations, implementation and outcomes evaluation should read Sections 7, 8 and 9.

A glossary of key terms is provided in Appendix E.

Throughout the document, coloured breakout boxes draw attention to different items, as follows:

**Design Note:** Blue design note boxes highlight significant design choices that were made.

**Scope Note:** Yellow scope note boxes clarify an area of functionality and indicate if it is likely to be restricted in the first release of the PCEHR System or if the functionality is an option requiring further consultation.

**eHealth Site Note:** Lavender scope note boxes highlight items that will be developed in one or more lead eHealth sites. These sites will be early adopters of the capabilities being developed to support the PCEHR System, and will provide practical experience that can guide the broader adoption of the PCEHR System into the future. The full set of lead eHealth sites is discussed in Section 8.5.
1 Overview of the PCEHR System

eHealth is important to the future of health care in Australia. For individuals and healthcare providers alike, it will enhance the way healthcare is delivered.

eHealth is an integral part of the Australian Government’s agenda for Health Reform, an agenda that aims to create a continuously improving healthcare system for the 21st century – a system that is accountable, affordable and sustainable, with safety and quality at its centre.

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 an individual’s healthcare providers, while enabling the individual to control who can access their PCEHR.

The Government has invested $467 million in the first release of the PCEHR System. The first release delivers the core functionality required to establish a PCEHR System that can grow over time. The first release will ensure that all individuals seeking care in the Australian healthcare system have the option to register for a PCEHR from July 2012.

The PCEHR System will build on the foundation laid by the introduction of the national Healthcare Identifiers for individuals, healthcare providers and healthcare organisations as well as the National Authentication Service for Health, clinical terminologies and methods for communicating health information between healthcare providers such as Discharge Summaries and electronic Referrals.

1.1 The need for a PCEHR System

The implementation and adoption of a national PCEHR System addresses a current challenge faced by the Australian health system — the fragmentation of information spread across a vast number of different locations and systems. In many healthcare situations, quick access to key health information about an individual is not always possible. Limited access to health information at the point of care results in:

• A greater risk to patient safety.
• Increased costs of care and time wasted in collecting or finding information.
• Unnecessary or duplicated treatment activities.
• Additional pressure on the health workforce.
• Reduced participation by individuals in their own healthcare information management.

The purpose of the PCEHR System is to address information fragmentation by allowing a person to more easily access their own health information and make their health information securely accessible to different healthcare providers involved in their care. This will result in:

• Improved continuity of care for individuals accessing multiple healthcare providers by enabling key health information to be available where and when it is needed to ensure safe ongoing care.
• Access to consolidated information about an individual’s medicines, leading to safer and more effective medication management and reductions in avoidable medication-related adverse events.
• Enabling individuals to participate more actively in their healthcare through improved access to their health information.
• Improved diagnostic and treatment capabilities through enhanced access to health information.
• Improved care coordination for individuals with chronic or complex conditions by enabling the individual’s healthcare team to make better-informed decisions at the point of care.

1.2 The PCEHR System

The national PCEHR System places the individual at the centre of their own healthcare by enabling access to important health information, when and where it is needed, by individuals and their healthcare providers.

Individuals can choose whether or not to have a PCEHR. If they choose to participate, they will be able to set their own access controls. With the individual’s permission, key pieces of health information may be viewed by participating healthcare providers across different locations and healthcare settings.

In order to deliver this vision, the PCEHR System will provide the necessary national infrastructure, standards and specifications to enable secure access to an individual’s health information drawn from multiple sources. Suppliers of eHealth systems will be able to enhance their products and services to become conformant with the relevant standards and specifications and support healthcare organisations in accessing the PCEHR System.

Clinical documents, such as Shared Health Summaries, Discharge Summaries, Event Summaries, Pathology Result Reports and Specialist Letters will be collected from a range of participating organisations, and stored within a number of secure repositories in the PCEHR System. The PCEHR System may

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1 An animation outlining the PCEHR System can be found at http://www.youtube.com/watch?v=3IOoUMwSGMI
also share key health information entered by the individual (such as over-the-counter medications and allergies), and access information from the Department of Human Services. This includes Medicare information, such as an individual’s organ donor status, dispensed medications funded under the Pharmaceutical Benefits Scheme (PBS), information about healthcare events from an individual’s Medicare claiming history and a child’s immunisation history. The PCEHR System will also collect information about the location of an individual’s advance care directive (if they have one).

**Figure 2: The PCEHR System**

The PCEHR System will provide a number of core services that will allow authorised users to search for clinical documents, view clinical documents and access reports.

A key feature of the PCEHR System is its ability to provide a series of views over different clinical documents in an individual’s PCEHR. These views will allow users of the system to easily see a consolidated overview of an individual’s allergies and adverse reactions, medicines, medical history, immunisations, directives and recent healthcare events from different information sources. Figure 3 provides an example of a Consolidated View.
Figure 3: Example Consolidated View²

1.3 Participation

1.3.1 Individuals

Individuals who would like to participate will be able to register from July 2012. They will then be able to experience the following benefits:

- **Access their health information:** The PCEHR System will provide secure, quick and easy access to an individual’s key pieces of health information by both the individual and their healthcare providers.

- **Receive improved healthcare:** The PCEHR System provides an individual’s healthcare providers with access to a wider source of health information, which will lead to opportunities for improved prevention, early intervention and treatment of chronic diseases as well as improved diagnosis and treatment in emergencies.

- **Be more informed about healthcare choices:** The PCEHR System will allow an individual to access their own PCEHR, view their own records and, in time, may link to health literacy information relating specifically to their needs.

Registration for those with a verified Individual Healthcare Identifier, or IHI, will be supported online, and assisted registration will also be supported through Medicare branded service points and by some healthcare providers.

Once registered, individuals will be able to set up a number of ‘access controls’ (see Section 1.4), which moderate access by participating healthcare organisations to their PCEHR.

Individuals may also nominate representatives (such as family members and carers) to access their PCEHR. Authorised representatives (such as parents

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² Note that this is a conceptual mock up of what the consolidated view might look like for a clinical user and is not an actual system.
and guardians) will also be able to register individuals in their care and access their PCEHR. Additional processes will be put in place to manage access when a child is old enough to manage their own PCEHR.

Individuals will be able to withdraw at any time from the PCEHR System. A PCEHR is not mandatory for receiving healthcare services.

1.3.2 Healthcare providers and organisations

Healthcare organisations will be able to access the PCEHR System from July 2012. They will then be able to:

- **Access health information more efficiently**: The PCEHR System will provide secure, quick and easy access to a Consolidated View of an individual’s key health information from participating healthcare organisations.

- **Ensure safer healthcare**: The PCEHR System will provide access to important information about an individual such as their allergies and adverse reactions, as well as their medicines, medical history and immunisations.

- **Deliver more effective healthcare**: Easier access to information provides opportunities for improved prevention, early intervention and treatment of chronic and complex diseases as well as improved diagnosis and treatment in emergencies.

In order to participate, the healthcare organisation will need to register, obtain a healthcare organisation identifier (HPI-O), use appropriate authentication mechanisms to access the PCEHR and use software that has satisfied conformance testing for the PCEHR System.

Healthcare organisations will be able to select which of their employees are authorised to access the PCEHR System as part of their role in healthcare delivery. Only healthcare providers with a healthcare provider identifier (HPI-I) will be able to contribute information to the PCEHR System.

1.4 Personal control

Central to the PCEHR System is the concept of personal control. Participating individuals can exercise control over their PCEHR in the following ways:

- **Decide whether or not to have an active PCEHR**: The PCEHR System operates on an opt-in model, where individuals elect to register and create a PCEHR. Individuals may de-activate their PCEHR and subsequently reactivate their PCEHR at any time.

- **Access information in their PCEHR**: Individuals will be able to view any health information contained in their PCEHR.

- **Set controls around healthcare provider access**: Individuals may determine and change settings around access to their PCEHR by participating healthcare organisations involved in their healthcare. Individuals may choose from a range of approaches to setting and managing these controls to give general or limited access. Some access controls may be overridden in situations where the individual requires emergency care.

- **Authorise others to access their PCEHR**: Individuals may nominate other persons (such as carers and family members) to access their PCEHR.

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3 As per the Healthcare Identifiers Act 2010, an ‘employee’ is either an individual who provides services for the entity under a contract for services, or an individual whose services are made available to the entity (including services made available free of charge).
Choose which information is published to and accessible through their PCEHR: Individuals may request healthcare providers to withhold certain information from their PCEHR.

View an activity history for their PCEHR: The PCEHR System will provide an audit trail so that individuals can view a history of actions on their PCEHR.

Make enquiries and complaints: Individuals may make enquiries and complaints in relation to the management of information in their PCEHR and the PCEHR System.

1.5 Using the PCEHR System

1.5.1 Individuals

Individuals will be able to access their PCEHR online via a Consumer Portal and will be able to:

- Access their health information stored in their PCEHR.
- Link to online health literacy information.
- Share information with their healthcare providers, including information about their allergies and over the counter medications. They will also be able to keep notes online as a memory aid for themselves and their carers.
- Manage their access controls and view the activity history on the PCEHR.
- Improve the quality of their health information by highlighting potential errors in their records and request the potential error be reviewed.

The PCEHR System will also provide the capability for independently operated conformant portals to connect to the PCEHR System, allowing individuals (in time) a choice of portal to access their PCEHR. A call centre will be provided to help support individuals in accessing their PCEHR and to answer general questions about the PCEHR System.

Additional avenues will be provided for access by individuals who do not have access to the Internet, are not able to use a computer, speak a language other than English or have specific accessibility needs.

1.5.2 Healthcare providers and organisations

Healthcare providers will be able to access the PCEHR System using a range of options including:

- Clinical Systems: Many healthcare organisations have already invested in a clinical system for healthcare delivery. In time, a range of new versions of many of those systems will become available with built in capability to access the PCEHR System. The PCEHR System will also support contracted service providers who operate healthcare software as a service on behalf of the contracting healthcare organisation.

- Provider Portal: Healthcare providers will be able to access health information stored in the PCEHR System via the Provider Portal. The Provider Portal is supplied as an alternative form of access to the PCEHR System. Access to the Provider Portal by healthcare providers needs to be authorised by the participating healthcare organisation.

Authorised users of these systems will be able to:

- Check whether an individual has a PCEHR (without viewing the record).
- Seek permission to access an individual’s PCEHR.
• View and search an individual’s PCEHR (only after permission to access the PCEHR has been obtained).
• Download and/or print clinical documents and views PCEHR (only after permission to access the PCEHR has been obtained).
• Upload clinical documents (feature only available through clinical systems).

A call centre will be provided to help support healthcare providers in accessing the PCEHR System and to answer general questions about the PCEHR System.

1.6 Ensuring privacy and security

A multi-layered approach will safeguard the PCEHR System, and will incorporate both technical and non-technical controls. These include:

• Accurate authentication of users accessing the PCEHR System.
• Robust audit trails.
• Proactive monitoring of access to the PCEHR System to detect suspicious and inappropriate behaviour.
• Rigorous security testing, to be conducted both before and after the PCEHR System begins operation.
• Education and training of users of the system.
• Requirements that healthcare providers and organisations comply with specific PCEHR System business rules and other relevant legislation.

Individuals will be able to make enquiries and lodge complaints regarding suspicious or unauthorised access to their PCEHR.

1.7 Implementation and adoption

The implementation and adoption of the PCEHR System will be based on a combination of ‘top down’ national initiatives and ‘bottom up’ lead eHealth sites. This allows for tangible eHealth project outcomes on the ground, while at the same time ensuring a focus on the central actions required to deliver a nationally interoperable system.

National initiatives will focus on delivering the core PCEHR System infrastructure. The Department of Health and Ageing will act as the program manager and engage a number of partners, including:

• **NEHTA** — who are responsible for managing the requirements and high-level architecture of the PCEHR System, as well as supporting the standards development process. NEHTA acts as a managing agent with the other partners on behalf of the Department of Health and Ageing.
• **Department of Human Services** — who will be responsible for providing support services through Medicare call centres, back-office processing (e.g. mail based registrations) and shop fronts, including enquiries, assisted registration and a point of contact for requests and complaints. The Department of Human Services will also operate a conformant repository enabling access to Medicare information, such as the MBS, PBS, ACIR and organ donor information, and provide a proof of record ownership service to assist with identifying and authenticating individuals during registration.
• **National Infrastructure Partner** — who will be responsible for delivering the infrastructure components of the PCEHR System. This role will be undertaken by a consortium led by Accenture.
• **Change and Adoption Partner** — who will be responsible for supporting the programs of work around communications and engagement as well as providing change management support to adopters of the PCEHR System.
This role will be undertaken by a consortium led by McKinsey and Company.

- **Benefits Evaluation Partner** — who will develop a benefits realisation and evaluation framework and assess the ongoing progress of the PCEHR System. The outcomes of the evaluation process will be used to help inform the ongoing implementation program and future investments. This role will be undertaken by a consortium led by PricewaterhouseCoopers.

An external delivery advisor (Ernst & Young) has been appointed by the Department of Health and Ageing to provide independent advice on the progress of the PCEHR Program.

A key part of the program is the provision of two waves of funding for 12 lead eHealth sites spanning different geographic and functional parts of the Australian health sector. The lead eHealth sites will collectively help support early adoption of the PCEHR System by aiming to enrol up to 500,000 individuals. These sites will:

- Deploy elements of eHealth infrastructure, specifications and standards in controlled, real world healthcare settings to inform future national rollout.
- Demonstrate tangible outcomes and benefits from funded eHealth projects.
- Build stakeholder support and momentum behind the PCEHR System work program.
- Provide a meaningful foundation for further enhancement and rollout of the PCEHR System.

While all Australians will have the option of registering for a PCEHR from July 2012, adoption of the PCEHR System capabilities by healthcare providers and their eHealth system suppliers will take time. Beyond July 2012, the government will work with healthcare providers and the ICT industry to build on the capabilities provided by the PCEHR System in order to incrementally expand the breadth and depth of adoption over time.
2 Background and approach

2.1 Background

Recent health reform reports [DOHA2009a, DOHA2009b and NHHR2009] recognise that the health system is facing a significant set of challenges, including:

- The increased prevalence of chronic disease.
- Discrepancies in health outcomes between advantaged and disadvantaged Australians.
- An increasing and ageing population.
- Increasing demand for more costly and complex procedures.
- A shortage of skilled health sector workers.

Together these challenges are driving increased healthcare service demands and costs, and call into question the very sustainability of the Australian healthcare system in the medium to long term.

In April 2010, the Council of Australian Governments (COAG) met to discuss the health reform agenda. These reforms will deliver better healthcare via eight streams of work around hospitals, primary healthcare, aged care, mental health, national standards and performance, workforce, prevention and eHealth. Additional COAG discussions in February 2011 have made further refinements to the health reform approach. The health reform approach is described in *A National Health and Hospitals Network for Australia’s Future: Delivering the Reforms* [DOHA2010c] and the *National Health Reform Agreement* [DOHA2011c].

As part of the eHealth stream within the health reform package, the Commonwealth has invested $467 million over two years into the key components for an electronic health record system, so that all Australians have access to a PCEHR if they choose.

This investment represents the next key step in the National E-Health Strategy [AHMAC2008] and builds on the foundations developed by NEHTA. These foundations include the Healthcare Identifiers Service (HI Service), National Authentication Service for Health (NASH) and Clinical Terminologies.

In order to fully realise the benefits of this investment, the states and territories will need to continue their planned or expected investments in core health information systems. States and territories will also need to provide the complementary investments to build their capacity in readiness for connection to the PCEHR System.

The Department of Health and Ageing and NEHTA are currently working with each of the state and territory health departments to implement a range of foundations, including Healthcare Identifiers, Discharge Summaries and Secure Messaging, all of which will be required for the PCEHR System.

2.2 Business drivers

The implementation and adoption of a national PCEHR System addresses a current challenge faced by the Australian health system — the fragmentation of information spread across a vast number of different locations and systems. In many healthcare situations, quick access to key health information about an individual is not always possible.
Limited access to health information at the point of care results in:

- A greater risk to patient safety.
- Increased costs of care and time wasted in collecting or finding information.
- Unnecessary or duplicated treatment activities.
- Additional pressure on the health workforce.
- Reduced participation by individuals in their own healthcare information management.

The purpose of the PCEHR System is to address information fragmentation by allowing a person to more easily access their own health information, and to make their health information securely accessible to different healthcare providers involved in their care.

This will result in:

- Improved continuity of care for individuals accessing multiple healthcare providers by enabling key health information to be available where and when it is needed to ensure safe ongoing care.
- Access to consolidated information about an individual’s medicines, leading to safer and more effective medication management and reductions in avoidable medication-related adverse events.
- Enabling individuals to participate more actively in their healthcare through improved access to their health information.
- Improved diagnostic and treatment capabilities through enhanced access to health information.
- Improved care coordination for individuals with chronic or complex conditions by enabling the individual’s healthcare team to make better-informed decisions at the point of care.

2.3 Vision and concept

The national PCEHR System aims to place the individual at the centre of their own healthcare by enabling access to important pieces of health information when and where it is needed by individuals and their healthcare providers.

Individuals will be able to choose whether or not to have a PCEHR, and if they choose to participate, they will be able to set their own access controls. Using the PCEHR System, individuals will be able to access their own healthcare information and allow their healthcare providers to access and use this information to provide more coordinated and effective care for the individual.

Individuals will have greater involvement in their care through increased access to their information and other resources and will not be required to remember all the details of their previous healthcare.
In order to deliver this vision, the PCEHR System will provide:

- Secure access for individuals and their healthcare providers to their eHealth records via a range of access channels.
- A national set of services that will allow streamlined access to eHealth records, drawn from multiple repositories, such as:
  - A Shared Health Summary including allergies and adverse reactions, medicines, medical history and immunisations.
  - Clinical documents such as Discharge Summaries, Event Summaries, and over time, other documents (e.g. Pathology Result Reports, Specialist Letters, etc.).
- Governance, legislation and oversight to ensure trust and confidence in the PCEHR System.
- The national specifications, standards, planning and core national infrastructure required to use the PCEHR System.
Key design features of the PCEHR System are explained below.

<table>
<thead>
<tr>
<th>The PCEHR System</th>
<th>and not</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>is opt in</strong> – if an individual or healthcare provider wants to participate, they need to register with the system.</td>
<td><strong>and not compulsory</strong> – both individuals and healthcare providers choose whether or not to participate.</td>
</tr>
<tr>
<td><strong>is an enhancement to medical treatment</strong> – the PCEHR System will allow an individual’s health information to be shared as and when needed to support the best possible care.</td>
<td><strong>and not a requirement for medical treatment</strong> – if a person does not wish to participate in the PCEHR System, they will continue to be able to access treatment and Medicare benefits.</td>
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<tr>
<td><strong>is a source of selected clinical data and documents</strong> – in addition to a Shared Health Summary in each PCEHR (which contains basic health data about an individual), clinical documents may be added to that individual’s PCEHR.</td>
<td><strong>and not a replacement for normal sharing of information between an individual and their healthcare provider</strong> – as currently occurs in medical practice, existing medical records are used as the starting point for the discussion about the individual’s health, rather than as the complete and authoritative source of current information.</td>
</tr>
<tr>
<td><strong>is an information system</strong> – where participating healthcare providers can access additional selected clinical documents during a consultation with an individual.</td>
<td><strong>and not a communication system</strong> – where participating healthcare providers are expected to review any new clinical documents loaded into a PCEHR in between consultations with the individual.</td>
</tr>
<tr>
<td><strong>is aligned with current privacy obligations</strong> – healthcare providers will have the same responsibilities in relation to privacy of information in PCEHRs as they currently do in relation to clinical information from other sources.</td>
<td><strong>and not immune to current sharing and reporting rights and obligations of providers</strong> – healthcare providers currently have rights and obligations in relation to disclosure of health information which will continue. These include the ability to access health information in life-threatening situations and the obligation to notify instances of certain diseases to government authorities.</td>
</tr>
<tr>
<td><strong>is a distributed system of service providers working in concert</strong> – government and private sector organisations will work together to deliver the PCEHR System to individuals and healthcare providers. The PCEHR System will be underpinned by a legislative framework intended to impose appropriate controls and standards on all the system participants.</td>
<td><strong>and not a single government store of personal information</strong> – while public sector bodies may provide some of the repositories which hold information for the PCEHR System, other private sector organisations may also participate as repositories where they meet relevant specifications and standards.</td>
</tr>
</tbody>
</table>
2.4 **Approach**

Delivery of a national outcome around PCEHR will be challenging. The proposed approach endorsed by Health Ministers recognises the multi-jurisdictional responsibilities for health services delivery and the complexity of the public-private mix of healthcare organisations that provide direct healthcare services. The approach also recognises the key foundational eHealth elements already underway and the different levels of readiness for connection to the national PCEHR System across Australia’s health sectors.

Consistent with the National E-Health Strategy, the strategy for delivering the PCEHR System also acknowledges the need for sustained systemic business-related change across multiple healthcare provider and consumer representative groups.

The following elements will be required to deliver the PCEHR System:

- **Government endorsement of, and support for, a national approach to governance to champion the PCEHR System, and provide national oversight of implementation and adoption.**
- **Top-level health sector leadership, in order to create sustained, visible leadership and commitment to the PCEHR System.**
- **Involvement of healthcare providers, consumer representatives and the ICT industry across the entire PCEHR program, including the development of strategies and approaches for targeted adoption.**
- **Planning and implementation of a comprehensive engagement and representation strategy.**
- **A national communications program that is understandable and compelling for both the Australian community and the healthcare sector.**
- **Delivery of a number of lead eHealth sites that align with the national work program. The purpose of these lead eHealth sites will be to:**
  - Deploy elements of eHealth infrastructure, specifications and standards in controlled, real world healthcare settings to inform future national rollout.
  - Demonstrate tangible outcomes and benefits from funded eHealth projects.
  - Build stakeholder support and momentum behind the PCEHR System work program.
  - Provide a meaningful foundation for further enhancement and rollout of the PCEHR System.
- **A national change management and adoption program that aligns with national health policy priorities and allows for tailoring to meet local requirements.**
- **An ICT industry program to aid suppliers of eHealth products and services in take up of relevant standards and specifications and subsequent conformance assessment.**
- **A change and adoption program targeting particular groups in the community likely to receive the most immediate benefit, including those suffering from chronic and complex conditions, older Australians, Aboriginal and Torres Strait Islander peoples, mothers and their newborn children, people with mental health conditions and people living in rural or remote communities.**
- **Research and evaluation strategies to identify and realise opportunities for collaboration, and leverage knowledge regarding the issues, challenges and solutions experienced in implementing the PCEHR program.**
2.5 Principles

Eleven key principles have been used to inform the design and approach of the PCEHR System:

1. **Personally controlled**: Individuals will be able to choose whether or not to have a PCEHR, and if they choose to have one, they will be able to set their own access controls.

2. **Value**: Deliver a PCEHR System that offers value to both individuals and their healthcare providers.

3. **Trust**: Deliver a PCEHR System that all users can trust is being governed effectively; individuals trust that their privacy has been addressed appropriately.

4. **Confidence**: Deliver a PCEHR System that users are confident in the quality and safety of the health information provided.

5. **National infrastructure**: Deliver core elements of PCEHR System infrastructure once, rather than duplicating development costs and efforts and increasing the likelihood of rework.

6. **Stakeholder engagement**: Actively engage key healthcare stakeholders in the design and delivery of the PCEHR System.

7. **Incremental approach**: Build the PCEHR System in an incremental and pragmatic manner, focusing initial investment in areas that deliver the greatest benefits.

8. **Recognising different starting points**: Balance active support for healthcare providers with less developed capability, while not constraining the ability for more advanced participants to progress.

9. **Leverage**: More effectively leverage and scale existing and planned eHealth activities, specifications and standards in the delivery of the PCEHR System.

10. **Balancing alignment and independence**: Drive alignment of PCEHR System implementation and adoption activities while not unnecessarily limiting the ability of participants and vendors to implement locally relevant solutions.

11. **Relevant skills**: Ensure sufficient numbers of skilled practitioners are available to support delivery of the PCEHR System.

2.6 Timeframe

The PCEHR System must be available so that, beginning July 2012, individuals can register for a PCEHR online. Key milestone dates are given in the implementation plan in Section 8.2.

2.7 Scope

The Commonwealth’s investment of $467 million will fund the national elements of the PCEHR System. The focus of this investment will be to deliver the core functionality required to establish a PCEHR System for Australia that can be built on over time.

The scope of the PCEHR System for delivery after July 2012 will be heavily informed by consultation with key stakeholders, the community and testing of system concepts in lead eHealth sites.

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4 These principles have been adapted from the seven principles outlined in the National E-Health Strategy [AHMC2008]. The ‘personally controlled’, ‘value’ and ‘trust’ and ‘confidence’ principles have been added as additional principles.
By July 2012, individuals will be able to register online for a PCEHR. As the use by healthcare providers increases, registered individuals will be able to progressively reap the benefits of having a PCEHR.

Beyond July 2012, the policy directions for eHealth are clear. The Government's complementary investment in tele-health, coupled with the rollout of the National Broadband Network, align with the National E-Health Strategy trajectory endorsed by the Australian Health Ministers' Conference in 2008. Additionally, the current two-year investment in the PCEHR Program, including in the lead eHealth sites, will inject significant momentum for PCEHR use in designated regions and consumer cohorts building towards a tipping point for broader adoption as the national infrastructure elements come online. The work of the PCEHR Benefits Evaluation Partner will also be critical in demonstrating tangible benefits and improvements against baseline activity.

It is recognised that the PCEHR System will grow over time. Government investments, user expectations and market forces will stimulate this growth. Government funding for the PCEHR System beyond July 2012 will be considered in the 2012-13 Budget. Further consultation, including collaboration with the states and territories, will be required to consider a sustainable model for ongoing operations of the PCEHR System (see Section 7), ongoing change and adoption (see Section 8) and further enhancements to the PCEHR System (see Section 2.8).

The scope and focus of the PCEHR System funded by the Commonwealth includes the implementation of:

• The core national infrastructure to support the operation of the PCEHR System, including key components such as:
  - Access channels, such as a Consumer Portal, Provider Portal, Report Portal, Administration Portal, B2B Gateway and Call Centre.
  - Core PCEHR services to support major functional areas around participation and authorisation, indexing, views, audit, reporting and contact management.
  - A National Repositories Service to hold a minimum critical set of healthcare information about participating individuals within multiple nationally operated repositories.
  - The capability to connect to conformant repositories and conformant portals as they become available.
  - Support for a range of systems accessing the B2B Gateway, such as clinical systems and contracted service providers.
  - A new foundation service for supporting templates.
  - A new foundation service for supporting proof of record ownership.

Each of these elements is described further in Section 6.

• Functional capability within the national infrastructure to support:
  - Registration and managing the ongoing participation of individuals and healthcare providers (see Section 3).
  - Access controls managed by the individual.

The access controls will include a number of basic and advanced features. Options for additional basic and advanced features may also be included. Access controls are discussed further in Section 5.

- The collection of health information from a range of points of care, including: Shared Health Summaries, Event Summaries, and Discharge Summaries. This will be complemented by collection of information from individual consumers, such as: Consumer entered health summary and Consumer notes.
This information, subject to the individual’s access controls, will provide the base information required to support sharing of important information around allergies and adverse reactions, medicines, medical history and immunisations. This information will facilitate improved continuity of care, medication management and consumer participation.

In addition to this, a range of optional information sources will be considered in the first release. The options include: Specialist Letters, Pathology Result Reports, Medicare Information (e.g. Medicare claims history, PBS data, ACIR and Organ Donor), Referrals, Prescriptions/Dispense Notifications.

These options will build on the base capability and further improve the breadth and depth of information available in the PCEHR System, thereby enhancing continuity of care, medication management, diagnostic test management and the consumer participation capabilities of the system.

The content available in an individual’s PCEHR from July 2012 will also depend on the readiness of further healthcare provider information systems to participate in the national PCEHR Program.

- The consolidation and analysis of information collected in the PCEHR System via:
  - Views to enable easy access to consolidated information about an individual’s allergies and adverse reactions, medicines, immunisations and medical history.
  - Reports to support the evaluation and operational requirements of the PCEHR System.

Managing PCEHR information is described further in Section 4.

- Establishment of an operational capability to support the ongoing operations of the PCEHR System (see Section 7).

- Standards and technical specifications used by the PCEHR System to enable the accurate and reliable collection and exchange of PCEHR-related information.

  Standards and technical services are discussed further in Section 6.1.2.

- Establishment of a national approach assessing the conformance of systems against the agreed standards and technical specifications.

  Conformance assessment is discussed further in Section 7.4.

- Establishment of lead eHealth sites to test and deploy National eHealth infrastructure, specifications and standards in real world healthcare settings and build stakeholder momentum.

  Lead eHealth sites are discussed further in Section 8.5.

- Development of a stakeholder change management strategy which accounts for the required work practice and business process changes.

  Engagement is discussed further in Section 8.4.1.

- Design and delivery of stakeholder communication strategies to drive adoption of the PCEHR System by individuals and healthcare providers.

  Change management is discussed further in Section 8.4.2.

- Governance and oversight of the national PCEHR System’s implementation, operation and adoption to address required delivery accountabilities and ensure appropriate clinical safety and quality outcomes.

  Governance is discussed further in Section 7.2.
2.8 Potential enhancements

The National E-Health Strategy proposed that the PCEHR System rollout be undertaken via an incremental approach, with the capabilities of the system being expanded over a four-year implementation period.

Potential enhancements could focus on delivering quality improvements and enhancements based on stakeholder demand and lessons learned from implementation and adoption activities. Candidates for later potential enhancements could include, but are not limited to:

- Enhancements to the registration processes.
- Support for collection of a broader range of health information from healthcare providers, such as:
  - Delivery of any optional elements delayed from the first release of the PCEHR System.
  - Advance care directives (i.e. storage of the directive itself in the PCEHR System rather than just information about the custodian).
  - Pathology requests.
  - Diagnostic imaging reports, images and requests.
  - Health information from registries.
  - Care plans.
  - Assessments tools.
  - Reports from practice-based diagnostic tools (e.g. electrocardiograms).
  - Pharmacy based medicine reviews and medication profiles.
  - Extensions to the Shared Health Summary to include fields such as infectious disease status, information about implants, etc.
  - Information to support an individual with disabilities.
  - Information around palliative care.
- The addition of consumer-oriented features, such as:
  - Integration with consumer-oriented personal health records enabling an alternative form of interaction by an individual with their PCEHR.
  - Collection of information from consumer devices such as blood pressure monitors, blood glucose monitors, etc.
- Access to information within other sources, such as:
  - Screening registers, such as the National Bowel Cancer Screening Register, BreastScreen Australia registries, pap smear registries, etc.
- Addition of new views to the PCEHR System to support the needs of specific groups, such as:
  - Views to support management of chronic diseases.
  - Views to support individuals and their representatives.
  - Views to support specific healthcare providers, such as nurses and allied health providers.
- Enhancements to the template service to support more dynamic and flexible approaches to templating.
- Enhancements to the reporting service to support a wider range of approved uses.
- Enhancements to the PCEHR System access controls.
- Enhancements to support mobile devices.
• Enhancements to facilitate implementation of clinical decision support tools within clinical systems and portals, which leverage information from the PCEHR System.

Initial consultation with a cross-section of stakeholders indicated that some of these features are important to pursue early. However, progress on the above enhancements depends on work being delivered outside the PCEHR Program.
3 Participation

3.1 Introduction

This section outlines the approach to participation by individuals, healthcare providers and organisations, and user systems.

3.2 Individuals

The PCEHR System is a voluntary opt-in system. Individuals who choose to participate will experience the following benefits:

- **Access their health information**: The PCEHR System will provide secure, quick and easy access to an individual’s key pieces of health information by both the individual and their healthcare providers.

- **Receive improved healthcare**: The PCEHR System provides an individual’s healthcare providers with access to a wider source of health information, which will lead to opportunities for improved prevention, early intervention and treatment of chronic diseases as well as improved diagnosis and treatment in emergencies.

- **Be more informed about healthcare choices**: The PCEHR System will allow an individual to access their own PCEHR, view their own records and, in time, may link to health literacy information relating specifically to their needs.

Once registered, individuals will be able to manage their access controls and notification details, view their PCEHR and create a consumer health summary and notes. Individuals will be able to nominate representatives and withdraw their participation at any time.

![Simplified view of key participation processes](image)

**Figure 5: Simplified view of key participation processes**

Individuals who decide not to have a PCEHR will not be disadvantaged in terms of their access to healthcare services.

3.2.1 Personal control

Central to the PCEHR System is the concept of personal control. Participating individuals can exercise control over their PCEHR in the following ways:

- **Decide whether or not to have an active PCEHR**: The PCEHR System operates on an opt-in model, where individuals elect to register and create a PCEHR. Individuals may de-activate their PCEHR at any time and subsequently re-activate their PCEHR. Registration and deactivation is discussed further in Section 3.2.2.

- **Access information in their PCEHR**: Individuals will be able to view any health information contained in their PCEHR. The content of the PCEHR is discussed further in Section 4.

- **Set controls around healthcare provider access**: Individuals may determine and change settings around access to their PCEHR by participating healthcare organisations involved in their healthcare.
Individuals may choose from a range of approaches to setting and managing these controls that will give general or limited access. Some access controls may be overridden in situations where the individual requires emergency care. Access control settings are discussed further in Section 5.5.

- **Authorise others to access their PCEHR:** Individuals may nominate other people (such as carers and family members) to access their PCEHR. Representatives are discussed further in Section 3.2.8.

- **Choose which information is published to and accessible through their PCEHR:** Individuals may request healthcare providers to withhold certain information from their PCEHR. Access controls are discussed further in Section 5.5.

- **View an activity history for their PCEHR:** The PCEHR System will provide an audit trail so that individuals can view a history of actions on their PCEHR. Audit is discussed further in Section 5.7.

- **Make enquiries and complaints:** Individuals may make enquiries and complaints in relation to the management of information in their PCEHR and the PCEHR System. Enquiries and complaints are discussed further in Section 3.2.12.

Appropriate information and support must be available to individuals to exercise proper decision-making and determine consent with regard to the controls described here. Establishment and maintenance of these controls will be available via a range of channels.

### 3.2.2 Registration

Individuals will be able to register using an online process or they can use an assisted registration process that will be supported by the Department of Human Services Medicare program and some healthcare organisations. An option to register for a PCEHR by post will also be provided for those individuals who cannot access online registration processes or assisted registration services.

The registration processes for the PCEHR System are expected to leverage existing registration and identity verification mechanisms to ensure that the right record is created for the right person. Individuals who wish to register for a PCEHR will need to have a verified Individual Healthcare Identifier (IHI) assigned by the Healthcare Identifier Service (HI Service) operated by the Department of Human Services Medicare program. Newborns and infants under 12 months may not always have a verified IHI and an alternative process will be put in place for these circumstances.

Individuals that are enrolled with Medicare or hold a Department of Veterans Affairs (DVA) treatment card have been allocated an IHI by the HI Service.

### Online registration

From July 2012, online registrations will be supported by the national consumer portal. Online registration is expected to include the following steps:

12 The individual creates a new consumer portal account or logs into an existing account (consumer portal account credentials are discussed further in Section 5.4.2).

13 The individual selects the option to ‘Register for a PCEHR’.

14 The individual reads and agrees to the terms and conditions for registering for a PCEHR.
15 The individual will be required to provide sufficient information to locate the IHI for the PCEHR they wish to create by providing:
   a. Full name
   b. Medicare card number (and Individual Reference Number (IRN)), DVA file number or IHI.
   c. Date of birth
   d. Sex

16 Once the individual has successfully located their IHI (and assuming they have not previously created a PCEHR), the individual will be required to verify their identity by selecting one of the available proof of record ownership methods and then answering additional identifying questions (see Section 6.5.1).

   If a parent is registering a minor, they will be given the option of using an online method to verify their relationship with the minor (see Section 6.5.1). If the relationship between the parent and the minor cannot be verified online, or the individual has some other form of right to act as a representative for the individual, the registration will need to be completed using assisted registration (see Section 3.2.8).

17 Once the individual has successfully validated their identity, a PCEHR is created and the individual will then be given the option to:
   - Enter their details and related information (see Section 3.2.3).
   - Permit access to their existing health information (see Section 3.2.6).
   - Establish a range of access controls and notification options (see Section 5.5).
   - Establish representatives (see Section 3.2.8).
   - Create their Consumer Entered Health Summary (see Section 4.3.9).
   - Create Consumer Entered Notes (see Section 4.3.10).

Individuals who are unable to complete this process online (for example, the individual does not yet have an IHI, Medicare has a returned mail flag set for the individual, etc.), the individual will be provided with other options for completing the process (e.g. via assisted registration).

Mail-based registration
From July 2012, mail-based registrations will be supported by the Department of Human Services Medicare program. Registration forms will be available from a range of sources, including Medicare shopfronts. Completion of registration will require:
   - Completion of an approved PCEHR registration form; and
   - A certified copy of the individual’s proof of identity in accordance with the Attorney General’s 100-point identification scheme.

Assisted registration
From July 2012, the PCEHR System will support a range of assisted registration processes by Authorised Registration Agents operating within Medicare branded service points, the Medicare call centre or via Medicare’s remote area support services. Some healthcare organisations may also offer to act as an Authorised Registration Agent.

Before providing assistance with registration, an Authorised Registration Agent will require the approval of the individual to act on their behalf. The Authorised Registration Agent will then use an Administration Portal to help the individual complete the registration process (see Section 6.3.6).
3.2.3 Participant details

As part of the registration process, the individual will be given the option of recording details about themselves. These details include:

- Contact details, including preferred contact phone number(s), mailing address and email address.
- Details about a person to contact in an emergency, including name, relationship (e.g. parent, guardian, family member, carer, support worker, case manager, other), contact phone number(s) and email address.
- Details about other contacts, including name, relationship (e.g. parent, guardian, family member, carer, support worker, case manager, other), contact phone number(s) and email address.
- Information about whether an individual requires an interpreter and whether languages other than English are spoken at home.
- Information about the custodian of any advance care directives, including name and contact details (if available).
- Preferences for the kind of notifications they would like to receive and where the notifications should be sent (see Section 5.5).

These details can be updated at any time, via the Consumer Portal. Authorised Registration Agents will also be able to help individuals update these details.

Design notes: Advance care directives allow individuals to make choices about future medical treatment in the event they are cognitively impaired or otherwise unable to make their preferences known. The consequences of acting on an individual’s preferences, as set out in an advance care directive can be significant, sometimes final. At this stage, the directive itself will not be uploaded on the basis that, if uploaded, it would raise issues of currency or contain legal implications that are outside the scope of the current work. Future work will look at including the directive itself (see Section 2.8).

3.2.4 Driving adoption by individuals

The national rollout of the PCEHR System will actively seek to register individuals who are likely to receive immediate benefit from having a PCEHR. This includes individuals who have complex and chronic conditions, older Australians, Aboriginal and Torres Strait Islander peoples, mothers and their newborn children, people with mental health conditions, people with disabilities and people living in rural or remote communities.
Registration of these individuals will involve a mix of information campaigns and assisted registration processes (where appropriate) to help support uptake.

3.2.5 Ensuring access in a range of different situations

The PCEHR System needs to be accessible in a range of situations, including situations where an individual may not have access to a computer or the Internet, may not be computer literate, may not speak English or may have an impairment or disability that may affect their ability to access the PCEHR System.

While achieving full equity of access may not be possible in a number of situations, the PCEHR System will put in place a number of options that will help facilitate access in a range of different situations. As the PCEHR System progresses, the range of options available will be enhanced.

Non-computer based access

While the use of computers and broadband is becoming increasingly pervasive across Australia, the PCEHR System will still need to support a number of avenues for individuals who either do not have access to the Internet or may not be able to use a computer. Individuals in this situation will be able to:

- Register (and withdraw) using an assisted registration process or a mail-based process.
- Access a 24-hour call centre to help them manage their PCEHR and answer general questions about the PCEHR System.
- Identify representatives to help them access and manage their PCEHR (see Section 3.2.8).

Assistance will also be provided to individuals via Medicare branded service points, call centre and remote area support services. Assisted registration agents, such as those operating within Medicare call centres and shop fronts, will not be able to view the contents of clinical documents within an individual’s PCEHR. Assisted registration agents will be limited to providing assistance with registration or managing a PCEHR.

Individuals without computers will be able to access their PCEHR via computers at a number of Medicare branded service points. Some healthcare providers may help some individuals to access their PCEHR information, by, for example, providing printed copies of relevant information to take home.

Support for languages other than English

Individuals accessing the PCEHR System will be able to make use of the Australian Government Translating and Interpreting Service (TIS) when accessing the call centre about registering for a PCEHR and managing their PCEHR.

The PCEHR System will have the ability to record whether an individual requires an interpreter and whether languages other than English are spoken at home. This information will be recorded as part of the individual’s details (see Section 3.2.3), and will be accessible to the individual’s healthcare providers.

The PCEHR System Operator will provide information packs in a range of languages other than English.

Accessibility

In line with the Disability Discrimination Act, the Consumer Portal will:

• Meet ‘Level A’ conformance with the Web Content Accessibility Guidelines (WCAG) [W3C2008a] by the end of 2012 and ‘Level AA’ by the end of 2013.

The primary goal of these guidelines is to ensure that Web content is accessible to people with disabilities.

3.2.6 Access to existing information

When a new PCEHR has been created for an individual, the individual can decide if existing information, from sources such as Medicare information, should be made accessible via their PCEHR.

The individual can allow information from one or more of the following existing sources to be included in their PCEHR:

• Information about healthcare events funded under the Medicare Benefits Schedule (MBS).
• Information about packets of medicines dispensed under the Pharmaceutical Benefits Scheme (PBS).
• Information about vaccinations given to children under the age of seven via the Australian Childhood Immunisation Register (ACIR).
• Donation decisions recorded with the Australian Organ Donor Register (AODR).

For each of the options above, individuals will be able to select if they wish pre-existing information to be available via their PCEHR or only information from the date of creation of their PCEHR. A description of the Medicare information available is given in Section 4.3.8.

Authorisation for access to information from Medicare information sources will be based on existing Medicare policies. If a child, for example, is listed on multiple Medicare cards, then an authorised representative will only be able to authorise access to information related to their own Medicare card. Medicare information related to a child on other cards cannot be released without the consent of the appropriate cardholder.

Individuals can change these settings at any time. If an individual chooses to have Medicare information included in their PCEHR and at a later time they change the setting, then their PCEHR will stop accumulating Medicare information from that point onwards and any existing Medicare information will remain in their PCEHR (unless they choose to remove it).

As more existing sources of information become available, for example conformant repositories holding an individual’s existing discharge summaries, the individual will be given the option of adding these new sources.

3.2.7 Withdrawal

Participating individuals (or their authorised representatives) may choose to withdraw at any time. If an individual withdraws, their PCEHR will be ‘de-activated’.

In a ‘de-activated’ PCEHR, any information that has been collected up to the point of being de-activated will continue to be stored, but the PCEHR will not be accessible via the PCEHR System to any healthcare providers, the individual, or their representatives. Records will only be accessible via the PCEHR System operator for maintenance, audit and other approved purposes.

Any information that a healthcare organisation has obtained from an individual’s PCEHR and added to their local records before the PCEHR has been de-activated will continue to be available to those healthcare providers through their local record.
After a cooling off period (initially proposed to be 90 days), information within a de-activated PCEHR will be archived and retained as per the retention policy described in Section 4.2.4.

If an individual chooses to re-activate their PCEHR during the cooling off period, the individual will be given the option of restoring their record to its previous state prior to de-activation or starting again with a ‘clean’ PCEHR.

After the cooling off period, a reactivated PCEHR will start ‘clean’ and access to previously collected information will not be available to the individual.

### 3.2.8 Representatives

The concept of representation is particularly relevant to health service delivery. Individuals are often supported by other people when accessing healthcare services and it is important that the provisions put in place are flexible enough to support the types of arrangements that might be needed.

For the purposes of managing an individual’s PCEHR, an individual may also be represented by an authorised representative or assisted by a nominated representative. These relationships will be recorded in an individual’s PCEHR.

**Authorised representatives**

It is important that everyone in Australia has the option of having a PCEHR. There are, however, individuals who have limited or no capacity to make decisions about their healthcare and healthcare information. These individuals may not be able to create and manage a PCEHR on their own behalf. The PCEHR System therefore allows participation through an authorised representative.

The Commonwealth, states and territories each have legislation that provides for a person to be authorised by law to represent another person for healthcare purposes, such as through powers of attorney provisions or guardianship orders. The PCEHR System will leverage this existing framework so that a person who is authorised by the law of any jurisdiction to be able to act on behalf of an individual for healthcare purposes will be recognised by the PCEHR System as an authorised representative.

The PCEHR System will need to verify the legal authority. This can either be done electronically using the Proof of Record Ownership Service (see Section 6.5.1) or by presenting the appropriate documentary evidence of their authority to an authorised registration agent.

Once the individual is registered for a PCEHR, the authorised representative will be given the same access and controls as the individual. There may be more than one authorised representative for an individual.

There is continuing investigation into whether other authorisation mechanisms can also be leveraged to enable individuals without formal authorised representatives to participate in the PCEHR System. The key consideration in this exercise is maximising access to the PCEHR System by vulnerable members of the community, without compromising proper protection of their information.

**Nominated representatives**

An individual or authorised representative may nominate other persons (such as carers and family members) to access their PCEHR.

Arrangements for nominated representatives differ from the arrangements for authorised representatives since a nominated representative is not recognised by the PCEHR System as having legal authority to act on behalf of the individual.

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5 For the purposes of this document, the definition of ‘carer’ is consistent with the *Carer Recognition Act 2010*. 
A nominated representative may view the individual’s PCEHR, but will not be able to manage the individual’s access controls, contribute to information in an individual’s PCEHR or provide consent for a healthcare provider to obtain access to the individual’s PCEHR.

It is proposed that there are no age restrictions on nominated representatives and a minor can be a nominated representative.

An individual can elect to have more than one nominated representative.

When an individual nominates a representative, they will be able to select whether the nominated representative has access to the audit trail (see Section 5.7) or ‘limited access’ information (see Section 5.5.3).

### 3.2.9 Minors

Australian law recognises that individuals aged 18 years and above have full legal capacity to make decisions about their own health and health information. Australian law recognises that children become increasingly competent as they progress toward adulthood, and the Privacy Act 1988 and other health information laws do not prescribe an age at which a child is determined to have capacity to make decisions about their healthcare and health information.

The PCEHR System would ensure that children up to 18 years can have a PCEHR through the authorised representative arrangements. It is proposed that participation arrangements will work as follows:

- **up to 14 years of age** – a parent or legal guardian will be responsible for the child’s PCEHR, including whether to register the child for a PCEHR and managing the access controls of the child’s PCEHR;

- **14 to 18 years of age** – a young person will be presumed to have capacity to make decisions in respect of their PCEHR. If the young person elects to manage their own PCEHR they can decide whether or not to participate in the PCEHR System and manage the access controls of their PCEHR, including choosing whether to allow their parent or legal guardian access. If a young person chooses not to manage their own PCEHR, the parent or legal guardian would continue to manage the young person’s PCEHR as an authorised representative;

- **18 years and over** – an individual takes responsibility for their own PCEHR. The PCEHR System will no longer allow a parent or legal guardian to access the individual’s PCEHR unless the individual grants access to the parent or guardian as a nominated representative. Alternatively, if the individual has limited or no capacity, the arrangements for authorised representatives will apply and the representative will need to provide evidence of their legal authority for verification by an authorised registration agent.

Requests by minors under 14 years of age to manage their own PCEHR will be considered on a case-by-case basis by an Authorised Registration Agent. For example, exceptional circumstances may exist where a minor younger than 14 years is deemed under existing arrangements to be a ‘mature minor’ or ‘independent minor’. In these circumstances the PCEHR System would allow for that child to manage their own PCEHR.

When registering a minor or registering a new authorised representative for a minor, the PCEHR System would need to verify the legal authority. The PCEHR System relies on the proof of record ownership service for online registrations (see section 6.5.1). It may not be possible to assert this relationship electronically and in such cases a person would need to present the appropriate documentary evidence of their authority to an Authorised Registration Agent.
3.2.10 Pseudonyms

Some individuals choose to use a pseudonym to access healthcare services. The motivations for having a pseudonym are varied and include the fear of being traced when escaping family violence or the fear of exposure due to the public nature of their work.

The HI Service already provides for pseudonymous healthcare identifiers. An individual can obtain a pseudonymous healthcare identifier from the HI Service, which would be used by the PCEHR System along with the associated pseudonymous identity details. Pseudonymous use of the PCEHR system is subject to the provisions of the HI Service relating to pseudonymous healthcare identifiers.

A pseudonymous PCEHR would not indicate the individual's true identity.

3.2.11 Deceased individuals

On the death of an individual, once the fact of death has been established, the individual’s PCEHR will be de-activated and all access will be suspended. The deceased individual's PCEHR will be handled in accordance with retention guidelines (see Section 4.2.4). The deceased individual's PCEHR can be accessed when it is required by law or required for an approved use, via the PCEHR System Operator (not via online portals).

The PCEHR System will rely on the fact of death data sourced from Births, Deaths and Marriages.

3.2.12 Enquiries and complaints

Individuals may make enquiries and complaints in relation to the management of personal information in their PCEHR and the PCEHR System.

Enquiries and complaints are discussed further in Section 5.2.2.

3.3 Healthcare providers and organisations

Participation by healthcare organisations and their associated healthcare providers will be strongly encouraged and supported. Healthcare organisations that choose to participate will have the opportunity to:

- **Access health information more efficiently**: The PCEHR System will provide secure, quick and easy access to a Consolidated View of an individual’s key health information from participating healthcare organisations.

- **Ensure safer healthcare**: The PCEHR System will provide access to important information about an individual, such as their allergies and adverse reactions, as well as their medicines, medical history and immunisations.

- **Deliver more effective healthcare**: Easier access to information provides opportunities for improved prevention, early intervention and treatment of chronic and complex diseases, as well as improved diagnosis and treatment in emergencies.

Access to the PCEHR System requires participation by the healthcare organisation. If an organisation chooses to participate and they register, they will be able to select which of their healthcare providers and other local users require access to the PCEHR System. At that point, authorised users will be able to obtain permission to access an individual’s PCEHR (based on the

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Note that suspension is not immediate. The retention requirements will provide a cooling off period before a PCEHR can be closed to allow for any remaining clinical documents to be added.
individual’s access controls, view and search a PCEHR and post new clinical documents into an individual’s PCEHR. Organisations that no longer meet the participation criteria will not be able to access the PCEHR System.

Figure 6: Simplified view of key participation processes

3.3.1 Registration

If a healthcare organisation chooses to participate, they would need to register with the PCEHR System Operator. Registration requires:

- Having a HPI-O.
- Conforming to the specific technical requirements (see below).
- Compliance with any prescribed terms and conditions.

From a technical perspective, the healthcare organisation will have a range of options:

- **Clinical Systems:** Participating organisations that prefer to use local clinical systems to access the PCEHR System must have:
  - A NASH conformant Digital Credential which asserts their HPI-O.
  - Software and services which have passed the conformance assessment process (see Section 7.4.1).

- **Contracted Service Provider:** Participating organisations that prefer to use a Contracted Service Provider (see Section 3.4.1) to access the PCEHR System must:
  - Establish an agreement for supply of conformant services with their Contracted Service Provider.
  - Notify the HI Service Operator of the Contracted Service Provider’s authorisation to operate on their behalf.

- **Provider Portal:** Participating organisations may also access the PCEHR System via a Provider Portal (see Section 6.3.2). The organisation must ensure that local healthcare providers who need access to the Provider Portal have an HPI-I/HPI-O link recorded in the HI Provider Directory Service.

3.3.2 Withdrawal

Participating organisations that no longer meet the participation criteria will be required to notify the PCEHR System Operator they are no longer able to participate.

Healthcare organisations that no longer meet the participation requirements are not permitted to access the PCEHR System. They are permitted to retain any information they may have previously printed or downloaded. Any downloaded information will be subject to existing privacy and health information obligations applicable to the healthcare provider.
### 3.3.3 Changes to organisational arrangements

In cases where one organisation is acquired by or merges with another organisation, ongoing access to the PCEHR System is dependent on the status of the merged organisation's HPI-O.7

If a merged organisation retains their existing HPI-O as part of the merger process, the merged organisation will retain access as per their existing arrangements.

If a merged organisation retires their HPI-O and creates a new one, then the access will be based on the participation status of the new HPI-O and it may be necessary to re-register and re-obtain authorisation to access an individual’s PCEHR.

### 3.3.4 Authorised users

The PCEHR System entrusts a participating organisation to grant access to healthcare providers and other local users who need to access the PCEHR System. These users are referred to as ‘authorised users’. An authorised user may be any employee8 who has a legitimate need to access the PCEHR System as part of their role in healthcare delivery. When authorised users access the PCEHR System, they are only permitted to access the PCEHR of individuals they are involved in delivering healthcare services to. All access to the PCEHR System is audited.

The PCEHR System will only accept clinical documents from healthcare organisations where the author has a HPI-I. Other authorised users without a HPI-I cannot be listed as the author of a clinical document submitted to the PCEHR System from a healthcare organisation.

The PCEHR System entrusts the participating organisation to verify the identity of authorised users prior to allowing them access the PCEHR System. The participating organisation may undertake a separate check or leverage existing verification of identity procedures (such as processes used by the organisation’s Human Resources department).

Guidelines for authentication of users within clinical systems, the provider portal and contracted service providers are discussed further in Section 5.4.1.

### 3.4 User systems

The PCEHR System infrastructure puts in place the necessary technical services to allow both healthcare provider systems and consumer-oriented systems to leverage the data within the PCEHR System. This means that, over time, users will have a choice of systems to access the PCEHR System. The PCEHR System also provides a Consumer Portal and a Provider Portal. The Provider Portal is an alternative access channel for healthcare providers where suitable clinical systems are not available.

It is also expected that these third-party systems will be able to add value to the base features of the PCEHR System. For example, healthcare provider systems can leverage information from the PCEHR System to enhance clinical decision support algorithms; a consumer-oriented portal might access the information from the PCEHR System to help diabetics self manage their care; or a service provider might offer a mobile device application.

The criteria for how different kinds of systems will be permitted to access the PCEHR System is outlined below.

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7 Rules around handing of HPI-Os in this case are provided by the HI Service.

8 As per the Healthcare Identifiers Act 2010, an ‘employee’ is either an individual who provides services for the entity under a contract for services or an individual whose services are made available to the entity (including services made available free of charge).
3.4.1 Clinical systems

In time the PCEHR System will be accessible from a range of clinical systems including GP systems, pharmacy systems, hospital systems, aged care systems, specialist systems, etc.

In order to connect to the PCEHR System, a clinical system must fulfil the following requirements:

- Implementation of the functionality, relevant standards and specifications and other requirements for clinical systems outlined in Section 6.2.2.
- Successful completion of the conformance assessment process and obtaining a Notice of Connection from the PCEHR System Operator (see Section 7.4.1).

**eHealth Site Notes:** A number of wave 1 and wave 2 eHealth sites will be working with suppliers of existing clinical systems to enhance their products to put in place the necessary building blocks to enable future conformance with the PCEHR System.

3.4.2 Contracted Service Providers

Some healthcare organisations may choose to use a third party service provider to deliver health software as a service (SaaS) and facilitate access to the PCEHR System on their behalf. These service providers are referred to as Contracted Service Providers. An example of a Contracted Service Provider might include a vendor that offers web based general practice or aged care software via a SaaS model.

In order to connect to the PCEHR System, the Contracted Service Providers must fulfil the following requirements:

- Compliance with any prescribed terms and conditions.
- Implementation of the functionality, relevant standards and specifications and other requirements for contracted service providers outlined in Section 6.2.3.
- Register with the HI Service Operator to:
  - Obtain a Contracted Service Provider Identifier (known as a CSP Identifier).
  - Register the Contracted Service Provider’s Responsible Officer and Organisation Maintenance Officer.
  - Request the NASH service operator to issue a NASH conformant digital credential which asserts their CSP Identifier.
  - Record the Contracted Service Provider’s authority to act on behalf of a healthcare organisation.
- Successful completion of the conformance assessment process and obtaining a Notice of Connection from the PCEHR System Operator (see Section 7.4.1).
- Contracted Service Providers which access the PCEHR System will be required to ensure that servers used for PCEHR System purposes and all personal information used for PCEHR System purposes must be held only within Australia.
- The Contracted Service Provider must be operated by an Australian legal entity and the entity must not operate a Contracted Service Provider unless it is subject to the Privacy Act or equivalent state or territory privacy protections.

Information stored within a Contracted Service Provider is treated as a separate record from the PCEHR System, and the Contracted Service Provider
will access and load information into the PCEHR System as per other systems. If a Contracted Service Provider wishes to host information on behalf of the PCEHR System, rather than simply access and load information, then it will be required to support the additional requirements of a conformant repository provider (see Section 3.4.4).

### 3.4.3 Conformant Portal Providers

The PCEHR System supports the capability for independent consumer-oriented portal services to access the PCEHR System. These portals will be used to offer value added features on top of the PCEHR System, such as self-managed care features, access to health literacy information, consumer-oriented decision support, etc.

In order to connect to the PCEHR System, Conformant Portal Providers must fulfil the following requirements:

- Compliance with any prescribed terms and conditions.
- Implementation of the functionality, relevant standards and specifications and other requirements for Conformant Portal Providers outlined in Section 6.2.1.
- Register with the PCEHR System Operator and obtain a Conformant Portal Provider Identifier (known as a CPP Identifier). Registration requires registration of the Conformant Portal Provider’s Responsible Officer and Organisation Maintenance Officer and agreement to the terms, conditions and service levels of a Conformant Portal Provider.
- A NASH Conformant Digital Credential, which asserts their CPP Identifier.
- Conformant Portal Providers which access the PCEHR System will be required to ensure that servers used for PCEHR System purposes and all personal information used for PCEHR System purposes must be held only within Australia.
- The Conformant Portal Provider must be operated by an Australian legal entity and the entity must not operate a conformant portal unless it is subject to the Privacy Act or equivalent state or territory privacy protections.
- Successful completion of the conformance assessment process and obtaining a Notice of Connection from the PCEHR System Operator (see Section 7.4.1).

Information stored within a Conformant Portal Provider is treated as a separate record from the PCEHR System, and the Conformant Portal Provider will access and load information into the PCEHR System as per other systems. For example, if the portal is used to help individuals self-manage their diabetes, then any information will only be held within the Conformant Portal Provider and not shared with the PCEHR System, unless loaded into it.

If a Conformant Portal Provider wishes to host information on behalf of the PCEHR System, rather than simply access and load information, then it will be required to support the additional requirements of a conformant repository provider (see Section 3.4.4).

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9 Services which offer provider-oriented portals are treated as a Contracted Service Provider (see Section 3.4.1).
**eHealth Site Notes:** The Medibank Private eHealth site and the Mater Misericordiae eHealth site will inform the development and implementation of consumer-oriented portals.

The Medibank Private Portal will allow individuals enrolled in the Medibank Private chronic disease management program to collect and share information with their healthcare providers. Medibank Private will not be using any of this information for the management of claims or eligibility for healthcare insurance benefits.

This work will also be required to collaborate with healthdirect Australia to ensure equity of access synergies are explored for the broader Australian community.

### 3.4.4 Conformant Repository Providers

The PCEHR System supports the capability to connect to additional conformant repositories. In order to connect to the PCEHR System, Conformant Repository Providers must fulfil the following requirements:

- Compliance with any prescribed terms and conditions.
- Implementation of the functionality, relevant standards and specifications and other requirements for Conformant Repository Providers outlined in section 6.6.2.
- Register with the PCEHR System Operator and obtain a Conformant Repository Provider Identifier (known as a CRP Identifier). Registration requires registration of the CRP’s Responsible Office and Organisation Maintenance Office and agreement to the terms, conditions and service levels of a Conformant Repository Provider.
- Conformant repositories will be required to ensure that servers used for PCEHR System purposes and all personal information used for PCEHR System purposes must be held only within Australia.
- The conformant repository must be operated by an Australian legal entity and the entity must not operate a conformant repository unless it is subject to privacy obligations under Australian law or equivalent state or territory privacy protections.
- A NASH conformant digital credential, which asserts their CRP Identifier.
- Successful completion of the conformance assessment process and obtaining a Notice of Connection from the PCEHR System Operator (see Section 7.4.1).

**eHealth Site Notes:** A number of wave 1 and wave 2 sites are planning to establish conformant repositories.
4 Managing PCEHR information

4.1 Introduction

The PCEHR System will collect information from a wide range of sources within a number of conformant repositories and be able to present that information in a range of ways to meet the needs of individuals, healthcare providers and other parties.

This section discusses the underlying information model of the PCEHR System (including record management issues such as data quality and retention). It also discusses the various information sources and ways of accessing that information via views, searching and reports.

![Diagram of PCEHR System](image)

**Figure 7: Managing PCEHR information**

4.2 Information model

The PCEHR System enables the collection of information from participating organisations, individuals and the Department of Human Services Medicare program within a series of conformant repositories. Information will be collected in the form of a clinical document.

For the purposes of the PCEHR System, a clinical document is an electronic document that contains personal health information about an individual. Examples include a Shared Health Summary, Event Summary, Discharge Summary, Pathology Result Report, Consumer Entered Health Summary, Medicare Information, etc.

Clinical documents will be extracted from source systems (see steps 1–2 in Figure 8) and loaded into one of the conformant repositories in the PCEHR System. While the specifics of the load process will vary, the intent is that clinical documents will be obtained by leveraging existing processes around discharge, referral, pathology, maintenance of practice-based health summaries, etc.
When a clinical document is loaded into a conformant repository, it will be validated against a common set of templates and the repository will inform the index that new information is available (see steps 3–4 in Figure 8).

When another user is ready to find clinical documents within an individual’s PCEHR, they will be able to use their local clinical system (or portal), to obtain authorisation to access an individual’s PCEHR, search the index and obtain a copy of the relevant documents from the pertinent repositories (see steps A–D in Figure 8). Once a clinical document has been reviewed, the local clinical system may give the healthcare provider the option of moderating information to store into their local electronic health record (see steps D–F in Figure 8)\(^\text{10}\).

The process described above is dependent on a minimum level of consistency between clinical documents. In order to ensure consistency, each clinical document will use a common set of ‘templates’, which describe the minimum data set for clinical documents and ensures consistency around information structure, clinical terminology and healthcare identifiers. In addition to common templates for clinical document, the PCEHR System will also be underpinned by common specifications and infrastructure for secure messaging and digital credentials.

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\(^\text{10}\) Note that the PCEHR System permits download of single documents and does not permit a user to download an individual’s entire PCEHR as a single request. All access to the PCEHR System is also audited.
This consistency ensures that when clinical documents are stored within
conformant repositories (see steps 3–4 in Figure 8), they can be validated and
safely indexed. Similarly, when a user needs to find a clinical document (see
steps A–E in Figure 8), they can be found, retrieved and imported into local
clinical systems (if required).

**Clinical Document Types and Templates**

Initially, the PCEHR System will support the collection of a range of clinical
document types, including:

- Shared Health Summaries (see Section 4.3.1).
- Event Summaries (see Section 4.3.2).
- Discharge Summaries (see Section 4.3.3).
- Specialist Letters (see Section 4.3.4).
- Referrals (see Section 4.3.5).
- Prescribing and Dispensing information (see Section 4.3.6).
- Pathology Result Reports (see Section 4.3.7).
- Medicare information (including Medicare claims history, PBS data, Organ
  Donor and the Australian Childhood Immunisation Register) (see Section
  4.3.8).
- Consumer Entered Health Summary (see Section 4.3.9).
- Consumer Notes (see Section 4.3.10).

The PCEHR System will support a range of additional clinical document types
(see Section 2.8). Also note that while the PCEHR System supports a diverse
set of clinical document types, the availability of the clinical documents from
the conformant repositories will depend on the readiness of healthcare
provider organisations to participate in the PCEHR Program.

All clinical document stored within the conformant repositories are based on a
common set of ‘templates’, which specify the minimum set of data each
clinical document is required to support.

In order to support indexing of clinical documents and to provide sufficient
information about the subject of care and the clinical document’s provenance,
the templates will ensure that all clinical documents contain the following base
metadata:

- Document control information, including: unique document identifier,
  version number, unique identifier of any previous version, document type
  information (e.g. Discharge Summary, Event Summary, etc.), document
  template (see Section 6.5.1), and date/time the document was reviewed
  (or created) by the supplier.
- Details about the individual, including: name, IHI, date of birth and sex.
- The document source, including: name of the author, HPI-I, healthcare
  provider speciality / sub-speciality\(^\text{11}\), organisation name, HPI-O,
  organisation address and communication details.

In order to support integration of source systems that are not yet ready to
supply full structured / atomised data, the templates will be specified at three
levels based on the amount of structure beyond the base set of metadata
required. These levels are:

- **Level 1 Clinical Document**: The clinical document has the base metadata
  listed above, but the body of the clinical document is provided as text
  with the option of an attached PDF.

\(^{11}\) Information around specialties / sub-specialties to be provided in accordance with HI Service Provider
classifications.
• **Level 2 Clinical Document:** The clinical document has the base metadata listed above and can provide all required fields described in the template in a structured form. Any coded data, such as a diagnosis or a medicine, that is not able to be provided using a community agreed terminology may be provided using text and optionally accompanied by coded data in a form the system is able to provide.

Any field marked as ‘required’ within a template must be filled in for the clinical document to be valid. If the author does not have information to put into a ‘required’ field, then they will be required to supply a reason why the field is not completed.

• **Level 3 Clinical Document:** Level 3 builds on level 2, with the exception that any coded data is supplied using a community agreed terminology relevant to the type of clinical document (e.g. Australian Medicines Terminology (AMT) and SNOMED CT-AU).

The design trade off accepted here is that in order to increase the breadth of content available in the PCEHR System, some views and reports may not be complete in the interim. In time, level 1 and potentially level 2 clinical document templates may be phased out as part of the change and adoption strategy and data quality strategy.

In order to ensure consistency of data structures between templates, the templates will use a common library of detailed clinical models (DCMs) to ensure consistency of information structures and clinical terminologies between different clinical document types [NEHT2010a]. This consistency is the basis for supporting a number of views and reports that extract data from different clinical documents.

### 4.2.1 Data quality

Ensuring a high standard of data quality is an essential requirement for the PCEHR System. High levels of data quality are required to assist healthcare providers and individuals in making safe healthcare decisions. Data quality within the PCEHR System will be ensured through a combination of validation of data loaded into the system, working with operators or source systems to improve the quality of data they are able to provide and by ongoing monitoring of data quality.

**Validation**

One tactic employed by the PCEHR System to ensure data quality meets a minimum standard is to validate clinical documents loaded into the system. Validation includes:

- Ensuring that the structure and content of clinical document matches the template describing its content structure and data types (see Section 6.5.1 for the template service).
- Ensuring the integrity of any included identifier for individuals, healthcare providers or organisation.

Clinical documents that fail validation will be rejected by the PCEHR System and the source system will need to supply a corrected version.

**Quality of data within source systems**

The PCEHR System relies on data extracted from a range of source systems, which means the quality of the data in the PCEHR System is dependent on the quality of the data in the source system.

To help ensure that source systems are capable of providing data to a minimum standard, any systems that connect to the PCEHR System will be required to undergo conformance assessment prior to obtaining a PCEHR System Notice of Connection (see Section 7.4).
To help healthcare organisations meet a set of minimum standards around data quality within their source systems, the Change and Adoption Program will include an element devoted to enhancing the quality of data within source systems (see Section 8.4.2).

**Monitoring data quality**

Achieving a high standard of data quality will be challenging, as it will require continuous measurement and targeted improvements in culture, policies, processes and technology. To help support this change over time, the PCEHR System will implement a quality management framework and system that addresses the fundamentals of data quality, including:

- Stakeholder-driven identification of key metrics and their associated collection protocols on quality dimensions such as accuracy, completeness, consistency, currency, timeliness, fitness for use, provenance and compliance.
- The identification of minimum levels to be achieved within a specified timeframe.
- Preventative and corrective actions to be taken to improve data quality (including technical solutions such as enhancing data entry screens or fixing back-end system issues and non-technical solutions such as training).
- The creation of a series of data quality reports (e.g. via a ‘data quality dashboard’) to help profile and track different metrics in relation to their targets.
- The introduction of an issue tracking system to track known issues and progress of corrective actions.

The quality management system will be embedded within a broader governance model (see Section 7.2) and will also be embedded within a Service Level Agreement and subject to performance management.

Achieving high standards of data quality is a not a single step process. It will be a process that runs over the entire life of the PCEHR System and will require continuous improvement.

### 4.2.2 Managing changes to clinical documents and correcting errors

Consistent with healthcare record management practices, clinical documents within a PCEHR will not be edited or deleted. Any changes will require a new version of the clinical document to be issued. If a document needs to be removed, it will not be deleted. It will be locked to prevent further access.

The PCEHR System treats the originating source system as the ‘source of truth’ and holder of the primary copy of the information. Any information held within a conformant repository is treated as a copy of information extracted from the source system. If a clinical document needs to be updated or amended, the source system must first be updated and a new version of the clinical document must be loaded into the relevant conformant repository.

The National Repositories Service and conformant repositories will be required to retain a history of previous versions of clinical documents for audit purposes.

Individuals and healthcare providers will be able to find clinical documents that have been recently amended using the index view (see Section 4.4.1). Access to previous versions of clinical documents is discussed below.
Requesting an error to be corrected within Clinical Documents

In the event that a clinical document contains incorrect information, the PCEHR System will support a number of processes to ensure that the information is corrected.

As mentioned above, if the information is incorrect, then the correction should be initiated within the source system and a new version of the clinical document should be issued to the PCEHR System.

The correction process is typically initiated by the healthcare organisation that supplied the document. Individuals or providers who wish to have a clinical document corrected should contact the healthcare organisation concerned to have the information corrected.

The PCEHR System Operator will help individuals with this process if they prefer not to approach the healthcare organisation directly.

Effective removal of clinical documents

In the event that a clinical document has been loaded into a PCEHR and it should not be there, the PCEHR System will support a process around the 'effective removal' of clinical documents. Such events may occur if:

- **Identification error:** the healthcare organisation has inadvertently misidentified the individual in the clinical document.
- **Clinical information error:** the healthcare organisation has supplied incorrect information and the clinical document needs to be removed.
- **Individual initiated removal:** the individual did not wish the clinical document to be included in their PCEHR.

This process may be initiated by the individual or the healthcare organisation supplying the clinical document via the call centre or consumer portal.

If the clinical document has been loaded incorrectly into the wrong PCEHR or contains a clinical information error, the PCEHR System Operator will first effectively remove the clinical document from the PCEHR and work with the healthcare organisation supplying the clinical document to ensure that the correct information is loaded into the correct PCEHR. The healthcare organisation will take the responsibility to ensure any errors within their source systems are corrected.

If the individual requests a clinical document be 'effectively removed' from their PCEHR, the individual will be required to indicate that they understand the implications of its removal (namely that the clinical document will no longer be accessible via their PCEHR and this may mean that in the future the individual may not receive the benefits of having this information available via their PCEHR in future episodes of care).

A clinical document that has been 'effectively removed' from an individual's PCEHR is not deleted. An effectively removed clinical document is no longer considered part of an individual’s PCEHR and is locked and a reason for removal is noted, preventing further access by an individual or their healthcare providers (including using emergency access). An effectively removed clinical document is only accessible to the PCEHR System Operator and may only be accessed for legal reasons.

If an individual elects to effectively remove a clinical document and later wishes for the clinical document to be restored within their PCEHR, they will need to contact the PCEHR System Operator.

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12 While a clinical document may be effectively removed from an individual’s PCEHR, it may still be available from other sources.
Access to prior versions of clinical documents

The PCEHR System Operator and Conformant repository operators will retain prior versions of clinical documents based on applicable retention policies (see section 4.2.4).

The PCEHR System will always ensure that individuals and healthcare providers are presented with the most recent version of a clinical document. If a prior version is available, individuals and healthcare providers will be given the option to access prior versions of clinical documents if they require. Any prior versions will be clearly marked as being a prior version.

4.2.3 Downloading and printing clinical documents and views

The PCEHR System permits users to download and/or print any clinical documents and views they are authorised to access. Downloaded information can be supplied either in PDF format or a standards conformant electronic format, where available, for loading into the organisation’s local electronic health record.

Users should only download and/or print information required to support the delivery of the individual’s care or to ensure that medico-legal integrity requirements are addressed. Once information has been downloaded and/or printed it becomes subject to the organisation’s local health information management policies and laws applicable to the organisation.

All downloaded and printed clinical documents and views need to be clearly marked with the date and time of download/printing.

4.2.4 Retention of records

The retention of information within the PCEHR System is dependent on the party holding the information. The following section highlights the proposed retention policies.

Information held by the PCEHR System Operator

Information held by the PCEHR System Operator, including information within the national repositories services, index service, audit trails, prior versions of clinical documents, etc., will be held according to the following retention policies:

• Active PCEHRs: While an individual continues to participate, their PCEHR will act as a lifelong record (from the time of its creation) and the PCEHR System operator will retain all clinical documents held within the national repositories service.

• Deactivated PCEHRs: If the PCEHR is deactivated, either via the individual withdrawing, Fact of Death being received, or the individual’s recorded age exceeding 130 years, the PCEHR System operator may archive any clinical documents held in the national repositories service after a ‘cooling off’ period (initially defined as 90 days).

• Archived PCEHRs: Any clinical documents archived by the PCEHR System Operator will be held for a minimum period as defined by PCEHR legislation (currently suggested as being a minimum of 15 years since last action on the record or until a minor turns 30, whichever period is longer). Clinical documents will not be retrieved from the archive unless disclosure is required under law.

• Other classes of information: Any other information held by the PCEHR System Operator, such as audit trail entries, system logs, prior versions of clinical documents etc., will be held for a period defined as part the PCEHR System Operator retention polices and meet all legal requirements.
4.3 Information sources

4.3.1 Shared Health Summaries

One of the key clinical documents shared via the PCEHR System is an individual’s Shared Health Summary.

A Shared Health Summary is a clinical document sourced from the individual’s nominated provider (see description below), which provides a clinically reviewed summary of an individual’s healthcare status and provides information about an individual’s allergies and adverse reactions, medicines, medical history and immunisations.

As the Shared Health Summary is a ‘point in time’ clinical document, it is complemented by the ‘Consolidated View’ (see Section 4.4.2). The consolidated view presents the shared health summary, together with information from other clinical documents received since it was created.

The Shared Health Summary must be supplied as a level 2 clinical document (level 1 clinical documents are not permitted). To enable easy extraction of Shared Health Summaries from GP systems, the fields within a Shared Health Summary will be congruent with the Royal Australian College of General Practitioners (RACGP) standards for health summaries [RACGP2010].

In addition to the common fields, a Shared Health Summary includes:

- Allergies and adverse reactions (required)\(^\text{13}\)
- Medicines (required)
- Medical history (required)
- Immunisations (required)

Nominated Provider

The author of a Shared health Summary is referred to as the individual’s ‘nominated provider’.

\(^{13}\) Note that ‘required’ in this case and later cases mean that a value must be supplied. If a value cannot be supplied, then a reason for why it cannot be supplied must be provided. For example, if the individual has no known allergies or adverse reactions, then ‘None Known’ can be used.
A nominated provider is an identified healthcare provider involved in the ongoing care of the individual who has agreed with the individual to create and manage their Shared Health Summary.

In addition to the meeting general participation criteria for the PCEHR (see section 3.3), in order to submit a Shared Health Summary, the nominated provider is required to assert that they:

- Are delivering continuing, coordinated and comprehensive care to the individual.
- Are a qualified medical practitioner, registered nurse or Aboriginal Healthcare Worker or other professional group permitted under the forthcoming PCEHR legislation.
- Have assessed and described all aspects of the Shared Health Summary and taken reasonable steps to verify the accuracy of information. In undertaking that assessment, the nominated provider will take into account other relevant information on the individual’s PCEHR.
- Have reviewed the Shared Health Summary with the individual and both parties agree that the provider can act as the individual’s nominated provider.

It is expected that for the majority of Australians, the nominated provider will be the individual’s regular General Practitioner (GP).

Where a GP who meets the above criteria is not available, another class of provider who meets the criteria may be engaged as nominated provider.

Nominated providers are not expected to update a Shared Health Summary outside of a consultation with an individual.

Individuals will have the option of being notified when a new Shared Health Summary has been posted to their PCEHR (see Section 5.5.2)

A regulatory approach will apply to the management of the above criteria, including specification of eligible healthcare providers. It is anticipated audit and other investigations will take place as quality control measures for Shared Health Summaries.

The Department will continue to work with AHPRA and NEHTA to enhance the classification of healthcare professions and to investigate if system mechanisms may be developed over time to assist with enforcement of these criteria.

**Design Note:** A number of models have been proposed around health summaries including models based purely on automatically created views, models based on a nominated provider and a ‘wiki’ style health summary that can be collaboratively edited by multiple healthcare providers.

No one model is perfect and each model has its own advantages and disadvantages in terms of its accuracy, completeness, consistency, currency, provenance, ease of implementation and ability to deal with different individual circumstances.

A hybrid model, which relies on a Shared Health Summary created by a nominated provider complemented by the Consolidated View, is the model currently being pursued, based on consultation feedback.

**eHealth Site Notes:** All wave 1 sites and a number of wave 2 sites will be informing the creation and management of shared health summaries.
4.3.2 Event Summaries

An Event Summary is used to capture key health information about significant healthcare events that are relevant to the ongoing care of an individual.

Any participating healthcare provider can submit Event Summaries to the PCEHR System. For example, a dentist, an emergency department, afterhours GP clinic, an outpatient clinic, a community pharmacy or an allied health clinic could use it.

An event summary is intended to be the ‘default’ clinical document type and is used when none of the other types of clinical document are appropriate. For example, an afterhours GP clinic may use it to provide information that is important to the ongoing care of the individual. Similarly, it can be used in cases where clinical document types have yet to be developed. For example, an allied health provider may choose to use an event summary in advance of an allied health clinical document types being developed.

An Event Summary may be provided as a level 2 or 3 clinical document. In addition to the common fields, a structured Event Summary contains additional fields including:

- Event details (including date of event (required) and a reason for visit (optional))
- Allergies and alerts (optional)
- Medicines (optional)
- Diagnosis (optional)
- Interventions (optional)
- Diagnostic investigations (optional)
- Observations (optional)

4.3.3 Discharge Summaries

The PCEHR System will support collection of Discharge Summaries. When a healthcare provider creates a Discharge Summary, it will be sent directly to the intended recipient, as per current practices, and a copy of the Discharge Summary may also be sent to the PCEHR System.

A Discharge Summary may be provided as a level 1, 2 or 3 clinical document. Structured Discharge Summaries must conform to the forthcoming Standards Australia specifications based on the NEHTA specifications [NEHTA2010e].

In addition to the common fields, a Discharge Summary may contain:

- Nominated primary healthcare providers (optional)
- Document recipients (required)
- Encounter details (required)
- Problems/diagnoses (including principal, complications and comorbidities) (required)
- Clinical synopsis (required)
- Diagnostic investigations (optional)
- Clinical interventions (optional)
- Current medications on discharge (required)

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14 Note that the NEHTA discharge summary specification predates the PCEHR System Concept of Operations. The nominated primary healthcare provider is a term identified in that document as the intended recipient of the discharge summary. This term should not be confused with the Shared Health Summary Nominated Provider.
• Ceased medications (required)
• Allergies and adverse reactions (required)
• Alerts (optional)
• Arranged services (optional)
• Recommendations (required)
• Information provided to patient and/or relevant parties (optional)
• Attachments (optional)

**Scope Notes:** Note that NEHTA Discharge Summary specifications are currently limited to the context of discharging an individual from an acute setting hospital and may not cover the specific requirements for some specific settings. Other forms of Discharge Summary will be supported via level 1 clinical documents in the first release.

**eHealth Site Notes:** All wave 1 sites and a number of wave 2 sites will be informing the creation and management of discharge summaries.

### 4.3.4 Specialist Letters

The PCEHR System will support the collection of Specialist Letters. When a specialist creates a Specialist Letter, it will be sent directly to the intended recipient, as per current practices, and a copy of the Specialist Letter may also be sent to the PCEHR System.

The PCEHR System will accept a Specialist Letter as either level 1, 2 or 3 clinical document.

In addition to the common fields, a structured Specialist Letter may contain:

• Specialist (required)
• Referring GP (required)
• Usual GP\(^{15}\) (required)
• Document recipients (required)
• Response details (required)
• Recommendations (required)
• Medicines list (required)
• Diagnostic investigations (optional)
• Attachments (optional)

**eHealth Site Notes:** All wave 1 sites and a number of wave 2 sites will be informing the creation and management of specialist letters.

### 4.3.5 Referrals

The PCEHR System will support collection of Referrals. When a healthcare provider creates a Referral, it will be sent directly to the intended recipient, as

\(^{15}\) Note that the NEHTA referral and specialist letter specification predates the PCEHR System Concept of Operations. The ‘usual GP’ referred to in those specifications should not be confused with the Shared Health Summary Nominated provider.
per current practices, and a copy of the Referral may also be sent to the PCEHR System.

The PCEHR System will accept Referrals as either level 1, 2 or 3 clinical document.

Structured Referrals will be conformant with the forthcoming Australian Standards, which are based on the NEHTA Referral specifications [NEHTA2010f].

In addition to the common fields, a Referral may contain:

- Benefits card details (optional)
- Patient’s nominated contact (optional)
- Referrer (required)
- Usual GP (optional)
- Referee (required)
- Referral details (required)
- Current and past medical history (required)
- Current medications (required)
- Allergies/adverse reactions (required)
- Diagnostic investigations (optional)
- Attachments (optional)

**Scope Notes:** Note that current NEHTA referral specifications only support GP to Specialist Referrals. Other forms of Referral will be supported via level 1 clinical documents in the first release.

### 4.3.6 Prescribing and Dispensing information

The PCEHR System will enable the collection of Prescribing and Dispensing information.

Participating prescribers and dispensers who have access to the PCEHR System will be able to upload a copy of Prescription and Dispensing information to the PCEHR System. This information is a copy of information that is also sent to the Prescription Exchange Service (PES).

Prescriptions and dispense records will be provided as a level 2 or 3 clinical document conformant with the NEHTA Electronic Transmission of Prescription Specifications [NEHTA2010f] and forthcoming Australian standards.

**eHealth Site Notes:** The FRED IT Group Medview eHealth site will be informing the development and implementation of the sharing of Prescribing and Dispensing information.

**Scope Notes:** The PCEHR System will include the capability to index a conformant repository containing Prescribing and Dispensing information from July 1 2012. NEHTA will work with the FRED IT Group Medview eHealth site to develop a transition plan.
4.3.7 Pathology Result Reports

The PCEHR System will support collection of Pathology Result Reports.

An essential requirement of the PCEHR System is to ensure that appropriate Pathology Result Reports are released to the PCEHR System after a healthcare provider has reviewed them, as per current clinical practice.

In the context of the PCEHR System, Pathology Result Reports will still be sent to the requestor and other intended recipients directly, who will review and then have the option of sending a message to the pathology provider indicating the result is to be made available to the PCEHR System. Healthcare providers who have requested a copy of the result report directly will also be able to authorise the release of the result report.

At this point the pathology provider’s system will either:

- Inform the PCEHR System that a new Pathology Result Report is available on the pathology provider’s conformant repository and should be indexed; or
- Send a copy of the Pathology Result Report to another conformant repository.

**Scope Notes:** From July 1 2012, the PCEHR System will have the capability to index pathology result reports held in conformant repositories. The most recent pathology funding agreement aims to have pathology results available from large private sector laboratories by 30 June 2013 and other providers by 30 June 2014 [DOHA2011d].

4.3.8 Medicare information

There is an opportunity to leverage the information collected by the Department of Human Services Medicare program. Whilst this information lacks the clinical richness of other information sources, such as discharge summaries, with consent, the Department of Human Services is able to provide a longitudinal source of information about an individual’s healthcare events, including:

- Information about healthcare events funded under the Medicare Benefits Schedule (MBS). This information includes:
  - Date of service
  - Provider
  - Service in hospital indicator
  - Item number
  - Brief Item description

- Information about packets of medicines dispensed under the Pharmaceutical Benefits Scheme (PBS). This information includes:
  - Date of supply
  - Date of Prescribing
  - Item Code
  - Brand
  - Brief item description
  - Quantity
  - Number of repeats
• Information about vaccinations given to children under the age of 7 via the Australian Childhood Immunisation Register (ACIR). This information includes:
  - Date vaccination received
  - Vaccine type and provider
  - Vaccine dose number
  - Natural Immunity
  - Information provider
  - Medical contraindications

• Donation decisions recorded with the Australian Organ Donor Register (AODR). This information includes:
  - Date of initial registration
  - Donor end date
  - Donor nominations
  - For each nomination that exists:
    o Donor’s consent
    o Donor’s intent
    o Donor nomination

Financial information associated within Medicare supplied information is not accessible by the PCEHR System.

### 4.3.9 Consumer-entered health summary

The PCEHR System will provide an avenue for individuals to enter summary information that they wish to share with their providers into the PCEHR via the consumer portal.

In addition to their contact details (see Section 3.2.3), an individual can also provide a consumer entered health summary, which contains:

- Allergies (including the substance/medicine/device name and the reaction they have had to it) (optional).
- Medications (including the branded name of the product (optional)).

### 4.3.10 Consumer-entered notes

The PCEHR System will provide an avenue for individuals to record notes within the PCEHR via the consumer portal. These notes are provided as a memory aid for individuals and their representatives and are not visible to healthcare providers.

The consumer-entered notes is the first step towards a strengthening involvement of individuals in their healthcare. The PCEHR System also allows for independently operated conformant portals to connect to the PCEHR System (see Section 3.4.3). It is envisaged that these portals will in time offer value added features around self-managed care. For example, this may include collecting information such as blood glucose levels and a food diary to help an individual work with their diabetes educator to manage their diabetes.
4.4 Views

In addition to providing access to individual clinical documents, the PCEHR System will provide a range of ‘views’, which assemble information from multiple clinical documents and present it in a more accessible way.

The PCEHR System will support the following views:

- Index View
- Consolidated View

These views will form the base of commonly accessible views and will be accessible to all users.

In time, a range of additional views will be added to support the specific needs of individuals and healthcare providers (see Section 2.8).

Some clinical systems accessing the PCEHR System may also provide their own custom views for presenting data accessed on the PCEHR System.

4.4.1 Index View

The Index View presents a list of information available via the Index in an individual’s PCEHR.

For each clinical document with an individual’s PCEHR, the Index View includes:

- The date of the clinical document.
- The type of clinical document (e.g. Event Summary, Discharge Summary).
- The service type\(^\text{16}\) of the HPI-O from where the clinical document was obtained (e.g. Rural General Practice, Paediatric Hospital, Community Pharmacy, etc.).
- The author name and speciality / sub-speciality\(^\text{17}\) (e.g. Dr John Smith, Endocrinologist).
- A link to the clinical document.

By default, the Index View will be sorted in reverse chronological order, with the most recent clinical documents first. The user will be able to sort the view by some of the fields (e.g. date, type, clinical setting, role of the author, name of the author, etc.).

The user will be able to filter the view by some of the fields (e.g. by date range and clinical document type / subtype). By default, the Index View will have no filters set.

Additional settings in the index view will allow the user to search for recently amended and/or changed clinical documents.

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\(\text{16}\) Service types are defined by the HI Service.

\(\text{17}\) Information around specialties / sub-specialties to be provided in accordance with HI Service Provider classifications.
4.4.2 Consolidated View

The Consolidated View is intended to provide an up-to-date picture of the individual’s health status with information drawn from their shared health summary and additional information drawn from other more recent clinical documents.

Information in the Consolidated View is grouped into categories such as Allergies and Adverse Reactions, Medicines, Medical History and Immunisations and it also provides a means of navigation into the full suite of documents available in the individual’s PCEHR.

As illustrated in Figure 9, users of the Consolidated View will be able to select a piece of information, identify where it came from and open the clinical document from which it was sourced.

The Consolidated View may be incomplete, as information may not be extracted from unstructured clinical documents, and will include a notice to this effect. The view will include a list of unstructured documents that may contain additional information since the shared health summary was last updated.

For users of the consumer portal, the consolidated view will also include a series of links to related health literacy material. Users of the consolidated view in the consumer portal will be able to follow links from allergies and adverse events, medicines, medical history and immunisations named in the consolidated view to a search on Healthinsite18. This in turn will allow individuals to access related health literacy resources and consumer medication information sheets (where available).

![Figure 9: Example Consolidated View](image)

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19 Note that this is a conceptual mock-up of what the consolidated view might look like for a clinical user and is not an actual system.
4.5 Search

In time, as the PCEHR System accumulates more clinical documents, the ability to find specific clinical documents via chronological views such as the Index View will become more challenging. In order to help users find clinical documents within a PCEHR more readily, the PCEHR System provides two search functions: basic search and advanced search.

4.5.1 Basic search

The basic search function allows users to find clinical documents within an individual’s PCEHR based on matching keywords. Users will, for example, be able to find all clinical documents that contain the term ‘kidney’ within the body of the clinical document.

The basic search is limited and will only support simple matching methods. In time, as the number of clinical documents within each PCEHR increases and demand for this function increases, more sophisticated matching techniques will be investigated.

4.5.2 Advanced search

The advanced search function allows the user to search an individual’s PCEHR for clinical documents via a number of parameters, including:

- Keywords
- Date uploaded
- Type(s) of clinical document
- Provider organisation
- Healthcare provider speciality / sub-speciality

The advanced search function is limited in its search capabilities. In time, as the number of clinical documents within each PCEHR increases and demand for this function increases, more search parameters will become available.

4.6 Reports

Actively monitoring the PCEHR System is essential to being able to effectively manage the PCEHR System from both an operational and a benefits realisation perspective.

To help meet this need, the PCEHR System includes a reporting service, which will be used to analyse information from multiple PCEHRs and additional information in the audit trails and operational logs of the system.

The purpose of this service is to support operational reporting, to help evaluate take-up rates and to track progress around key performance indicators. In time, the reporting service may be extended to support additional approved uses (see Section 5.2.3). The report service will be able to provide a range of reports, including:

- Operational reporting, such as, but not limited to:
  - Reporting against metrics in PCEHR System infrastructure Service Level Agreements and conformant repository Service Level Agreements (e.g. uptime, incident reports, incident resolution times, call centre reporting, etc.).
  - Audit reports.

---

Information around specialties / sub-specialties to be provided in accordance with the AHPRA Provider classifications.
• Data quality ‘dashboard’ (see Section 4.2.1).

• PCEHR System uptake and usage reporting, including access to pre-defined reports showing:
  - Numbers of individuals registering, using the PCEHR System and withdrawing.
  - Numbers of authorised users and healthcare organisations using the PCEHR System.
  - Viewing of clinical documents, views and reports.
  - Uploading new clinical documents.

  This data can be broken down by:
  - Demographics (age, location, gender).
  - Time (time of day, day of week, month).
  - Healthcare provider role (e.g. GP, specialist, ED doctor).
  - Kind of information accessed or uploaded (view name or clinical document types).

• Reports related to outcomes realisation related key performance indicators (see Section 9.2.1).

  Most reports will contain de-identified data. In some cases where reports may contain potentially identifiable data (e.g. audit reporting), only appropriately authorised users will be permitted to create and view the reports.

  The types of reports available are expected to evolve over time as operational reporting requirements and key performance indicators mature.
5 Privacy and security

5.1 Introduction

Privacy protection and appropriate security are critical aspects of the PCEHR System. Successful delivery of both will increase an individual’s access to, and control over, their health information, limit any opportunity for inappropriate access and ensure trust and confidence in the system.

The protection of privacy and security is being considered from the outset of the PCEHR System design. It should be recognised that there is no single solution to address privacy and security issues. The PCEHR System has significant potential to address the problems created by fragmented information in the current healthcare system and to provide individuals and their healthcare providers with better access to their healthcare information. A combination of technical, policy, governance and legislative safeguards will need to be in place to facilitate access by the right people and prevent inappropriate access and use of healthcare information.

Individuals will have significant control over their PCEHR and how it is used. Individuals can choose to have (or not have) a PCEHR, can access all information in their PCEHR, set access controls around healthcare provider access, apply greater controls to sensitive information, and choose which information is not available through their PCEHR. These and other controls provide numerous options for individuals. Many individuals who choose to have a PCEHR will probably not exercise all these options. However, when building a national system we must allow for those people with specific sensitivities to participate in a way that is respectful and responsive to their concerns.

In addition to this, the PCEHR System will record details of every access made to an individual’s PCEHR. Individuals will be able to view this information through an online audit record and make enquires and complaints about potentially inappropriate access.

Furthermore, additional safeguards will underpin the PCEHR System, including: technical security measures, training, effective and transparent governance arrangements, legal protections and penalties, and regulatory oversight.

This Concept of Operations focuses primarily on the technical control and business process layers required for a PCEHR System. The PCEHR System’s governance arrangements, regulatory framework, including complaints management and sanctions are being developed. A Legislation Issues Paper has been issued for consultation [DOHA2011b].

5.2 Privacy

The privacy concepts supported by the PCEHR System are modelled on the National Privacy Principles (NPPs) found in the Commonwealth Privacy Act 1988.

Currently, depending on where the PCEHR System is operated and used, different privacy laws could apply. The PCEHR System will be subject to appropriate privacy requirements.

The core privacy concepts to be supported by the PCEHR System are outlined Table 1.
Table 1: How core privacy concepts are supported

<table>
<thead>
<tr>
<th>Privacy concept</th>
<th>Summary of how the concept is supported</th>
</tr>
</thead>
</table>
| Collection            | The PCEHR System will only collect personal information for the purposes of providing individuals with access to their own personal health information and enabling them to make this information more readily available to their chosen healthcare providers.  
Any information collected as part of the identity verification process will be limited to the minimum information required for proof of record ownership to be effective.  
The kinds of information proposed to be collected by the PCEHR System are defined in Section 4. Proof of record ownership is discussed in Section 5.4. |
| Use and disclosure     | The personal health information within an Individual’s PCEHR is intended for use and disclosure by the individual, their representatives and their healthcare providers for the purposes of the individual’s healthcare. Whilst the PCEHR is primarily about providing healthcare to the Individual during their lifetime, if the Individual includes their Organ Donor Status in their PCEHR, this information may also be used and disclosed for the purpose of administering their organ donor preferences.  
Information contained within the PCEHR System will also be reported against for operational and management purposes, e.g. to ensure that the system is running effectively or to monitor audit trails.  
How information is used and disclosed (including reporting) by the PCEHR System is described in Section 4. Research and other permissible uses are described in Section 5.2.3. |
| Data quality          | The PCEHR System will use new and existing conformance, compliance and accreditation processes to ensure that the information it collects, uses or discloses is of sufficient quality to support safe and effective care.  
The approach to data quality is defined in Section 4.2.1. |
| Data security         | The PCEHR System will protect the personal information it holds through strong authentication of individuals and users, provision of access controls, auditing, security testing and education and training of users.  
Security is discussed further in Section 5.3. |
| Openness              | The PCEHR System Operator will implement policies on its management of personal information. Once developed, these policies will be publicly available.  
In addition to being able to access the full set of terms and conditions in an easy to read manner, any related terms and conditions will be presented in a ‘just in time’ approach at the relevant point of data entry or when a particular choice about access control is made. |
<table>
<thead>
<tr>
<th>Privacy concept</th>
<th>Summary of how the concept is supported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access and correction</td>
<td>All personal health information held within an Individual’s PCEHR will be accessible to the individual concerned via a consumer portal. If an individual believes that information within the system is incorrect they will be able to instigate corrective action. The consumer portal is discussed further in Section 6.3.1. Correction is discussed further in Section 4.2.2.</td>
</tr>
<tr>
<td>Identifiers</td>
<td>The PCEHR System will adopt the identifiers supplied by the HI Service operated by the Department of Human Services for individuals, healthcare providers and healthcare organisations. The HI Service provides reliable identifiers and is backed by strong legislation and oversight by government.</td>
</tr>
<tr>
<td>Anonymity</td>
<td>Individuals have the option of applying for a pseudonym with the HI Service in the event that they wish to use a pseudonymous identity for the purposes of healthcare.</td>
</tr>
<tr>
<td>Transborder data flows</td>
<td>All elements of the PCEHR System infrastructure and any connected conformant repositories, conformant portals and contracted service providers must operate according to the forthcoming PCEHR legislation and be subject to Australian law.</td>
</tr>
<tr>
<td>Sensitive information</td>
<td>Individuals will be able to request that certain information is not made available on the PCEHR System. Individuals will also be able to control access and limit disclosure to that information once it has been uploaded. Limiting disclosure of information is discussed further in Section 5.5.</td>
</tr>
</tbody>
</table>

Development of privacy protections will also be informed by a Privacy Impact Assessment (PIA), which will be undertaken by DOHA. The PIA will involve further stakeholder consultation on specific privacy related matters.

### 5.2.1 Legislative proposals to support the PCEHR System

If individuals, healthcare providers and healthcare organisations are to actively participate in the PCEHR System, there must be a high level of trust and confidence in its operation. A legislative framework that provides clear, transparent and flexible oversight of the operation of the system as it develops and evolves is required.

A Legislation Issues Paper has been developed which outlines the key legislative requirements for the operation of the PCEHR System and the rights and responsibilities of participants who use the system [DOHA2011b].

The proposals outlined in that paper propose that the legislative framework will:

- Establish arrangements for operating the PCEHR System.
- Establish processes for participation.
- Establish processes for enquiry and complaint.
• Recognise the risks that a PCEHR system will present.
• Recognise that there are existing regulatory frameworks in place to support the appropriate flow of health information for healthcare and other public interest purposes.
• Recognise that the PCEHR system will also be supported by other laws and through means other than legislation, for example standards and education.

The Legislation Issues Paper also highlights other applicable legislation and privacy laws. The Legislation Issues Paper proposes that the PCEHR legislative framework will generally integrate with, rather than override, existing statutory and service delivery regimes, wherever this is feasible for effective delivery of the PCEHR System. The Commonwealth will work with states and territories to identify any existing reporting or secrecy provisions that may impact on the operation of the PCEHR System.

It is proposed that sanctions would be included in PCEHR legislation covering matters related to inappropriate use of the PCEHR System by healthcare organisations, healthcare providers, portal providers, contracted service providers, repository operators and other parties. Matters related to cybercrime will also be considered.

Consultation on legislation issues closed on the 3rd of August 2011, and input from that process is being used to inform drafting of legislation.

5.2.2 Complaints handling scheme

The PCEHR System Operator will provide a range of avenues for individuals to make enquiries and complaints, including via the call centre, shop fronts and portals. To help support the receipt, tracking, management and escalation of enquiries and complaints, the PCEHR System includes a contact management service (see Section 6.4.7).

Individuals who are unhappy with the way their personal information is handled by the PCEHR System Operator, repository operator or portal operator will have the ability to make a complaint to the PCEHR System Operator. If they are not satisfied with the response, they may escalate their complaint to a range of regulators, including the Australian Information Commissioner and state or territory privacy or health service regulators (where relevant).

The Commonwealth, in collaboration with the states and territories, is developing proposals for a single entry point for PCEHR privacy complaints, which are then referred to the appropriate regulator(s). It is likely that this will be an administrative arrangement rather than a legislative one.

5.2.3 Research and other permissible uses

It is proposed that particular secondary uses and disclosures of personal information permitted under the Privacy Act will continue to be allowed in the PCEHR System.

Those secondary uses and disclosures include:
• Use or disclosure authorised or required by or under law (including public health and child welfare reporting obligations in state and territory legislation). It is proposed that the ability to subpoena information from the PCEHR System will be limited to specific circumstances.
• Use or disclosure to prevent or lessen a serious threat to an individual’s life, health or safety or a serious threat to public health or safety.
• Research in line with research uses permitted under the national privacy principles.
In the case of research, the existing design would support participants in Clinical Trials providing access to their PCEHR to researchers, if they chose to. If the clinical trial is operated by a healthcare organisation, then the PCEHR can be accessed as per current arrangements for healthcare organisations. Trials operated by other parties may require the use of the nominated representative.

In the case of wider public health research, generally using de-identified data, the PCEHR system has been designed to enable this research to be conducted as part of later releases (see Section 4.6 which covers extraction of de-identified data via the report service). Later releases would need to establish appropriate governance frameworks to enable de-identified research activity.

When the functionality and research frameworks are established, the PCEHR System would only use or disclose information for health research purposes in accordance with existing law, forthcoming PCEHR legislation, governance and any policies and procedures of the PCEHR Operator. There would be strong emphasis on:

- The use of information, which does not identify any person, where possible.
- The role of consent of any person who is identified in the data.
- Supporting research with a proper ethical basis and public benefit.

One area where the PCEHR System may possibly depart from existing secondary uses and disclosures is where state or territory legislation imposes reporting or secrecy obligations that are inconsistent with the operation of the PCEHR system. In those cases, there may be some need for legislation to address the interaction of the state and territory law, and the operation of the PCEHR System. The aim is to disturb existing state and territory obligations as little as possible.

5.3 Security

Trust is one of the many critical success factors for the PCEHR System. Therefore it is essential to ensure that:

- People seeking access to information are who they claim to be.
- Information received from a claimed person is from that person.
- Information transmitted across networks is appropriately encrypted and has arrived at its destination point without being tampered with.
- Access to information is appropriately authorised.

A multi-layered approach will safeguard the PCEHR System, and accordingly the system’s Security and Access Framework will need to incorporate both technical and non-technical controls. These include:

- Accurate authentication of users accessing the PCEHR System.
- Robust audit trails.
- Proactive monitoring of access to the PCEHR System to detect suspicious and inappropriate behaviour.
- Rigorous security testing, to be conducted both prior to and after commencement of operation of the PCEHR System.
- Education and training of users of the system.
- Requirements that all participants and organisations comply with relevant system rules, specifications and legal requirements.

The Security and Access Framework for the PCEHR System will ensure that the confidentiality, integrity and availability of information within the PCEHR System are not compromised.
Security has been designed to be ‘fit for purpose’, and to address health and information policy objectives. The objective of the PCEHR System Security and Access Framework is to:

- Minimise the risk of unauthorised access to the PCEHR System and the information it contains.
- Enable detection of unauthorised information access or modification, and any other breach of information security (including privacy).
- Facilitate appropriate response to, and investigation of, any such breaches.
- Assure the continued availability of the PCEHR System.
- Provide a means to continually improve security protections (including protection of privacy, confidentiality, integrity and availability).

The completion of a security and access framework is contingent on the assessment of a full range of personal, logical/systems and physical security threats and risks to be assessed and a layered set of solutions be implemented to address these threats and risks. The following frameworks will be used as inputs into that assessment process:

- Attorney-General, Protective Security Policy Framework (PSPF) [AG2010];
- Attorney-General, National Identity Security Strategy [AG2010];
- Department of Finance and Deregulation, National E-Authentication Framework (NEAF) [DOFD2009];
- NEHTA Security and Access Framework [NEHT2011b].

5.4 Authentication

Ensuring that people seeking access to information are who they claim to be will be an essential issue to be addressed in the PCEHR System.

5.4.1 Authorised users

Access from Clinical Systems

Once an organisation has authorised a user to access the PCEHR System, local organisational authentication mechanisms will be used to authenticate the user accessing the PCEHR System. When accessing the PCEHR System, the local system will authenticate itself to the PCEHR System using the organisation’s digital credentials and pass on user details, including name, speciality / sub speciality, HPI-I (if they have one), the HPI-O of the point of access for the purposes of audit. Generic/shared user credentials for authorised users are not permissible.

Access via a Contracted Service Provider

Once an organisation has authorised a user to access the PCEHR System via a contracted service provider, the CSP’s system will authenticate itself to the PCEHR System using the CSP’s digital credentials. The CSP will pass on user details, including name, speciality / sub speciality, HPI-I (if they have one), HPI-O of the point of access for the purposes of audit. Generic/shared user credentials for authorised users are not permissible.


22 As per HI Service Provider classifications.

23 As per HI Service Provider classifications.
Access from the Provider Portal

Healthcare providers wishing to use the provider portal to access the PCEHR System will need to be linked to the healthcare organisation within the HI Provider Directory Service (HI-PDS) and will need to use a NASH token (e.g. smart card or USB token) asserting their identity to log in.

If the healthcare provider is linked to multiple healthcare organisations, they will be required as part of the login process to select the organisation on whose behalf they are accessing the PCEHR System.

An officer of the organisation will be identified as being responsible for maintaining the links between the organisation and the healthcare provider and for removing the links when the healthcare provider leaves the organisation.

5.4.2 Individuals and representatives

Authentication to the Consumer Portal and Conformant Portals

All authentication to the consumer portal and other conformant portals shall be in accordance with the safeguards identified in the NEAF [DOFD2009].

The Consumer Portal and conformant portals will implement a range of safeguards to reduce the likelihood of threatening events occurring, enable their early detection or reduce the harm arising from them. These safeguards include:

• Informed use consent, including acknowledgement of the importance of protecting e-Authentication credentials.

• Continual reinforcement of the importance of protecting e-authentication credentials through user education, warnings or notices displayed or each online session.

• Implementing challenge-response questions for important transactions.

• Informing users of:
  - The number of recent accesses and the date of last access.
  - Access attempts using invalid passwords.
  - Important categories of transactions that require verification by means of "out of band" channels such as Post or SMS.

The NEAF makes specific reference to safeguards in relation to health and safety including:

• Limiting transactions which can be conducted through particular channels

• Requiring stronger e-Authentication for sensitive data (for example, challenge-response using knowledge-based approach or using one-time password)

The Consumer Portal will make use of username/password authentication process combined with challenge-response using shared knowledge questions and one-time passwords.

It is envisaged that conformant portal providers may select from a number of mechanisms for delivering eAuthentication, which would be compliant with NEAF and PCEHR System requirements. Some conformant Portal providers may, for example, also support supplementary Authentication methods, such as smart card based authentication.

Authentication via Call Centre

When contacting the call centre, individuals and their representatives will be required to authenticate themselves by providing sufficient identifying information to help the operator locate the individual’s PCEHR, and by answering a series of questions they have set at registration.
5.5 Authorisation and access control

Access to information within the PCEHR System will be moderated by a series of access controls managed by the individual. For each individual’s PCEHR, the PCEHR System will maintain:

- An ‘access list’.
- A series of either basic or advanced access control settings.

Each of these items are discussed below. To help individuals understand the access controls, the consumer portal will provide an online interactive tutorial. Individuals will also be able to call the call centre to seek support in understanding the access controls.

Some access controls may also be overridden in situations where the individual requires emergency care (see Section 5.5.4).

The access controls described here apply to information held within the PCEHR System. Once information has been downloaded from the PCEHR System it will be subject to local access control policies and locally applicable laws.

5.5.1 The access list

At the core of access control to an individual’s PCEHR is the ‘access list’. The access list provides a set of organisations that are permitted to access an individual’s PCEHR.

Through the exercise of access controls, the individual can control how an organisation is added (or removed) from the list.

Individuals will be able to see the access list and update it at any time via a number of channels (including the consumer portal, shop front services, etc).

In general, organisations will remain on the access list for a period of 3 years from the last time they accessed an individual’s PCEHR. After 3 years of inactivity the PCEHR System will automatically remove the organisation from the access list and the organisation will need to re-obtain access based on the individual’s access control settings.

5.5.2 Basic access controls

If an individual opts for their PCEHR to be operated using basic access controls, the PCEHR will operate on a ‘care based access’ model.

Under this model, any healthcare organisation involved in the care of the individual may, unless the individual requests otherwise, access the individual’s PCEHR. Upon gaining access, the healthcare organisation is automatically added to the access list.

Notifications

All access to the individual’s PCEHR will be audited and the individual will be given the option of setting up a range of notifications, including notifications when:

- a new organisation is added to the access list.
- A notification when a new shared health summary has been uploaded to their PCEHR.
- A notification if a nominated representative has accessed their PCEHR.

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24 The access list contains a list of healthcare organisation’s HPI-Os and by inference includes all network HPI-Os beneath the participating organisation HPI-O.
Controlling load of clinical documents

The individual has the right to ask for clinical documents to not be loaded to their PCEHR.

If the individual does not want the clinical document added to their PCEHR, the healthcare provider will not upload it.

The onus is on the individual to inform their healthcare provider that they do not want the clinical document loaded, although the healthcare provider should inform the individual if a clinical document may not be appropriate to upload to their PCEHR.

If a clinical document is loaded to their PCEHR and the individual does not wish it to be there, then they may use either the consumer portal or call centre to request the clinical document to be ‘effectively removed’ from their PCEHR. Effective removal of clinical documents is discussed further in Section 4.2.2.

5.5.3 Advanced access controls

Individuals will be given the option of creating a series of advanced access control settings. The advanced access control settings will include all basic access control settings as well as some additional access controls.

Advanced access control settings are only accessible via the consumer portal. Due to the nature of these controls individuals will need to assert they have completed the online interactive tutorial before using the settings.

Additional options available under advanced settings include:

- Setting up a Provider Access Consent Code (PACC).
- Restricting organisations from being on the access list.
- An ability to prevent a PCEHR from being found.
- Managing document level access.

Provider Access Consent Code (PACC)

If the individual chooses to set up a PACC (effectively a PIN or passphrase), then organisations will not be able to add themselves to the access list unless they have the PACC.

If the individual opts to set up a PACC, then they will also be requested to answer the following question:

- If you forget your PACC, do you wish participating organisations to be able to access your PCEHR by obtaining your consent?

If the individual responds ‘no’, then access will not be granted to the organisation without the valid PACC.

If this setting is set to ‘yes’, then participating organisations will be able to access the individual’s PCEHR without the valid PACC when the individual forgets their PACC. The reason for accessing their PCEHR without a PACC will be recorded in the audit trail. The organisation will only be granted access to ‘general access’ information (see below).

If this setting is set to ‘yes’, the individual will also be asked:

- Do you want to be notified if your PCEHR is accessed without your PACC?

If the individual opts to be notified, they will be notified via their preferred method whenever access without their PACC occurs.

Restricting organisations

Individuals will be able to mark organisations on their access list as being ‘revoked’.
If an organisation is marked as being ‘revoked’, then they will not be able to access the individual’s PCEHR, unless the individual either provides them with a PACC (see below) or they use emergency access (see section 5.5.4). The other option is for the individual to change the organisations access level via the consumer portal.

An individual does not need to set up a PACC to use this feature.

Clinical documents that have been downloaded by a revoked organisation will still remain within the organisation’s system and will be subject to local health information management policies and locally applicable laws.

**PCEHR visibility**

Individuals will be able to select if they want their PCEHR to be ‘findable’ or not. If the individual chooses the option for their PCEHR to be ‘not findable’, then when an individual arrives at a new healthcare organisation not currently on their access list, any search for their PCEHR will return ‘not found’. Similarly, if the organisation is marked as ‘revoked’ on the access list then it will not be able to find the individual’s PCEHR.

By default, a PCEHR will be findable, unless the individual changes this setting.

A PCEHR can still be found with emergency access if the individual has selected this option.

An individual does not need to set up a PACC to use this feature.

**Document level access controls**

If the individual chooses to set up a PACC, they will also be given the option of controlling access to clinical documents.

Under this option, then the individual will be able to set an access control level on each clinical document in their PCEHR and be able to describe what level of access each organisation on their access list is afforded (either ‘general access’ or ‘limited access’). The levels available include:

**Table 2: Access control options for clinical documents**

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
<th>Possible consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘general access’</td>
<td>The clinical document will be accessible by any healthcare organisation that has access to the individual’s PCEHR.</td>
<td>The clinical document will be available when needed for an individual’s care by any healthcare organisation that currently has permission to access the individual’s PCEHR.</td>
</tr>
<tr>
<td>‘limited access’</td>
<td>The clinical document will be accessible via the individual’s PCEHR to a more limited group of healthcare organisations selected by the individual (see below). The clinical document is still accessible to the healthcare organisation that supplied it and in an emergency situation (see Section 5.5.4). Shared Health</td>
<td>The individual has opted for more control over the healthcare organisations that can access these clinical documents, allowing them to decide the level of access based on the kind of care they are seeking. The individual will take the responsibility that this information may be important to ensuring that individual receives the right care. Where the healthcare provider does not know this information, it</td>
</tr>
<tr>
<td>Option</td>
<td>Description</td>
<td>Possible consequences</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Summaries and Consumer Entered Health Summaries cannot have ‘limited access’ option applied to them.</td>
<td>Nominated representatives may be granted access to ‘limited access’ information by the individual or authorised representative.</td>
<td>may mean that the individual is given inadequate or inappropriate care.</td>
</tr>
</tbody>
</table>

**Level of access applied to clinical documents at time of load**

The application of access levels to clinical documents is managed by the individual within the consumer portal. Healthcare providers do not need to select the level of access to be applied to a document when it is uploaded.

The default access level for a clinical document when posted to a PCEHR will be same as the level of access the healthcare organisation currently has within the access list. For example, if a healthcare organisation with General Access has uploaded a clinical document, then it will be marked as ‘General Access’. If a healthcare organisation with Limited Access has uploaded a clinical document, then it will be marked as ‘Limited Access’.

If a healthcare organisation is not listed on the access list, are currently excluded or emergency access has expired, and they upload a clinical document to the PCEHR, the clinical document will be marked as ‘general access’.

In some cases an individual may be seeing a healthcare provider for two different healthcare issues, one that needs to be managed at a ‘general access’ level and one that is managed at a ‘limited access’ level. In this case, the onus is on the individual to use the consumer portal to adjust the access level of the clinical document accordingly.

**Granting access to ‘Limited Access’ clinical documents**

By default healthcare organisations on the access list will have access to the individual’s ‘general access’ documents.

In order to authorise a healthcare organisation to access limited access documents, the individual will be required to create a special provider access consent code (PACCX), which can be used at the point of care to authorise an organisation to access limited access documents.

If the individual forgets their PACCX, the individual will be required to call the call centre or use the consumer portal to reset it.

Creation of a PACCX is only available to individuals who have opted to set up a PACC.

**Viewing ‘Limited Access’ clinical documents**

Within views such as the Consolidated View and Index View, healthcare organisations with general access will not be able to see that ‘Limited Access’ clinical documents exist. For healthcare organisations with access to ‘limited access’ clinical documents, these views will show the presence of these clinical documents as well as any extracted information in the case of the Consolidated View.
**Design Notes:** Limiting access to clinical documents is challenging.

A number of the controls described above aim to accommodate the need for all individuals to set some basic controls around their PCEHR. It is recognised however that some individuals may wish add information to their PCEHR over which they wish to apply tighter access restrictions (and closer management). It is also recognised that concerns have been raised by healthcare providers about the utility and potential impacts of this feature. However, failure to include this feature may result in some individuals changing their behaviour (e.g. withdrawing participation, refusing to grant access, withholding information, etc.) to work around the absence of this feature. Therefore in line with the central concept of a personally controlled EHR, ‘limited access’ has been included as an advanced feature.

The inclusion of this feature means that improving health literacy will become more essential and individuals need to be educated about the consequences of limiting access. As a result, the individual is required to assert they have reviewed the educational material around access controls before using the more advanced controls.

Implementation of the limited access feature has also been acknowledged as challenging. The proposed approach does not require the source system to support the feature and limits the ability to change the status of a clinical document to being accessible only via the consumer portal. The design trade off means that only individuals who are able to use the portal and have set up a PACC/PACCX will be able to access this feature.

With regard to visibility of ‘limited access’ information, users will not be aware of its presence if they do not have access to it. This decision was made so that the individual is not pressured into revealing the limited access information.

### 5.5.4 Emergency access

The PCEHR System provides the option of emergency access for use in situations where the individual is in need of emergency care and is not capable of giving or communicating consent.

Emergency access is not required for individuals with basic level access controls, as the organisation may simply assert that they are providing healthcare services to the individual and then access the individual’s PCEHR.

Emergency access is required if the individual has opted to set up advanced access controls which may prevent access to the individual’s PCEHR in an emergency situation (e.g. a PACC code has been set, the organisation is ‘revoked’ in the access list or the individual has marked information as ‘limited access’).

Emergency access will add the healthcare organisation to the individual’s access list and provide the organisation with access to ‘limited access’ and ‘general access’ clinical documents. After a period of 5 days from the time of last access to the individual’s PCEHR, the organisation’s access level will revert to the previous access level prior to emergency access.

If the time-out occurs and access is still required, the healthcare organisation could either assert Emergency Access again or obtain a more persistent form of access from the individual (or their authorised representative).

Before emergency access can be used the authorised user will be provided with a warning message highlighting that they are about to use emergency access and the emergency access will be logged. The authorised user will be required to indicate that they wish to proceed.
A 'revoked' organisation is still able to use emergency access to find and access an individual’s PCEHR. If a healthcare organisation is revoked on the access list, then the warning message will also highlight that the individual prefers the organisation not access their PCEHR.

Emergency access cannot be used to access clinical documents that have been effectively removed from a PCEHR (see Section 4.2.2).

All use of emergency access will be logged (see Section 5.7).

### 5.5.5  Forward consent

In the context of referring individuals who have a PACC, it may be necessary for the recipient of a Referral to have access to the individual’s PCEHR ahead of the individual presenting to a healthcare organisation.

In order to provide this access, the referring healthcare provider can generate a cryptographic key known as a Transferrable Access Key (TAK) and electronically attach it to the Referral. When the recipient receives the Referral, they can use the TAK to be added to the access list.

If the individual has advanced access controls set up, a TAK will by default grant the receiving organisation access to the same level of access as the sending organisation.

If the organisation has been revoked in the access list, it will be changed to be able to access the same level of access as the referring organisation.

If a referring organisation used emergency access to obtain access to an individual’s PCEHR, then access will be granted at the same level that the referring organisation has at the time of sending the TAK.

### 5.6  Ensuring data provenance

In order to ensure trust in the information available via PCEHR System, users will require information about the source of a clinical document.

As mentioned in Section 4.2, all clinical documents will be accompanied by document source information stating where the document was created, when it was created and who created it. The healthcare provider uploading the document will be required to have a HPI-I, and the healthcare organisation submitting the clinical document will be required to have a HPI-O.

Clinical documents will be digitally signed by the supplying healthcare organisation using the healthcare organisation’s NASH digital credential and will be used to ensure that the clinical document has not been modified since it was submitted to the PCEHR System.

### 5.7  Audit

One of the measures to ensure accountability is an audit trail. In previous consultations, it was widely agreed that an audit function is essential to ensure confidence by both individuals and healthcare providers.

The PCEHR System will provide an audit service to record all activity on the National eHealth infrastructure services and PCEHR-conformant repositories.

The audit service will identify who has accessed the services, what they accessed, when they accessed it and what authorisation they obtained in order to access it.

The audit log will record the following information:

- The PCEHR which was accessed (including IHI, name, sex and date of birth).
- The Date and Time that access was obtained (UTC Time).
• The user’s name.
• The user’s role (e.g. ‘self’, ‘authorised representative’, ‘nominated representative’, ‘system operator’, HPI-O role, etc.).
• The system they used to access the PCEHR (e.g. consumer portal, conformant portal, provider portal, CSP, clinical system, etc.).
• In the case of access by a healthcare organisation, the HPI-O for the participating organisation and the HPI-O accessing organisation (where the HPI-O is different from the participating organisation’s HPI-O).
• Whether the PCEHR was accessed using the Individual’s Provider Access Consent Code (PACC), a Transferrable Access Key (TAK), by override (emergency or forgotten PACC) obtained by the healthcare provider, representative using the consumer portal, etc.
• Details of what was accessed, including information about the action (e.g. create, read, update, delete) and the item accessed (clinical documents, view, personal data, etc.).

The audit trails will be accessible by both individuals and providers. Based on who is accessing the audit trail, the view will differ as follows:
• Individuals (and their representatives) will only be able to see the audit trail relating to their PCEHR and individuals they represent. Individuals (and their representatives) will not be able to see the names of authorised users (only their role). If the individual wishes to know who accessed the information, they will need to formally request this information from the PCEHR System operator.
• Healthcare providers will only be able to see their own activity in the audit trail via the provider portal.
• The OMO will be able to see any activity relating to their organisation via the B2B Gateway.
• The CSP and CPP will be able to see any activity relating to their service via the B2B Gateway.

If the nominated representative or healthcare provider does not have access to ‘limited access’ information (see section 5.5.3), then any audit trail entries related to limited access information will not be visible.

The information in the audit trail will be utilised in two ways:
• Real time audit rules, based on regularly updated common patterns of misuse, will constantly monitor index usage and notify appropriate parties of a potential breach.
• Any user who is authorised to access an individual’s records, including individuals, authorised representatives and healthcare providers, will be able to request a summary of the audit trail to ensure that access was appropriate.

If it is suspected that the information has been used inappropriately, it will be escalated to the appropriate body for investigation.

Information within the audit trail will be retained in accordance with the retention policies described in Section 4.2.4.
6 PCEHR System components

6.1 Introduction

The PCEHR System is a ‘system of systems’, consisting of a number of core services and conformant repositories. As illustrated in Figure 10, the proposed approach will leverage existing foundations, such as the Healthcare Identifiers (HI) Service, NASH and Clinical Terminologies. The core national services include:

- A Participation and Authorisation Service, which stores individuals’ participation preferences and manages access controls to an individual’s PCEHR.
- An Index Service, which records the location(s) of a participating individual’s records in a range of PCEHR-conformant repositories.
- An Audit Service, which audits all activity across the PCEHR System.
- A View Service and a Report Service, which are capable of extracting information from PCEHR-conformant repositories in order to support a range of different ways of viewing and reporting on information.

These services will be complemented by new foundation services that operate alongside the other foundation services, such as the HI Service and NASH. These new foundation services include:

- A Proof of Record Ownership Service, which can verify that an individual has supplied sufficient information to correctly identify themselves or to verify their relationship with another individual (e.g. parent / child relationships).
- A Template Service, which provides definitions about the types of healthcare information that can be shared via the PCEHR System (and other systems).
- A National Healthcare Provider Service Directory, which is a new directory to provide portal users with a ‘Yellow Pages’ style directory to help locate healthcare providers and organisations.

These infrastructure services will be used to facilitate access via a service coordination layer to a range of PCEHR-conformant repositories. This includes a national repositories service and the capability to link to other independent conformant repositories, such as repositories offered by the Department of Human Services Medicare program, Diagnostic Service Providers, regional operators, State/Territory public health system(s) and other parties.

The PCEHR core services and repositories will be accessible via a range of channels and user systems, including:

- Nationally provided Consumer and Provider-oriented portals, as well as independently provided consumer-oriented conformant portals.
- A call centre for individuals and healthcare provider support.
- A Business-to-Business (B2B) Gateway, to allow a range of systems to access the PCEHR System, such as: clinical systems, systems integrated via a gateway and contracted service providers acting on behalf of healthcare organisations.
- A Report Portal to support operational and evaluation based reporting.
- An Administration Portal and Contact Management Service to aid a range of agents with supporting PCEHR users.

Access to the PCEHR System will be based on Australian and International standards for ensuring interoperability of eHealth systems as well as other relevant specifications.
6.1.1 End-to-end system attributes

Even though the PCEHR System is a ‘system of systems’, the system as a whole will be required to ensure common levels of service around the following attributes.

Table 3: System attributes

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connectivity</td>
<td>The PCEHR System needs to accommodate a range of users with different levels of connectivity. This includes users with current broadband connectivity and emerging NBN connectivity, as well as users with lower levels of connectivity, such as users accessing the system via satellite connections or with intermittent connectivity.</td>
</tr>
<tr>
<td>Performance</td>
<td>The PCEHR System needs to achieve a high standard of performance and ensure that its performance does not hamper its ease of use.</td>
</tr>
<tr>
<td>Scalability</td>
<td>The PCEHR System needs to be scalable, with the capability to add extra capacity as the demand for access to the PCEHR System increases.</td>
</tr>
<tr>
<td>Availability</td>
<td>The PCEHR System portals, core services and repositories need to be available 24/7 with inbuilt redundancy measures. The call centre will also be available 24/7.</td>
</tr>
<tr>
<td>Business continuity</td>
<td>The PCEHR System will be required to meet clear expectations on how it will recover and restore interrupted critical functions within a predetermined time</td>
</tr>
<tr>
<td>Attribute</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Serviceability</td>
<td>The PCEHR System will be required to be built from components that can be operated, configured, maintained, enhanced and replaced by a 3rd party.</td>
</tr>
<tr>
<td>Security</td>
<td>The PCEHR System must meet or exceed the security requirements set out in Section 5.3.</td>
</tr>
<tr>
<td>Data Quality</td>
<td>The PCEHR System must meet or exceed the data quality requirements discussed in Section 4.2.1.</td>
</tr>
<tr>
<td>Clinical Safety</td>
<td>The PCEHR System must meet or exceed clinical safety requirements discussed in Section 7.4.2.</td>
</tr>
<tr>
<td>Usability</td>
<td>The PCEHR System needs to be intuitive and easy to use. Users with basic internet skills and no or limited training should be able to use the basic features of the system. It is anticipated that some more advanced features may require additional training.</td>
</tr>
<tr>
<td>Standards Conformance</td>
<td>The PCEHR System will use a standards-based approach and will leverage existing Australian and International Standards and technical specifications. This is discussed further in Section 6.1.2.</td>
</tr>
</tbody>
</table>

These attributes will be built into specifications and/or Service Level Agreements for the different components of the PCEHR System. A number of these attributes will also be leveraged from standards and specifications to be implemented by conformant systems that connect to the PCEHR System.

**Design Note:** As far as permissible with system policy settings, the aim of the PCEHR System is to maximize the above system attributes whilst retaining the flexibility around implementation. Achieving appropriate levels of responsiveness, availability and security will be challenging in a federated system. Therefore the design choice has been made to implement a number of services nationally (such as the “Index Service”, “Participation and Authorisation Service” and a “National Repositories Service” for key information). It is likely that Conformant Portals and Repositories will also need to be tightly regulated.

### 6.1.2 Common standards and other technical specifications

The PCEHR System will use a standards-based approach and will leverage existing Australian and International Standards and technical specifications.

NEHTA has engaged a consortium to review and consult on the set of standards required for the PCEHR System [RDHG2011]. The outcomes of the consortium review will be used to inform the final set of standards used by the PCEHR System. Standards identified within that review process are classified as either:

- **Required:** Standards identified as ‘Required’ will be necessary for adoption within the implementation of the PCEHR. Conformance to this
standard will be used as a basis for design assessment and participation acceptance.

- **Recommended**: Adoption of the Standard is recommended and proposals which adopt and implement solutions conformant with this standard will be considered favourably and those that do not will need to articulate their alternative approach and reasoning.

- **Informative**: The Standard is provided for information and guidance only. Implementers and adopters of the PCEHR System are advised to consider this Standard when formulating their designs.

NEHTA will work with Standards Australia and the standards community to use, profile or develop the relevant Australian Standards and/or technical specifications.

All components of the PCEHR System infrastructure and source systems will leverage a set of the foundation standards and specifications listed below (where appropriate).

It should also be noted that some of the standards and specifications require profiling and/or extension to align with the foundations, the PCEHR System requirements and the needs of the Australian community. The standards and specifications, which will be profiled and/or extended, are listed below with Standards Australia work program identifiers.25

The standards and related specifications identified in this section are not exhaustive. New standards and specifications may be identified during the implementation process.

Standards supported by the PCEHR System will be complemented by a conformance assessment program (see Section 7.4).

The foundation standards and related specifications are outlined below.

Additional proposed candidates are highlighted in the relevant section for each system component described in the next sections.

**Table 4: Foundations Standards and Related Specifications**

<table>
<thead>
<tr>
<th>Area</th>
<th>Standards and/or Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• The IHI, HPI-I and HPI-O number consists of a unique 16-digit number that complies with International standards for the assignment of healthcare identifiers [ISO7812] (required).</td>
</tr>
<tr>
<td></td>
<td>• The IHI Records are compliant with Australian and International Standards [AS5017, ISO/PDTS 22220] and contain no clinical information (required).</td>
</tr>
<tr>
<td></td>
<td>• The HPI-I records are compliant with the healthcare provider description portion of the Australian Standard Provider Identification [AS4846] (required).</td>
</tr>
<tr>
<td></td>
<td>• The healthcare organisation service type is based on the HI Service specifications for organization classification [NEHT2010d] (required).</td>
</tr>
<tr>
<td></td>
<td>• All HI Service system interface specifications are available from the Department of Human Services Medicare program</td>
</tr>
</tbody>
</table>

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25 Standards Australia work program described at: www.e-health.standards.org.au
### PCEHR System

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### Area | Standards and/or Specifications
--- | ---

**General**

- Health Authority Based PHR Functional Profile [HL72007] (informative)

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### Table 5: Solution Standards and Related Specifications

<table>
<thead>
<tr>
<th>Area</th>
<th>Standards and/or Specifications</th>
</tr>
</thead>
</table>
| Authentication | - X509v3 (format of Public Key Certificates) (required).  
- RSA as per PKCS#1 (type of public keys to be used) (required).  
- LDAP as per RFC 4523 (for credential lookup/validation) (required).  
- HTTP as per RFC 2585 (for credential lookup/validation) (required).  
- RFC 5280 (for rules about certification path validation) (required).  
- PKCS#12 (for transporting private keys and certificates to a certificate holder) (required).  
- Microsoft CAPI, PKCS#11, CDSA/CSSM (to be supported as standard APIs for accessing and using NASH credentials/tokens (required). |
| Secure Messaging | - Standards Australia Technical Specification ATS 5820 for E-health Web Services Profiles [AS WS-1] (for the purposes of point to point messaging).  
<table>
<thead>
<tr>
<th>Area</th>
<th>Standards and/or Specifications</th>
</tr>
</thead>
</table>
  • SCT-AU (SNOMED CT® Australian release) (including relevant reference sets and related cross mappings) (required).  
  • Australian Medicines Terminology (AMT) (required).  
  • Clinical information models for common elements, such as allergies/adverse reactions, problem lists, medication lists, etc. will be based on NEHTA detailed clinical model specifications [NEHT2010a] (recommended).  
  • ISO 21090 harmonized data types [ISO21090] (recommended).  
  • AS 2828 Part 2: Digitized Healthcare records [AS2828-2] (informative for level 1 clinical documents).                                                                                                                                 |
| (All)                |                                                                                                                                                                                                                                   |
| Shared Health Summary| • ATS SHS - Logical info model (IT14 proposed #61) (required).  
  • ATS SHS - CDA exchange spec (IT14 proposed #60) (required).  
|                      |                                                                                                                                                                                                                                   |
| Discharge Summary    | • ATS DS - Logical info model (IT14 proj 100212) (required).  
  • ATS DS - CDA exchange spec (IT14 proj 200211) (required).                                                                                                                                                                      |
| Event Summary        | • ATS ES - Logical info model (IT14 proposed #59) (required).  
  • ATS ES - CDA exchange spec (proposed IT14 #16) (required).                                                                                                                                                                      |
| Specialist Letter    | • ATS eSL - Logical info model (IT14 proposal #57) (required).  
  • ATS eSL - CDA exchange spec (required).                                                                                                                                                                                             |
| Pathology Result     | • AS 4700.2 Implementation of HL7 (v2) - Pathology & diagnostic imaging (diagnostics).                                                                                                                                           |
### Area | Standards and/or Specifications
--- | ---
Referral | • ATS eReferral - Logical info model (IT14 proj 100504).
• ATS eReferral - CDA exchange spec (IT14 proj 100095).
Medicare Information | • Approach to be defined in conjunction with the Department of Human Services Medicare program.
Prescriptions and Dispense Notifications | • ATS 4700.3.1 (fast track) Platform independent (logical) information model to support ETP.
• ATS 4700.3.4 (fast track) Dispense record CDA implementation guide.
• ATS 4700.3.5 (fast track) Prescription CDA implementation guide.
Consumer Entered Health Summary | Approach to be confirmed.
Consumer Entered Notes | Approach to be confirmed.

### 6.2 User systems

#### 6.2.1 Conformant Portals

**Purpose**
The purpose of the conformant portal is to allow independently operated consumer-oriented portals to access the PCEHR System, thereby giving individuals a choice in how they access their PCEHR.

**Functionality**
From within a conformant portal, the individual (or their representative) will be able to:

- Access general information about the PCEHR System in a consumer-oriented form.
- Manage their portal account:
  - Register to have a portal account created.
  - Login/logout of their portal account.
  - Retrieve lost login credentials and update passwords.
  - Manage contact details.
- Manage participation, including:
  - Register to have a PCEHR created.
  - Request to de-activate a PCEHR.
  - Request to re-activate a de-activated PCEHR.
  - Associate/disassociate themselves with other individuals as their representative. (Note that this may require additional proof to be provided to the PCEHR System operator.)
- Link their conformant portal account to a PCEHR (if they already have one).

• Access a PCEHR, including:
  - Access PCEHR views (see Section 4.4).
  - Search a PCEHR (see Section 4.5).
  - Download and/or print clinical documents.

• Manage privacy, including:
  - Manage access controls, provider access keys, access lists and notifications, etc (see Section 5.5).
  - View the audit trail (see Section 5.7).

• Access support services:
  - Access online help.
  - Contact the conformant portal operator and request support.
  - Request an erroneous record be corrected.

This list is not exhaustive and consultation will be required to refine it.

Conformant portals may provide a range of value adding services or innovative features that may not be available in the nationally operated consumer portal.

**Relevant standards and specifications**

- HealthInsite Minimum Publishing Standards [DOHA2010d] (required)
- Standards and specifications required for foundations (see Section 6.1.2) (required)
- Standards and specifications required for the B2B gateway (see section 6.3.4) (required)
- HB 306 User interface requirements for the presentation of health data [HB306] (informative)

### 6.2.2 Clinical systems

**Purpose**

The PCEHR System will be accessible from a range of clinical systems, including GP systems, pharmacy systems, hospital systems, aged care systems, specialist systems, etc.

How the clinical system is integrated with the PCEHR System will vary from system to system. Some systems may have inbuilt features to access the PCEHR System and others may rely on a combination of backend gateways and provider portal integration to access the PCEHR System.

This section outlines the functionality required of a clinical system in order to access the PCEHR System.

**Functionality**

These systems will be able to:

- Utilise National eHealth foundations, including:
  - HI Service
  - NASH
  - Secure Messaging
  - Clinical Terminology
• Access a PCEHR, including:
  - Find a PCEHR.
  - Add the organisation to the access list (PACC may be required).
  - Obtain emergency access.
  - Access PCEHR views (see Section 4.4).
  - Search a PCEHR (see Section 4.5).
  - Download and/or print clinical documents and views.
• Upload clinical documents into the PCEHR System.
• Access support services:
  - Access online help about the PCEHR System.
  - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

**Relevant standards and specifications**

Relevant standards and specifications include:

• Standards and specifications required for foundations (see Section 6.1.2) (required).
• Standards and specifications required for the B2B gateway (see section 6.3.4) (required)
• HL7 EHR-S Functional Profile [HL72007] (recommended)
• Guidelines from Standards Australia on implementing clinical terminologies within clinical systems (planned as part of IT-14 work program) (recommended)
• HB 306 User interface requirements for the presentation of health data [HB306] (informative)
• HB 307 Guide to the principles and desirable features of clinical decision support systems [HB307] (informative)

### 6.2.3 Contracted Service Providers

**Purpose**

The PCEHR System will be accessible from a range of third party contracted service providers who offer health software as a service (SaaS) and support access to the PCEHR System on behalf of a healthcare organisation. Examples could include companies who supply primary care and aged care software as a service.

This section outlines the kind of functionality required of a contracted service provider in order to access the PCEHR System.

**Functionality**

These systems will be able to:

• Utilise National eHealth foundations, including:
  - HI Service
  - NASH
  - Secure Messaging
  - Clinical Terminology
• Manage user access to the system, including the ability for the OMO to authorise users to access the PCEHR System.
• Access a PCEHR, including:
  - Check whether an individual has a PCEHR (without viewing the record).
  - Add the organisation to the access list (PACC may be required).
  - Obtain emergency access.
  - Access PCEHR views (see Section 4.4).
  - Search a PCEHR (see Section 4.5).
  - Download and/or Print Clinical Documents and Views.
• Upload clinical documents into the PCEHR System.
• Access support services:
  - Access online help about the PCEHR System.
  - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

Relevant standards and specifications
• Standards and specifications required for foundations (see Section 6.1.2) (required)
• Standards and specifications required for the B2B gateway (see section 6.3.4) (required)
• HL7 EHR-S Functional Profile [HL72007] (recommended)
• Guidelines from Standards Australia on implementing clinical terminologies within clinical systems (planned as part of IT-14 work program) (recommended)
• HB 306 User interface requirements for the presentation of health data [HB306] (informative)
• HB 307 Guide to the principles and desirable features of clinical decision support systems [HB307] (informative)

6.3 Access channels

6.3.1 Consumer Portal

Purpose
The purpose of the consumer portal is to provide a nationally operated portal to allow individuals to access their own PCEHR.

Functionality
From within the Consumer Portal, the individual (or their representative) will be able to:
• Access general information about the PCEHR System in a consumer-oriented form.
• Manage their consumer portal account:
  - Register to have a consumer portal account created.
  - Support login via user credentials issued by the Australian Government Online Service Point (AGOSP).
  - Manage notification details.
• Manage participation, including:
  - Register to have a PCEHR created.
- Request to de-activate a PCEHR.
- Request to re-activate a de-activated PCEHR.
- Associate/disassociate themselves with other individuals as their representative (note that this may require additional proof to be provided to the PCEHR System operator).
- Link their consumer portal account to a PCEHR (if they already have one).

• Access a PCEHR, including:
  - Access PCEHR views (see Section 4.4).
  - Search a PCEHR (see Section 4.5).
  - Download and/or print clinical documents.

• Manage privacy, including:
  - Manage access controls, provider access keys, access lists and notifications (see Section 5.5).
  - View the audit trail (see Section 5.7).

• Access support services:
  - Search the National Healthcare Service Provider Directory.
  - Access online help.
  - Contact the PCEHR System operator and request support.
  - Request an erroneous record be corrected.

This list is not exhaustive and consultation will be required to refine it.

Additional requirements
The consumer portal shall support:

- Popular desktop web browsers, including, but not limited to Internet Explorer, Firefox, Safari and Chrome.
- Links to the Australian Government funded healthdirect Australia consumer portal (222.healthdirect.org.au).
- Context sensitive links to health literacy information from HealthInsite on www.healthdirect.org.au. For example, the individual should be able to follow a link from their medical history and find related articles on HealthInsite.
- Space within portal pages for information about current public health campaigns.
- Links to online government campaigns around staying safe online (e.g. www.staysmartonline.gov.au).
- The Web Content Accessibility Guidelines version 2.0 [W3C2008a]. By following these guidelines, the portal will make content accessible to individuals with disabilities.
- Information kits in a range of different languages to support those individuals who are unable to read English.

Relevant standards and specifications
- HTML (xHTML 1.1 or HTML 4.01), CSS (CSS2) and HTTP 1.1 (required)
- Web Services for Remote Portlet (WSRP) [OASIS2008] and/or JSR286 Portlet Specification 2.0 [JCP2010] (required)
- HealthInsite Minimum Publishing Standards [DOHA2010d] (required)

• meet 'Level A' conformance with the Web Content Accessibility Guidelines (WCAG) [W3C2008a] by the end of 2012 and 'Level AA' by the end of 2013 (required).

• Standards and specifications required for foundations (see section 6.1.2) (required)

• Standards and specifications required for the B2B gateway (see section 6.3.4) (required)

• HB 306 User interface requirements for the presentation of health data [HB306] (informative)

### 6.3.2 Provider Portal

#### Purpose
The purpose of the Provider Portal is to complement existing local health record systems by providing an alternative form of access to the PCEHR.

#### Functionality
From within the Provider Portal, healthcare providers will be able to:

• Access general information about the PCEHR System in a healthcare provider-oriented form.

• Login to the Provider Portal using their healthcare provider NASH token containing their digital credentials.

• Select which organisation they are accessing on behalf of (if the healthcare is linked to multiple healthcare organisations in the HI Provider Directory Service).

• Access a PCEHR, including:
  - Find a PCEHR.
  - Add the healthcare organisation to the access list (PACC may be required).
  - Access PCEHR views (see Section 4.4).
  - Search a PCEHR (see Section 4.5).
  - Download and/or print clinical documents.

• Access support services:
  - Search the National Healthcare Service Provider Directory
  - Access online help.
  - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

#### Additional requirements
The Provider Portal shall support:

• All popular web browsers, including, but not limited to Internet Explorer, Firefox, Safari and Chrome.

• Older browsers used within some healthcare organisational standard operating environments.

• Ability to support NASH based tokens for healthcare providers.
• The Web Content Accessibility Guidelines version 2.0 [W3C2008a]. By following these guidelines, the portal will make content accessible to individuals with disabilities.

**Relevant standards and specifications**

• HTML (xHTML 1.1 or HTML 4.01), CSS (CSS2) and HTTP 1.1 (required)
• Web Services for Remote Portlet (WSRP) [OASIS2008] and/or JSR286 Portlet Specification 2.0 [JCP2010] (required).
• HealthInsite Minimum Publishing Standards [DOHA2010d] (required)
• Standards and specifications required for foundations (see section 6.1.2) (required)
• Standards and specifications required for the B2B gateway (see section 6.3.4) (required)
• HB 306 User interface requirements for the presentation of health data [HB306] (informative)

**Scope Notes:** In the first release the Provider Portal will be primarily a read-only system. Clinical documents can only be created from Clinical systems.

### 6.3.3 Report Portal

**Purpose**

The PCEHR System will provide a Report Portal to support access to information within the report service (see Section 6.4.6). This portal will be accessible to users evaluating the PCEHR System and users who have permission to use data within the PCEHR System for approved uses.

**Functionality**

The Report Portal will allow users to:

• Access general information about the PCEHR System reporting functions.
• Manage their Report Portal account:
  - Register to have a Report Portal account created.
  - Login/logout of their Report Portal account.
  - Retrieve lost login credentials and update passwords.
  - The PCEHR System operator will be able approve requests for a Report Portal accounts and authorise the types of reports they are able to access.
• Access a series PCEHR reports, including reports outlined in Section 4.6.
• Access support services:
  - Access online help.
  - Contact the PCEHR System operator and request support.

**Additional requirements**

• Production of reports in a graphical form (bar charts, pie charts, etc).
• Production of report data as a downloadable comma separated value file, suitable for import into other analysis tools.
Relevant standards and specifications

- HTML (e.g. xHTML 1.1 or HTML 4.01), CSS (e.g. CSS2) and HTTP 1.1 (required).
- Standards and specifications required for foundations (see section 6.1.2) (required).
- Standards and specifications required for the B2B gateway (see section 6.3.4) (required).
- HB 306 User interface requirements for the presentation of health data [HB206] (informative).

6.3.4 B2B Gateway

Purpose
The purpose of the B2B gateway is to provide outward facing system interfaces for participating systems to access the PCEHR System.

Functionality
- Provision of outward facing system interfaces for 3rd party systems to access the PCEHR System, including support for:
  - Clinical Systems
  - Contracted Service Providers
  - Conformant Portals
  - Consumer Portal(s)
  - Provider Portal(s)
  - Report Portal(s)
  - Administration Portal(s)
  - Call Centre System(s)

Additional Requirements
- Provision of documentation, sample code, a sandpit test environment and/or client side software libraries to help support access by conformant system suppliers. Platforms such as .Net and Java are preferred for sample code and/or libraries.

Related standards and specifications
- W3C SOAP Version 1.2 (required)
- W3C Web Services Description Language (WSDL) Version 2.0 (required)
- W3C Web Services Policy 1.5 (required)
- OASIS WS-Security 1.1: SOAP Message Security 1.1 (required)
- OASIS WS-Security Policy 1.3 (required)
- OASIS WS-I Basic Profile Version 2.0 (required)
- IETF/RFC 1305 Network Time Protocol (required).
- Standards and related specifications for Participation and Authorisation Service (see Section 6.4.1) (required).
- Standards and related specifications for Index Service (see Section 6.4.3) (required).
- Standards and related specifications for View Service (see Section 6.4.5) (required).
• Standards and related specifications for Audit Service (see Section 6.4.4) (required).
• Standards and related specifications for Report Service (see Section 6.4.6) (required).
• Standards and related specifications for National Repositories Service and other conformant repositories (see Section 6.6) (required).

6.3.5 Call Centre

Purpose
The PCEHR System operator will provide a Call Centre to allow individuals to obtain general information about the PCEHR System, register/withdraw from the PCEHR System and manage their access controls.

The Call Centre will also provide support to healthcare organisations.

Functionality
The Call Centre is available to both individuals and providers and will be able to support:
• General enquires about the PCEHR System.
• Assistance around the registration process.
• Assistance in managing basic access controls26.
• Assistance in resolving issues around the PCEHR System.
• Resolution of complaints.
• Feedback around the PCEHR System.

Further functions may be added in time.

Additional requirements
• The Call Centre will be responsive and be built to meet agreed metrics around targets such as abandonment rates, average speed to answer, time service factors, first call resolutions, etc.
• The Australian Government provides a Translating and Interpreting Service (TIS) for people who do not speak English. A non-English speaker will be able to use this service when contacting the PCEHR Call Centre.

Relevant standards and specifications
• Standards and specifications required for foundations (see Section 6.1.2) (required).
• Standards and specifications required for the B2B gateway (see Section 6.3.4) (required).

6.3.6 Administration Portal

Purpose
The PCEHR System will provide an Administration Portal to enable Service and Support Agents, Authorized Registration Agents and Call Centre Agents working in one of the channels (e.g., call centre, Medicare shop front, etc) to assist individuals with registration, help individuals manage their PCEHR, access support information about the PCEHR System and access the contact management service.

26 Note that advanced access controls can only be managed via the consumer portal.
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Functionality
The Administration Portal will allow users to assist individuals with:

- Registration and proof of record ownership (see section 6.5.1).
- Completion of a partially complete registration.
- Updating their details (see Section 3.2.3).
- Managing access control setting (see Section 5.5).
- Accessing the audit trail for their PCEHR.
- Deactivating and/or reactivating their PCEHR.
- Resolving consumer portal account management issues (such as resetting lost passwords).
- Ensuring that complaints and concerns are recognised and resolved (please refer to the contact management service described in Section 6.4.7).
- Handling their feedback.
- Access general information about the PCEHR System.

The Administration Portal will allow users to assist participating organisations and healthcare providers with:

- Accessing the audit trail for their activities on the PCEHR System.
- Obtaining access to an individual’s PCEHR on behalf of the provider’s organisation (subject to the individual’s access controls).
- Ensuring that complaints and concerns are recognised and resolved (please refer to the contact management service described in Section 6.4.7).
- Handling their feedback.
- Obtaining general information about the PCEHR System.

Additional requirements
- The administration portal will not allow the user to access clinical documents in an individual’s PCEHR.
- Users of the administration portal will not be able to undertake emergency access to an individual’s records. Providers will be required to use their clinical systems or provider portal for this.
- Access controls need to be built into the administration portal to limit the degree of functionality available to the user based on the tier of support they are authorised to provide.

Relevant standards and specifications
- HTML (e.g. xHTML 1.1 or HTML 4.01), CSS (e.g. CSS2) and HTTP 1.1 (required).
- Standards and specifications required for foundations (see Section 6.1.2) (required).
- Standards and specifications required for the B2B gateway (see section 6.3.4) (required).
- HB 306 User interface requirements for the presentation of health data [HB206] (informative).
6.4  Core PCEHR services

6.4.1  Service Coordination Layer

Purpose
The service coordination is a technical service, which supports orchestration of the underlying core PCEHR services.

Functionality
Functions include:
• Service Registration.
• Service Discovery.
• Service Orchestration.
• Enforcement of Security Policies around Access Control and Audit.
• Service Monitoring.

Related Standards and Specifications
• None.

6.4.2  Participation and Authorisation Service

Purpose
The Participation and Authorisation Service has three major functions:
• Managing the participation process for registration of individuals and their representatives.
• Capturing administrative information, settings and preferences about individuals and their representatives.
• Controlling access to an individual's PCEHR based on their access control settings.

The participation process and authorisation process are discussed in more detail in Sections 3 and 5 respectively.

Functionality
The Participation and Authorisation Service supports the following functions for an individual:
• Manage participation, including:
  - Register to have a PCEHR created.
  - Request to de-activate a PCEHR.
  - Request to re-activate a de-activated PCEHR.
  - Associate/disassociate representatives with an individual (note that this may require additional proof to be provided to the PCEHR System operator).
  - Update contact details, details of the person to contact in an emergency and notification details.
• Manage access controls (see Section 5.5), including:
  - Update access control settings.
  - Set/Reset PACC and PACCX.
  - Manage access lists.
- TAK generation.

In order to support these functions the Participation and Authorisation Service will need to record the following information:

- Details (name, date of birth, sex and IHI).
- PCEHR status (active, de-activated).
- Contact details (phone number, mailing address, email address).
- Person to contact in an emergency details (name and contact details).
- Custodian information for advance care directive (name and contact details).
- Notification details (email address or mobile number for SMS).
- Authentication details (e.g. user name, password).
- Date(s) of sign up and exit.
- Details about representatives, including for authorised representatives, the basis for authorisation (e.g. parent, guardian, power of attorney), evidence of authorisation, effective date and expiry date.
- Access control settings, including:
  - Access control mode (basic or advanced)
  - Is a PACC required to be added to the access list (Y/N)
  - The PACC (PIN/passphrase)
  - Can access without a PACC be undertaken if individual forgets PACC (Y/N)
  - Is notification required when access without PACC undertaken (Y/N)?
  - Is notification required when new organisations are added to the access list (Y/N)
  - The access list (list of organisations and level of access (‘general’, ‘limited access’, ‘revoked’))
  - The PACCX (optional)

Related standards and specifications

- XACML 2.0 [XACML] (recommended)
- Security Assertion Markup Language 2.0 (SAML 2.0) [SAML] (recommended)

6.4.3 Index Service

Purpose

If the individual chooses to participate, the index will associate an individual with a range of his/her clinical documents already stored within the PCEHR-conformant repositories.

The index stores metadata (i.e. data that serves to provide contextual information about other data) about each clinical document; the actual content of the clinical document is stored within a PCEHR-conformant repository.

Functionality

Key functions of this service include the ability to:

- Clinical document registry functions:
- Register a new clinical document.
- Update an existing clinical document index entry.
- Deregister a clinical document.
- Search the index.
- Execute quality functions to assess the integrity of the data.

- Repository management:
  - Register new conformant repository.
  - List available conformant repositories.
  - Update conformant repository details.
  - Deregister conformant repository.

In order to support this functionality, for each registered clinical document, the index service stores:

- The individual’s IHI.
- The clinical document ID (a unique identifier for the information).
- The template ID (see Section 6.5.1).
- The type of clinical document (e.g. Discharge Summary, Event Summary).
- A keyword list for search function.
- The location where the clinical document can be retrieved.
- The date and time at which when the clinical document was created.
- The name, speciality / sub speciality27 and HPI-I of the healthcare provider that created the Clinical document.
- The name and HPI-O of the healthcare organisation where the clinical document was created.
- The name and HPI-O of the participating healthcare organisation that created the record.
- Versioning information about the clinical document.
- Management information about the integrity of the link (e.g. last time the link was checked, flag to indicate potential duplicate, etc.).
- A label indicating if the information is ‘general access’ or ‘limited access’.
- A flag indicating the clinical document had to be ‘effectively removed’ and a reason why it was removed (e.g. removal request by individual, incorrectly identified individual, error in clinical information) and the date/time of removal.
- An annotation indicating if the clinical document has been archived or disposed of in the conformant repository.

The index service will also maintain information about available conformant repositories and manage the registration process.

**Related standards and specifications**

IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] or HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (recommended).

---

27 As per HI Service Provider classifications.
6.4.4 Audit Service

Purpose
The PCEHR System will provide an Audit Service to record all activity on the national eHealth infrastructure services and PCEHR-conformant repositories.

The Audit Service will identify who has accessed the services, what they accessed, when they accessed it and what authorisation they obtained in order to access it.

Audit is discussed in the section on privacy and control in Section 5.7.

Functionality
Key functions of the audit service include:
• Add audit entry.
• Access audit trail summary.
• Request full audit trail.
• Archive old audit trail entries.
• Perform rule-based analysis of audit trail.

Related standards and specifications
• IHE Audit Trail and Node Authentication (ATNA) Integration Profile [IHE2010a] and IHE Consistent Time (CT) Integration Profile [IHE2010a] (recommended).
• ISO/DIS 27789 Audit trails for electronic health records [ISO27789] (informative).

6.4.5 View Service

Purpose
The purpose of the View Service is to allow authorised users, individuals and their representatives to access a series of ‘views’ of an individual’s PCEHR. These views are intended to allow the underlying information within a PCEHR to be reassembled in different ways for different categories of users with different needs.

Functionality
The View Service will support the following functions:
• Request View (The types of views to be supported by the PCEHR System are discussed in Section 4.4).
• Update View Content (see below).
• Execute quality functions to assess the integrity of the data.

Related standards and specifications
Interface specifications candidates include either:
• IHE Retrieve Information for Display (RID) [IHE2010a] or
• HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (recommended).
**Design Note:** In some cases the View Service will assemble views using information from the index or other services. For some kinds of views, such as the Index View, this approach is appropriate as such information can be readily requested from the Index Service. However, for other kinds of views, such as the Consolidated View, which have greater performance demands, it may be necessary to update the view as new information is added to the PCEHR System. It is likely that the View Service will need to maintain an atomic data store specifically for this purpose.

In the case of the Consolidated View, for example, when a new Shared Health Summary or Event Summary is loaded into the national repositories, the Consolidated View for that individual will need to be updated.

How this update will be supported will be defined by the national infrastructure partner. One possible process relies on the repository first updating the index, which in turn notifies the View Service that new information is available. The View Service then in turn pulls a copy of the new Shared Health Summary or Event Summary from the national repositories and uses that information to update the Consolidated View.

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**Figure 11: Update of Views**

### 6.4.6 Report Service

**Purpose**

The Report Service is designed to support reporting and analysis of information across the set of personal health information managed by the PCEHR System. In the first release, the report service will only be used for operational reporting and evaluation of the PCEHR System. Reporting is discussed further in section 4.6.

**Functionality**

Key functions of the Report Service include:
• Data extraction, transformation and loading services to load PCEHR data into a data warehouse.
• De-identification services (including the option of making data re-identifiable if required).
• Data warehouse and related data mart services to store data and enable creation of the reports identified in Section 4.6.

Related standards and specifications

6.4.7 Contact Management Service

Purpose
The intent of the contact management service is to ensure there is a common view of requests and complaints raised by participants across multiple channels, including a call centre, portals and via physical locations (e.g. Medicare shop fronts, healthcare organisations which support assisted registration, etc.).

From the perspective of the participant that raises the request or complaint, there will be a unique identifier used to log the request or complaint that they can use when contacting the call centre to track progress of resolution. The participant that raises the request or complaint will be informed of the expected service response time for resolution of the issue, how they can track progress and options they have around escalation.

Functionality
Functionality includes:
• Management of contact records with participants who have made a request or raised complaints about their PCEHR.
• Management of service requests, including general enquiries, feedback, complaints (including data quality issues) and other service requests.
• Management of routing and workflow to ensure resolution of requests and enquiries, in particular where it is necessary to route a request through to specialised business support team for resolution
• Management of escalations of requests and enquiries based on defined business rules around service management levels and other key service requirements

Related standards and specifications
None.

6.4.8 Repository Access Layer

Purpose
The purpose of the repository access layer is to help coordinate national infrastructure access to the national repositories service and other conformant repositories.

Functionality
Functionality includes:
• Repository registration management.
• Distributed repository retrieval and update services.
• Data quality review and integrity check services.
• Record retention and archival services.
• Repository monitoring.

Related Standards and Specifications
• IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] or HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (recommended).

6.5 New national infrastructure services

6.5.1 Proof of Record Ownership Service (POROS)

Purpose
The purpose of the Proof Of Record Ownership Service (POROS) is to verify that individuals have supplied sufficient information to correctly identify themselves for the purposes of creating a PCEHR. The POROS can also be used to verify an individual’s relationship with another individual (e.g. parent/child relationships) for the purpose of creating a PCEHR on behalf of another individual.

The PCEHR System will permit individuals to have a choice of verification services. The first verification services will be built by leveraging existing infrastructure within the Department of Human Services, and will include the following:

• Fast Track, which has been developed for assisted registration processes, where an authorized registration agent can view an approved piece of photo identification and supply sufficient information to locate the individual’s IHI. The individual will be issued with an Identity Verification Code (IVC), which can then be used to create a PCEHR.

• Online Proof of Record Ownership (Online PORO), which has been developed for both assisted registration and self-service registration processes. This service will rely on information held by the Department of Human Services to provide a series of questions the individual must answer to prove they own the record. Each question has a point value and an individual must achieve a threshold to validate their identity. In circumstances where the individual uses an assisted registration process, the individual will be provided with an IVC, which can then be used to create a PCEHR.

POROS will also provide a range of options around establishing relationships between individuals. Initially, it is proposed that Medicare Card Grouping information, where the age of the individual is over 18 and the dependent is under 18, will be used to assert this relationship.

In time, other options for asserting this relationship may be made available.

Functionality
Key functions of the POROS include:
• Verify identity based on identifying information, features include:
  - Fast Track
  - Online PORO
• Verify relationship between individuals

Additional Requirements
• Access controls over which authentication methods are available via different channels will be required and will depend upon the assisted registration agents permissions.
Related Standards and Specifications

- XACML 2.0 [XACML] (recommended)
- Security Assertion Markup Language 2.0 (SAML 2.0) [SAML] (recommended)

6.5.2 Template Service

Purpose

The Template Service provides a mechanism for sharing, storing, finding, retrieving and managing the lifecycle of templates. A template is used to provide metadata about each of the major clinical document types and includes data definitions, data validation rules, information about how to render a clinical document and links to supporting material (such as implementation guides).

The PCEHR System uses the template service to ensure that the structure and semantics of different types of clinical documents stored within the PCEHR System are consistent with a 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. For example, a Shared Health Summary cannot be loaded into the PCEHR System unless it meets the data validation rules within the template.

The PCEHR System also leverages the lifecycle management processes within the Template Service to help support governance over information that can be shared via the PCEHR System. New forms of information cannot be shared via the PCEHR System unless an approved template is available via the Template Service.

Other eHealth applications may use the Template Service in time to publish new templates. For example, the Template Service could be used to publish a range of specialised referral templates.

Functionality

The Template Service supports the following functions:

- Template lifecycle management, including:
  - Load draft template definition and related information (e.g. schemas, schematron assertions, style sheets, etc.).
  - Approve template (subject to governance controls identified in section 7.2).
  - Update template definitions and related information.
  - Deprecate templates.
- Find templates.
- Retrieve template and related information.

In order to support these functions, the template service contains:

- A template ID (including the version number).
- A flag indicating that the template is currently supported by the PCEHR System.
- The type of record (e.g. Discharge Summary, Event Summary, etc.).
- Usage notes.
- Logical data structure information (structure, attributes names, field definitions, value domain information around data types and terminologies, etc.).
- Links to conformant message and document definitions.
• Links to schemas and schematron assertions for validating content.
• Links to default style sheets for viewing/printing clinical documents.
• The date of publication/deprecation.

Templates will need to accommodate clinical documents with a mix of narrative and structured data and cater for the possibility of attachments being included in a clinical document.

**Standards and related specifications**

• XSD, XSLT, XSL-FO, CSS and Schematron (required).
• ISO/IEC 11179 (required).
• Support for solution standards and related specifications identified in Section 6.1.2 (required).

### 6.5.3 National Healthcare Service Provider Directory

The National Healthcare Service Provider Directory (NHSPD) provides ‘Yellow Pages’ style directory services for healthcare organisations.

The directory is similar to a national version of the Victorian Health Services Directory (HSD) and will provide value added directory services, which can be leveraged by a range of systems including consumer and provider portals.

**Scope Notes:** The National Healthcare Provider Service Directory is a separately funded and complementary activity to the PCEHR program.

### 6.6 Repositories

The PCEHR System will provide the necessary national infrastructure, standards and specifications to enable secure access to an individual’s health information drawn from both national repositories and other conformant repositories.

The PCEHR System accommodates a graded set of conformance levels for repositories. These levels are described in the following table.
<table>
<thead>
<tr>
<th>Level</th>
<th>Functionality</th>
<th>Standards and related specifications</th>
</tr>
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</table>
| **L0 Repository:** This is the most basic level of conformance and provides the operations required to read (or access) documents within a repository and to keep the index service up to date. This is likely to form the basis of conformance for most repositories. A L0 conformant repository is effectively a read only data store, where information is placed into the repository via another means other than the PCEHR System. | • Retrieve clinical document based on PCEHR Specifications.  
• Update the index service based on PCEHR Specifications | • All Clinical documents retrieved from a repository must be conformant with the content specifications, as identified by the template service  
• Retrieve and index functions from IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] or HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (recommended). |
| **L1 Repository:** This level of conformance provides all of the operations required to read (or access) and write (store) documents within the scope of a repository. A L1 builds on L0 and permits both read and write capabilities using specifications conformant with the PCEHR System. | • All L0 Functions  
• Load clinical document based on PCEHR specifications.  
• Update clinical document with a new version based on PCEHR specifications. | • All L0 standards and related specifications.  
• All Clinical documents retrieved loaded into a repository must be conformant with the content specifications, as identified by the template service.  
• Load functions from IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] or HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (recommended). |

### 6.6.1 National Repositories Service

**Purpose**

The National Repositories Service is a L1 conformant repository service ensures that there is capacity to store a minimum critical set of health information about participating individuals. The National Repositories Service does not consist of a single central data repository. It will consist of a number of nationally operated repositories. The minimum critical set of health information managed by this service includes:

- Shared Health Summaries
- Event Summaries
- Discharge Summaries
- Specialist Letters
- Consumer Entered Health Summary
- Consumer Notes
**Functionality**
The National Repositories Service supports the functions required for L1 conformance.

**Standards and related specifications**
The National Repositories Service supports the standards and related specifications required for L1 conformance.

### 6.6.2 Conformant Repositories

**Purpose**
In addition to the National Repositories Service, the PCEHR System will have the capability to connect to other conformant repositories operated by a conformant repository provider.

Examples of conformant repositories may include:

- Department of Human Services operated repositories holding Medicare history, PBS history, organ donor information and childhood immunisation information.
- Pathology service repositories holding Pathology Result Reports.
- Regional or State/Territory operated repositories.

**Functionality**
Functionality will be consistent with the level of conformance of the repository.

**Additional requirements**
- Repository operators will have an obligation to ensure that information within a repository is available via other means (e.g. by placing it in escrow) if the repository is to be shut down.

**Standards and related specifications**
The conformant repository will support the relevant standards and related specifications required consistent with the level of conformance.
## 7 Operating model

### 7.1 Introduction

The PCEHR System will be delivered by a single PCEHR System Operator, who will be required to manage the various channels, core services, National Repositories Service and operational aspects of the system. Participants accessing the PCEHR System will be supported by a range of services around change and adoption. The system as a whole will be subject to a common form of governance and assurance.

Governance, assurance and the PCEHR System Operator are described below. Related topics around program management and the role of partners, such as NEHTA, Department of Human Services, Change and Adoption, Benefits and Evaluation are discussed in Sections 8 and 9.

![Operating model diagram](image)

**Figure 12: Operating model**

### 7.2 Governance

The PCEHR Program clearly requires robust and appropriate governance structures and mechanisms to provide management and oversight of the national PCEHR program and its operation. This will require a governance model that provides a focus on delivering capabilities that meet the needs of the Australian health sector while at the same time ensuring fiscally responsible expenditure of the government investment.

During the PCEHR planning phase to June 2012, the primary accountability for the PCEHR system rests with the Department of Health and Ageing.

The program will transition to a longer-term operational governance model once the PCEHR System has been designed and as it becomes operational. The approach to program management and sourcing model is discussed further in Section 8.3.

Long-term governance arrangement around the management and operation of the PCEHR System and eHealth more generally are still being developed. The principles for long-term governance have been canvassed in the National
E-Health Strategy and the report *A National Health and Hospitals Network for Australia’s Future: Delivering the Reforms.*

The National eHealth Strategy notes that the current governance arrangements for eHealth reflect the degree of ultimate accountability that Australian governments have for national healthcare funding and the delivery of outcomes.

The Strategy identifies a set of seven governance principles that should underpin the design of the national eHealth governance structure: accountability, transparency, appropriate stakeholder representation, sustainability, support for activity at multiple levels, effective leadership and coordination, and balancing local innovation and national outcomes.

The key functions, which need to be provided for through the governance arrangements, include:

- **Strategic:** The strategic oversight function would include high-level decision-making and planning such as developing and implementing national policies and determining directions, at the direction of Health Ministers or in consultation with Health Ministers.

- **Operational:** The operational management function would include responsibilities such as managing assets, maintaining and upgrading equipment, and engaging and managing service providers for the information communication technology infrastructure. This would also extend to benefits realisation and change and adoption activities and work programs.

- **Regulatory:** The regulatory oversight function would concern issues such as the development, accreditation and enforcement of operational and system standards, compliance and possibly the imposition of penalties following complaint investigations for breaches.

The issues identified as potentially requiring some form of day-to-day management and requiring a primary and secondary legislative response will most likely include, but are not limited to:

- Commonwealth requirements for participation and access settings;
- National infrastructure and asset management, including repositories;
- Contractor and contract management;
- Determination of operational and system standards;
- Compliance framework for standards;
- Training and system education;
- Establishment and operation of a call centre and a consumer enquiry capacity;
- Establishment and monitoring of audit activities;
- Investigation and penalties framework for misuse of the system;
- Liability and responsibility of repository providers;
- Development of privacy and consent arrangements;
- Clinical governance;
- Development of national components such the National Authentication System for Health;
- Definition of compliance schedules; and
- Establishment of repository compliance standards.

It is anticipated that the PCEHR system operator will be prescribed in PCEHR legislation. The Government is considering this issue as part of the governance discussion. Input around governance has been received from the
consultation of the Concept of Operations. Further input around governance is being sought via the consultation process on legislation issues.

### 7.3 PCEHR System Operator

The PCEHR System will be operated by a single system operator who will take on the responsibility for operating the national infrastructure.

It is proposed that the legislation would establish the PCEHR System Operator, prescribe the Operator’s functions and responsibilities and establish an administrative framework for setting the service levels and operations rules that the operator must meet [DOHA2011b].

The operator will be subject to the future operational governance model of the PCEHR System and be required to meet a common set of service levels (see system attributes described in Section 6.1.1).

The operator also must not perform the role of PCEHR System Operator unless it is subject to the Privacy Act.

The PCEHR System Operator will be responsible for supplying operational capabilities around:

- Channel Management of the consumer and provider portal, administration portal and the B2B gateway.
- Management of core services, such as the participation and authorisation service, index and view service, report service, audit service and contact management service.
- Management of the National Repositories Service.
- Supply of operational capabilities around service support, service delivery, infrastructure management, security management, application management, asset management and corporate services (such as HR and finance).

The core elements of the PCEHR infrastructure (including portals, core services and the National Repositories Service) will be operated within dual data centres. The data centres will be required to meet all appropriate government standards for operating a national system.

### 7.4 Assurance functions

The PCEHR System will include a range of assurance functions, covering critical aspects of assurance around conformance assessment, clinical safety and data quality.

#### 7.4.1 Conformance assessment

Suppliers of clinical systems, conformant portals and conformant repositories that interface with the PCEHR System will require a Notice of Connection (NOC) from the PCEHR System Operator.

The NOC verifies that suppliers’ software products have been correctly interfaced with the PCEHR System’s online channels. Suppliers must book in for and complete this verification process prior to gaining access to the PCEHR System production environment.

As a precursor to undertaking the verification process, the supplier will be required to provide evidence of passing a suite of independently conducted conformance assessments against the relevant Australian standards and other relevant specifications (see Section 6.1.2).

Using conformance assessment as a key element of the PCEHR System operating model will:
• Ensure an agreed level of interoperability, which in turn supports improved patient safety and quality of care.
• Reduce the risks in eHealth system procurement.
• Facilitate access to international eHealth markets (if products are assessed against international standards).

The Medical Software Industry Association (MSIA), Australian Information Industry Association (AIIA), National Association of Testing Authorities (NATA), Joint Accreditation System of Australia & New Zealand (JAS-ANZ) and NEHTA, have achieved consensus on the basis of an approach that will be leveraged for the PCEHR System [NEHT2009c].

7.4.2 Clinical safety

The governing body (or bodies) responsible for the PCEHR System will be responsible for ensuring that any identified clinical safety risks associated with the appropriate use of the PCEHR System have been mitigated. To help support this requirement the PCEHR System Operator will need to implement a clinical safety management system that:

• Considers clinical safety risks from a range of perspectives, including patient and healthcare provider perspectives.
• Follows best practice principles adopted in the safety critical software industry and is compliant with international standards relating to the management of clinical risk, such as ISO/IEC 80001 [IEC80001].
• Provides policy, procedures and document templates for managing patient safety for a software release and documenting the clinical safety case.
• Involves the participation of representatives of relevant colleges and other organisations in the process of assessment and recommendations for mitigation.
• Has a process for continuous improvement that will over time refine the approach to clinical safety.

The clinical safety management system is a logical extension to the operator’s and governing bodies’ risk management system(s) and its application will highlight:

• Potential clinical safety risks in the development lifecycle processes.
• Product quality and design flaws around clinical safety

It will be possible to:

• Identify the scale and scope of the risks and issues faced.
• Manage clinical safety risks.
• Identify and prioritise recommendations for improvement.

From time to time, the governing body (or bodies) will request an independent audit of the clinical safety aspects of the PCEHR System.

7.4.3 Data quality

The governing body (or bodies) and the PCEHR System Operator will be required to take reasonable steps to ensure the quality of the data in the system. The governing body (or bodies) may request an independent audit of the data in the PCEHR System. Data quality was discussed earlier in Section 4.2.1.
7.4.4 Privacy

The governing body (or bodies) and PCEHR System Operator will be required to take reasonable steps to ensure the protection of privacy of PCEHR System participants. The governing body (or bodies) may request a privacy audit. Privacy was discussed earlier in Section 5.2.
8 Implementation and adoption

8.1 Introduction

The establishment of a national PCEHR System is a complex undertaking, given the number of systems to be integrated and the magnitude of stakeholders who will require support to adopt the system.

This section outlines an implementation approach, including strategy, the PCEHR Program, change and adoption approach and lead eHealth sites. Outcomes evaluation is covered in Section 9.

8.2 Implementation and adoption strategy

Given the fragmentation of Australia’s health sector and the breadth of autonomous and independent stakeholder systems that will need to be integrated, implementation of a national PCEHR System will need to be driven at both the national and the regional/local level. Focusing on one area but not the other will simply lead to the creation of regional and local information silos or the building of national infrastructure with no ability for local systems to integrate with it.

The proposed approach to building a national PCEHR System is based upon a combination of ‘top down’ national infrastructure initiatives and ‘bottom up’ lead eHealth Sites. This will allow the delivery of tangible eHealth project outcomes on the ground, which is critical for building healthcare provider, individual and political support for the national PCEHR agenda, while at the same time ensuring a focus on the national frameworks and actions required to deliver a nationally interoperable PCEHR System.

For the proposed approach to be successful it must integrate effectively with the national hospital and health reform agenda and be supported by a number of core streams of activity: Governance and Legislation; Lead eHealth sites; Change and adoption; Benefits and evaluation; Standards, Foundations and architecture and National infrastructure.

The diagram below represents the key activities and milestones across each of the core streams. It includes ongoing consultation with key stakeholders and the Australian community throughout 2011 and 2012. The consultation process has been about informing the design of the PCEHR System through the Concept of Operations and obtaining input to the drafting of national legislation. There also continues to be a focus on working with healthcare providers and the ICT industry on developing the necessary specifications to enable the PCEHR System.

The implementation plan includes a number of lead eHealth sites, which will continue to build momentum throughout 2011 and 2012 and provide valuable lessons relating to adoption of eHealth across communities throughout Australia. Importantly these lead sites will inform a national change and adoption strategy, which will provide further insights to options for broader adoption of the PCEHR System across the health sector.

At a national level, work will continue in 2011 and 2012 on the design and implementation of the national infrastructure and core PCEHR specifications. Further, progress will also continue to be made on related foundation eHealth services, such as the Healthcare Identifier service, which are necessary for the deployment of the PCEHR System.

The Department has engaged a number of delivery partners to support the delivery of activities within these core streams. A more detailed description of their roles and responsibilities is outlined in the following sections.
Figure 13: PCEHR Implementation Timeline
8.3 **The PCEHR Program**

The Department of Health and Ageing is responsible for the management of the PCEHR Program, and the program will transition to a longer-term operational governance model once the PCEHR System has been designed and becomes operational.

The program needs to satisfy all the Australian Government review processes, recommended by the Department of Finance and Deregulation (Australian Government Information Management Office and Gateway Unit).

The Department’s role in the delivery of the PCEHR Program includes:

- Overall accountability for delivery of the PCEHR Program.
- Management of relationships with the Minister’s Office and Australian Government initiatives and programs.
- Setting policy.
- Being responsible for communications and, if agreed they are required, any further national business case development.
- Determining overarching strategies for the implementation and adoption of the PCEHR System.
- Leading the establishment of governance mechanisms, assessment of privacy requirements and the development of relevant legislation.
- Leading nationally focused stakeholder engagement.

The Department will source a number of partners (see Figure below), including a national infrastructure partner, a benefits evaluation partner and a national change and adoption partner to help deliver the PCEHR System. In addition to these partners, ancillary contracts will be undertaken with a program management service provider, a strategic advisory and an external delivery assurance advisor. The external delivery advisor will provide independent advice on the progress of the PCEHR program. Ernst & Young have been selected to provide the role of external delivery assurance advisor.

NEHTA under contract to the Department will:

- Develop specifications and work with the community, Standards Australia and other standards bodies to develop standards\(^{28}\) to support the PCEHR System.
- Develop solution architecture and high-level design for the PCEHR Program.
- Undertake acceptance and related testing of PCEHR Program infrastructure and solutions interfacing with infrastructure.
- Leverage existing forums and networks for stakeholder engagement and communications activities.
- Oversee and manage lead eHealth site activity.
- Plan and manage cross program activities.

The Department of Human Services (DHS) in collaboration with the Department of Health and Ageing will:

- Support services through Medicare call centres, back-office processing (e.g. Mail) and shop fronts including enquiries, assisted registration and a point of contact around requests and complaints.

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\(^{28}\) Readers please note that NEHTA does not create standards. Standards Australia and other standards bodies are responsible for creating standards.
• Provision of proof of record ownership service(s) to support online and assisted registration processes (see Section 6.5.1).
• Providing a conformant repository enabling access to the MBS, PBS, ACIR and Organ Donor information.
• Operation of the Healthcare Identifiers Service (and any specific extension of the HI Service).

While DHS will not be building the core system, its operational role necessitates close involvement with the National Infrastructure Partner and the PCEHR System Operator.

The National Infrastructure Partner will provide system integration services across the lifecycle for development of national infrastructure, including:
• Delivery of product and solutions across a range of product bundles built as part of the PCEHR System.
• Provide supporting services necessary to oversee the effective and efficient delivery of the National Infrastructure.

The National Change and Adoption Partner will:
• Leverage health sector and ICT industry knowledge and capability to inform the rollout of the PCEHR Program.
• Develop a national change and adoption strategy for the rollout of the PCEHR Program that will encourage adoption and uptake of the PCEHR System.
• Coordinate and conduct policy-related stakeholder engagement forums, including report writing.
• Cooperate with NEHTA in order to utilise and leverage its existing stakeholder engagement forums and networks.
• Interact with the National Infrastructure Partner to exchange knowledge of change and adoption frameworks for large ICT infrastructure projects to inform the rollout of the PCEHR Program.
• Lead the delivery of the PCEHR Program marketing and communications campaign in line with the marketing and communications strategy provided by DoHA and NEHTA.
• Provide event management and logistical support to DoHA for its stakeholder engagement activities.
• Design, develop and deliver products and services to support healthcare organisations, workforces and individuals to transition into the PCEHR System. This will be undertaken in line with policy, strategy and direction provided by DoHA and NEHTA.
• Leverage the lessons learnt from international change and adoption activities for the implementation and adoption of electronic health record systems.
• Participate in and provide governance support to DoHA and NEHTA.

This National Infrastructure Partner role will be undertaken by a consortium led by Accenture.

The National Change and Adoption Partner has been selected and this role will be undertaken by a consortium led by McKinsey and Company.

The Benefits and Evaluation Partner will:
• Develop and deliver a PCEHR Program Benefits Realisation Framework.
• Design and deliver a PCEHR Program monitoring and measurement capability.
• Provide a deep and thorough PCEHR Program analytical and evaluation capability.
• Provide a complementary research capability to support and assist policy development for the PCEHR Program.
• Provide a capability to support, advise and report to the Department on applying all aspects of the above services to the successful delivery of the PCEHR Program by other major partners.

The Benefits and Evaluation Partner has been selected and this role will be undertaken by consortium led by PricewaterhouseCoopers.

The lead eHealth sites will:
• Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.
• Demonstrate tangible outcomes and benefits from eHealth projects.
• Build stakeholder support and momentum behind the PCEHR Program.
• Provide lessons learnt that will inform the future adoption of PCEHR System infrastructure and standards in other sites.

The lead eHealth sites have been selected. The sites are covered in Section 8.5.
Figure 14: Sourcing Model
8.4 Change and adoption

The successful implementation and benefits realisation of a national PCEHR System will require individuals and healthcare providers to be motivated and appropriately supported to contribute to and use the system. This is a two-way relationship, as the quality of the underlying PCEHR System and the information contained in it will also play a critical role in driving stakeholder take-up and support of the PCEHR System.

Indeed, the costs and benefits for the diverse set of stakeholders (including individuals, healthcare providers and organisations) will differ, and will change over time. Therefore the change and adoption approach needs to address not only how to motivate people to register for and adopt the PCEHR, but most ultimately how to change their delivery of healthcare and/or experience of healthcare as a result, and realise the potential benefits.

Given the requirement for a voluntary participation model, meaningful adoption will not be achieved without a deliberate strategy of engagement with the healthcare sector to drive awareness of the PCEHR capabilities and support the change required to embed their use into clinical practice. While national coordination of change and adoption efforts will be required, engagement must also occur at the grass-roots level to ensure the PCEHR System is locally relevant and to ensure realisation of benefits.

While many of the change and adoption activities will be undertaken and managed at local and regional levels across the Australian healthcare system, these will be conducted within a nationally agreed strategy. There is a need for an overarching framework and central coordination of those devolved change and adoption activities to ensure consistency and alignment between national, regional and local activities. These include national awareness and education campaigns, the establishment of national PCEHR stakeholder reference groups and the creation of stakeholder adoption support regimes.

The change and adoption strategy will build on existing knowledge and engagement forums. Much work has already been completed in conjunction with industry bodies, consumer networks, clinical reference groups, round tables and lead implementation sites. As the strategy is designed and implemented, mechanisms such as NEHTA’s clinical networks and the events like the 2010 e-health Conference will continue to provide critical touch points with the community.

The national change and adoption activities will focus on communication and engagement, in the context of broader support for change management.

A change and adoption partner will support this activity (see Section 8.3).

8.4.1 Communication and engagement

An effective communication and engagement strategy will be critical to ensure take-up of the PCEHR System. A phased approach to communication and engagement will be undertaken and the style used will reflect the current stage of development of the PCEHR System.

The communication and engagement approach will be tailored to different groups of stakeholders, including:

- Individuals and their representatives (e.g. parents/guardians and carers) and their communities
- Healthcare providers
- ICT industry
- Government
- Media
The communication and engagement approach will recognise that the introduction of the PCEHR System is not taking place within a ‘Greenfield’ environment. Much has already been done at national, state and local levels. Therefore the communication and engagement approach will integrate existing work and utilise, leverage and, as required, reorient existing channels of communication to ensure stakeholder requirements are addressed across the breadth of the PCEHR program.

Throughout the program three key messages need to be acknowledged in all PCEHR communication and engagement activities. These messages are:

- Trust is critical for the success of the rollout and uptake of the PCEHR System and related changes to practices related to healthcare delivery and experience.
- Communication with stakeholders needs to be customised to ensure a gradual transition and acceptance of the PCEHR System, and reflect the diverse context of adoption relevant to different locations, work practices and healthcare needs.
- Stakeholders need to be informed, educated and supported about the approach and benefits of the PCEHR System.

**Marketing and communications**

A range of targeted communications programs will be put into place, including social marketing programs, delivered via appropriate channels and communities, for individuals, healthcare providers, government agencies and other stakeholders to specifically raise understanding and awareness of the national PCEHR program.

The public will be made aware of the benefits of having a PCEHR, what services they can access and when, how to use those services, and how these services will give them better control over their healthcare and information.

To ensure the messages being delivered are consistent, there will be one broad, cohesive national marketing plan developed by the Department of Health and Ageing, supporting timely, tailored local delivery.

The marketing and communications activities will be multi-faceted with a coordinated approach developed for the overall program. Specific marketing will then be segmented to address the different needs of well individuals and those ‘actively receiving healthcare’ (e.g. aged care, antenatal care, chronic disease management, etc.) and different healthcare provider groups, and tailored locally to the specific context of PCEHR adoption and usage.

**Engagement**

In the area of engagement, the PCEHR development team will actively work to increase awareness of key stakeholders through a consistent approach to stakeholder engagement. The team will do this by:

- Engaging where relevant in public consultation on key issues.
- Assigning relationship/account managers to priority stakeholder organisations and communities to ensure accountability for coordinated engagement.
- Utilising reference groups associated with each work program area to ensure that a representative group of key stakeholders, including consumers, are actively involved in the work program.
- Operating a clinical leaders program that embeds practicing healthcare providers into the work program on a part time basis to ensure the outcomes are clinically relevant.
8.4.2 Change management and adoption support

To help create an understanding of what is required to support change management, the Change and Adoption Partner will develop a change management plan.

The change management plan will include activities for analysis of work practices and training and awareness activities. Ongoing evaluation of the success of take up strategies and learning lessons from lead eHealth sites will be the key focus of the work.

Lessons learned from the lead eHealth sites around the full life cycle of implementation and adoption of the PCEHR System will be used to inform tools, techniques and guidelines for:

- **Pre-implementation**: activities done in the lead up to PCEHR becoming available. This may include planning for PCEHR going live, assessing readiness for change, communicating the change, benchmarking of existing work practices to support later benefits measurement, completion of any final testing, etc.

- **Implementation**: activities done during the introduction of a new system. This may include initiating new processes, training of onsite support staff and users and assistance with system migration and data quality assurance.

- **Post-implementation**: activities done after PCEHR is operating and has successfully been used in normal clinical practice. This may include ongoing support, measuring and monitoring benefits, responding to changes, project closure, etc.

The lessons learned will be built into a knowledge base that can be used as part of broader adoption support mechanisms provided by the PCEHR System Operator and the Change and Adoption Partner. This support includes:

- Call Centre support by the PCEHR System operator for implementers of the PCEHR System.
- Web-based information resources for implementers of the PCEHR System.
- Creation of training courses for implementers of the PCEHR System, which can be offered by the PCEHR System operator.
- Training and support for implementers, local change agents and clinical champions.
- Working with professional bodies to identify opportunities for including PCEHR System related training in ongoing professional education.

By far the most critical element above is training and support for local change agents and clinical champions, as international implementation experiences have demonstrated that the success or failure of an implementation is highly sensitive to the skills of these critical individuals.

8.5 Lead eHealth sites

While all Australians will have the option of registering for a PCEHR, adoption of the PCEHR System capabilities by healthcare providers is likely to be initially focussing on a range of lead eHealth sites.

The lead eHealth sites will be used to:

- Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.
- Demonstrate tangible outcomes and benefits from funded eHealth projects.
• Build stakeholder support and momentum behind the national PCEHR System work program.
• Provide a meaningful foundation for further enhancement and rollout of the national PCEHR System.

The profile for each of these lead eHealth sites will represent a natural grouping of stakeholders (healthcare providers and individuals) sharing the same PCEHR change journey.

These eHealth sites will demonstrate the capacity to address:
• Breadth of coverage (i.e. to a large population).
• Depth of coverage (thorough coverage of healthcare participants e.g. acute, primary, aged care, allied health).
• Ability to demonstrate early benefits.
• Ability to implement innovative solutions.

There are two waves of lead eHealth sites, which have been funded.

The first wave of lead eHealth sites includes three divisions of General Practice: GPpartners in Queensland, GP Access in New South Wales and Melbourne East GP Network (MEGPN) in Victoria. Each site will support a community of services for individuals using a range of community and health service providers with appropriate linkages to clinical support. The wave 1 projects aim to support up to 243 participating practices and 90,000 individuals. Pharmacies, afterhours services and public outpatient services will also be engaged.

The second wave of lead eHealth sites includes nine additional sites:
• Medibank Private Limited Project will implement a consumer-oriented portal, called ‘Health Book’. The ‘Health Book’ will be initially made available to all Medibank Private customers and their healthcare providers enrolled in Medibank’s Chronic Disease Management programs. Medibank Private will not be using any of this information for the management of claims or eligibility for health care insurance benefits.
• Brisbane South Division Limited Project will deliver a substantial eHealth site in one of Australia’s major capital cities. The project will aim at enrolling up to 25,000 individuals in the Brisbane and Ipswich region. A key focus will be on individuals with disabilities and their carers, war veterans and war widows, and children commencing school. The project will bring two Divisions of General Practice on board, Brisbane South and Ipswich and West Moreton, and public and private hospitals, allied health and GP’s. The project will leverage wave 1 infrastructure.
• Mater Misericordiae Health Project will deliver an eHealth site to enhance healthcare for pregnant women. The population reach of the project is women enrolled in Mater’s Maternity Shared Care Program and involves General Practices from three GP Divisions (South East Alliance, Brisbane South and the South East Primary HealthCare network), local specialist obstetricians.
• Northern Territory Department of Health and Families Project will deliver a lead eHealth site for Indigenous Australians living in the Northern Territory, South Australia and Western Australia. The project will leverage the existing NT shared electronic health record and extend the existing service to all Northern Territory residents and Indigenous individuals in the Kimberly region of Western Australia and remote South Australia.
• Greater Western Sydney eHealth Consortium (NSW Department of Health) Project will implement key building blocks for state-wide eHealth infrastructure that will allow NSW Health to connect to the PCEHR System when it becomes available. The initial focus will be on priority consumer groups in the Greater Western Sydney region. The project includes four
GP Divisions (WentWest, Nepean, Blue Mountains and Hawkesbury-Hills) and will leverage previous technology investments. With a population reach of 1,750,000, the project will be able to expand the entire solution quickly to encompass a significant geographic area and ultimately the whole of NSW.

- **Cradle Coast, North-West Area Health Service Project** will provide policy lessons for the PCEHR System around advance care directives. The project targets aged and palliative care patients and their families, palliative care medical specialists and clinical nurse consultants. The project will leverage the state infrastructure which will enable later integration to the National PCEHR infrastructure.

- **St Vincent’s and Mater Health Sydney Project** will establish a lead eHealth site based around St Vincent’s Sydney, in conjunction with partnering Divisions of General Practice, participating specialists and software vendors including Smart Health, Precedence, HCN and Best Practice. The project will also aim to improve clinical communication between the GPs in Murrumbidgee region of Australia and Private Specialists in St Vincents through the delivery of key PCEHR components and e-referral.

- **FRED IT Group MedView Project** will demonstrate the ability for healthcare providers to access an individual’s prescribing and dispensing history via a medicines repository using national electronic prescription and other standards. The project will deploy MedView to all pharmacies and GPs in the Geelong region and to a further 10% of this target market nationally. The project will bring together a grouping of private sector eHealth vendors including FRED, eRx, Best Practice, Zedmed, iCare, Microsoft and SIMPL.

- **Calvary Healthcare Project** will support a cross-border population of approximately 800,000 individuals in the ACT and regional NSW by bringing together a major grouping of private sector eHealth vendors. The vendors involved include HCN, HealthLink, Smart Health Solutions and Precedence HealthCare.

As described in the lavender boxes throughout this document, each site will specifically target elements of the proposed system design in controlled settings to inform the future national rollout.

The operational management of the eHealth site program is being managed by NEHTA under contract to the Department. In addition, the 12 sites selected as part of waves 1 and 2, will be required to work collectively with the Department to ensure strategic health policy alignment, leverage of complementary national infrastructure and toolsets, adherence with national equity and access principles and communication program synergies.

Once the design of the national system has been completed, an assessment of the 12 lead eHealth sites will be undertaken and a transition plan developed for integration to the national PCEHR System. This will allow early adoption of the PCEHR System for individuals participating in the eHealth lead sites from July 2012, including the capability to target approximately 500,000 individuals enrolled in those sites.
9 Outcomes evaluation

The learning from organisations that have implemented large-scale eHealth technologies is that outcomes and benefits are not automatically delivered through the deployment of new eHealth systems, but rather the value has to be actively managed [FISH2004]. This reinforces the importance of measuring outcomes and benefits for the purpose of informing course correcting activities and driving change. In order to sustain the case for investment in a PCEHR System, it is critical to show how the outcomes and benefits will be demonstrated as the system is developed and deployed.

The outcomes and benefits are likely to start modestly due to the need to implement the foundational capabilities of the PCEHR System before progressing to more advanced functionality, the need to educate stakeholders on the benefits delivered by the PCEHR System, and finally the need to allow the supporting vendor landscape to mature. However, it will be critical to show meaningful progress towards the desired PCEHR System outcomes and benefits through a focus on whether adoption and meaningful use is occurring, and as a result whether leading indicators of benefits are being achieved.

In order to realise the value of the PCEHR System, a benefits realisation and evaluation framework is being established. This framework will:

- Specifically address how stakeholders will be impacted by the PCEHR System. This will cover those directly impacted such as consumers and providers (including the differences between different groups of each), but also consider the impacts upon parties such as regulators, IT vendors and other participants in the health system.
- Specify the capabilities required for outcomes realisation and clarify the ownership and commitments by different parties to establish these capabilities and realise the outcomes.
- Illustrate the real world enablement of the benefits and outcomes through a cohesive set of clinical scenarios, which will use specific capabilities and drive corresponding outcomes and benefits.
- Identify candidate outcomes and benefits, source evidence for their achievability and build consensus around the final set of outcomes to be sought. Critically, the framework will also identify where particular outcomes may be disbenefits, particularly for specific stakeholders.
- Define the metrics, level of specificity, measurement techniques, frequency of outcomes reviews and how double counting will be avoided.

The framework logic is illustrated in Figure 15.
9.1 Outcomes and benefits

The implementation and adoption of a PCEHR System will enable more person-centred healthcare and will support a range of benefits and outcomes, including the following:

<table>
<thead>
<tr>
<th>Area of outcome</th>
<th>Type of outcome and/or benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appropriateness of care</strong></td>
<td></td>
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</tbody>
</table>
| Quality — supporting the provision of coordinated care across different healthcare providers over time and the application of evidence-based best practice at the right place and the right time. | The PCEHR System shall enable easier and more timely access to Shared Health Summaries, Discharge Summaries and other related clinical documents by both healthcare providers and the individual, and will contribute to improvements in:  
  • Assessment and treatment.  
  • Coordination and continuity of care, particularly chronic disease management by healthcare providers.  
  • Consumer engagement and self-management.  
  • Quality of recommendations provided by decision support systems using information from the PCEHR System.  
  • More opportunities to provide preventative care. |
| Safety — avoid or minimise situations which can harm or have the potential to harm patients during the course of care delivery. | Access to better quality, more timely patient health information will contribute to:  
  • Improvements in medication safety (e.g. a reduction in medication adverse events and near miss events).  
  • A reduction in avoidable/unplanned hospital admissions, emergency department attendances and GP visits. |
### Area of outcome

**Access** — the ability of individuals to obtain healthcare at the right place and right time irrespective of socio-economic status, physical location and/or cultural background.

<table>
<thead>
<tr>
<th>Type of outcome and/or benefit</th>
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<tbody>
<tr>
<td>The PCEHR System has the opportunity to contribute to improvements in:</td>
</tr>
<tr>
<td>• Out of hours care.</td>
</tr>
<tr>
<td>• Geographic flexibility and mobility.</td>
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</tbody>
</table>

**Sustainability of care**

### Efficiency

- achieving the desired results with the most cost efficient use of resources (i.e. avoiding wasted equipment, supplies, personnel and energy).

<table>
<thead>
<tr>
<th>Access to better quality, more timely health information will have the opportunity to contribute to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical efficiency, i.e. allowing clinical staff to spend more time delivering health services instead of locating information.</td>
</tr>
<tr>
<td>• A reduction in duplicate testing.</td>
</tr>
<tr>
<td>• A reduction in avoidable/unplanned hospital admissions, emergency department attendances and GP visits</td>
</tr>
<tr>
<td>• Improved planning and resource utilisation.</td>
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</tbody>
</table>

**Society** — building a strong and resilient society through meeting the population’s legitimate expectations regarding their health system.

<table>
<thead>
<tr>
<th>The PCEHR System will contribute to improving the broader economy and society through:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increased consumer satisfaction with their healthcare delivery.</td>
</tr>
<tr>
<td>• Entrepreneurial opportunities for both established and new businesses.</td>
</tr>
<tr>
<td>• A stronger healthcare workforce due to improved job attractiveness and satisfaction rates.</td>
</tr>
<tr>
<td>• Economic flow on effects through significant program investments and a healthier population</td>
</tr>
</tbody>
</table>

### Measurement, analysis and evaluation

A benefits realisation and evaluation framework will be established early in the PCEHR System implementation and adoption lifecycle to ensure that the PCEHR System is strategically aligned with government policy, strategy, objectives and health reform decisions and there is robust take-up and meaningful use across the community.

The evaluation framework will include use of research and evaluation monitoring principles, methodologies and toolsets to ensure consistent application across the PCEHR System program’s lifecycle. Importantly, it will be developed to also accommodate potential future functionalities of the PCEHR System, incorporating a comprehensive approach to definition of stakeholders, capabilities, benefits and metrics. This will allow for flexibility as the PCEHR System evolves. The expected benefits will be mapped and actual
real-life results captured and measured across all stages and levels of implementation and adoption.

All metrics will be linked to outcomes that are the result of improved appropriateness and sustainability of healthcare delivery. The following represent some of the key categories of evaluation metrics:

- **Capability enablement** — as capabilities within the PCEHR System are delivered (such as enabling infrastructure), progress will be measured by outcomes such as on-time delivery, and the meaningful use and operation of the capability.

- **Stakeholder activities** — specific stakeholder actions will be required to translate PCEHR System capabilities to realisable benefits. By tracking these actions, the PCEHR Program will gain an understanding the adoption rates and usage rates that serve as precursors for achieving benefits.

- **Intermediate indicators** — some benefits will be realised over a multi-year timeframe, so the ability to track intermediate progress will help ensure that these longer term benefits will ultimately be realised. Although they do not represent benefits themselves, intermediate indicators have been selected based on a proven relationship with their corresponding benefit.

- **Stakeholder outcomes** — the outcomes for each stakeholder group, including consumers, healthcare providers, government and the ICT industry need to be assessed and regularly monitored.

- **Health system outcomes** — ultimately full health system impacts will start to be understood. In the long term, it may be possible to measure benefits nationally.

As the lead eHealth sites commence, local outcomes will be captured and measured. This information will be used as the basis to confirm that further rollout and use can be justified based upon take-up and use within each site.

The benefits realisation and evaluation framework will allow the PCEHR System to be implemented in a way that ensures the needs of the community, healthcare sector and governments are able to be achieved. From this foundation, a formal monitoring and evaluation plan will be designed in consultation with key stakeholders. This plan will form the foundation for:

- Providing transparent and credible evidence of both tangible (eg. financial, lives saved, duplicate tests avoided) and intangible (eg. patient experience) benefits that will stand the scrutiny of a broad range of Government and independent processes, whilst also capturing and communicating the real impact on the lives of individual Australians and the work of their clinicians.

- Understanding the contribution that PCEHR program investments and the PCEHR system make to the achievement of benefits in the context of other activities that may also be contributing, and helping to shape the program as a result of the insight that these can bring.

- Delivering the depth of analysis and research required to go beyond the reporting of program delivery and outcome benefits achieved (or not) to also understand the underlying reasons. These insights are essential to making informed decisions on how best to steer the PCEHR program and stakeholder initiatives.

The final step in the benefits realisation and evaluation framework is most significant — analysing what is occurring (or has occurred) to enhance the PCEHR System value over time. Consistent with the National E-Health Strategy's principle of evidence-based implementation and adoption, the lessons learned will form an essential pillar of the ongoing governance and management of PCEHR System investment, and will inform decisions such as:
• Appreciation of potential functionalities that could be incorporated into the PCEHR System to drive greater benefits and outcomes.
• Further investment to ramp-up and accelerate promising results achieved in early phases.
• Redirection or re-phasing of investment where experience shows that planned outcomes cannot be achieved or require alternative approaches.
• Escalation and consideration of health system impacts and options that can take advantage of the outcomes being achieved.

9.2.1 Draft key performance indicators (KPIs)

The table below shows a summary of the stages of implementation and adoption alongside key performance indicators (KPIs) that might be used in evaluating the success of the PCEHR System. Overall, the performance metrics should not only show an effectively functioning program but should also show realisation of benefits around more appropriate and sustainable healthcare including improved satisfaction of individuals receiving healthcare and progress towards meeting the objectives of health reform.

Lessons from other work on KPIs and minimum datasets indicate that embedding their capture into the PCEHR System’s design, reporting tools, and evaluation program and change management strategies will ensure greater compliance than if developed as a separated function. The next steps will include a piece of work associated with the evaluation framework to develop a confirmed set of KPIs for the PCEHR program, including taking into account the costs of their measurement. The table below presents a high level consideration of KPIs for the PCEHR System.

Table 6: Key performance indicators

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Example metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capability Enablement</td>
<td>Metrics and indicators against key enablers and infrastructure for the PCEHR</td>
<td>Work Program Metrics&lt;br&gt;Availability of the ability for individuals and healthcare organisations to register&lt;br&gt;Availability of change and adoption support material for individuals, healthcare providers and the ICT industry&lt;br&gt;Availability of conformance testing for vendors&lt;br&gt;Progress of specifications through the standards development process</td>
</tr>
<tr>
<td>Stakeholder activities</td>
<td>Metrics and indicators collected by lead eHealth sites and nationally</td>
<td>Numbers of sites implementing PCEHR solutions (e.g. number of hospitals, number of general practices)&lt;br&gt;Numbers of vendor products conformance tested&lt;br&gt;Numbers of PCEHRs created&lt;br&gt;Number of clinical documents added to repositories&lt;br&gt;Viewing rates on PCEHRs by individuals and healthcare providers (including 'repeat' viewing rates after the first look at an individual’s PCEHR).</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Short-term metrics</td>
<td>Number of individuals with a shared health</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Example metrics</td>
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<td>--------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>indicators</td>
<td>linked to stakeholder and health system outcomes</td>
<td>summary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data quality metrics from the data quality dashboard</td>
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<tr>
<td></td>
<td></td>
<td>Percentage of individuals accessing consumer centric education resources from the consumer portal</td>
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<tr>
<td>Health system outcomes</td>
<td>Metrics linked to the National Health Performance Framework</td>
<td>Reduction in avoidable readmissions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduction in duplicate testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reductions in reported adverse events</td>
</tr>
<tr>
<td>Stakeholder outcomes</td>
<td>Metrics collected nationally across all participants</td>
<td>Consumer satisfaction rates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Healthcare provider satisfaction rates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Government investment in eHealth</td>
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<tr>
<td></td>
<td></td>
<td>ICT Industry size and growth rates</td>
</tr>
</tbody>
</table>
Appendix A  Consultation

A.1 HealthConnect Consultations, 2004 – 2005

Many of the outcomes from the previous public consultation on HealthConnect were considered in this report.

A.2 IEHR Consultations, June 2008

NEHTA conducted two Clinician and Consumer Roundtable sessions in June 2008 as part of the consultation for the then Individual Electronic Health Record (IEHR) service proposal. One in Brisbane (5 & 6 June) with an urban focus and one in Alice Springs (11 & 12 June) discussed issues relating to a rural and remote context. A Peak Body Summit was also held in Canberra (18 June). The aim of the Summit was to present and validate the key recommendations from the Roundtables in Brisbane and Alice Springs. In total, over 150 people attended the sessions.

A.3 Privacy Blueprint, July 2008

NEHTA’s Privacy Blueprint for the Individual Electronic Health Record (IEHR) was released for public comment on 3 July 2008 [PRIVROF08]. It was distributed to a range of key stakeholders and also published on NEHTA’s website.

In total 37 submissions were received. Of these, six were submitted in confidence. Copies of the non-confidential submissions have been published on NEHTA’s website.

This report provides a summary and analysis of the key themes that emerged from the submissions. It also outlines the next steps NEHTA will be taking to further the work on privacy and eHealth initiatives [NEHTA2008a].

A.4 IEHR Consultations, September 2009

A workshop was held on 18 September 2009 in Sydney to demonstrate the use of IEHR scenarios for future consultation. This workshop was attended by Clinical and Consumer representatives. The event was positioned as a working discussion rather than a consultation session. Previous consultation on the IEHR has centred on ‘round table’ discussion of policy and privacy issues.

The workshop provided the opportunity to:

• Discuss how the IEHR solution could be demonstrated.
• Test ideas and concepts with representatives prior to the commencement of consultation.
• Understand and capture key issues and concerns so that NEHTA can consider these prior to commencement of consultation.
• Improve understanding, share ideas and gather feedback on the IEHR.

A.5 NEHTA Quantitative Survey Report, August 2008

This quantitative survey was undertaken throughout the month of July 2008. In total 2,700 people were asked their opinion on a number of issues relating to the implementation of an IEHR Service for all Australians [NEHT2008b]. The number of respondents from each state and territory was as follows:

• NSW – 500
• Victoria – 500
• Queensland – 400
• South Australia – 400
• Western Australia – 400
• Tasmania – 300
• Northern Territory – 200

A.6 eHealth Conference, November 2010

On the 30th of November 2010 and 1st December 2010, the Department of Health and Ageing conducted an eHealth conference. The conference had a specific focus on two topics: telehealth and PCEHR; and included both local and international speakers. Over 400 delegates were invited to attend.

The Conference included a number of specific sessions aimed at engaging the community on the topic of PCEHR.

In the lead up to the conference NEHTA conducted a series of ‘roundtable’ sessions with specific groups, including: consumers, medical providers, nurses, allied health and the ICT industry.

The findings of the eHealth conference and lead up roundtables have been summarised in the Report of the National e-Health Conference [DOHA2011a].

A.7 NEHTA Reference Group Meetings, July 2010 – Present

In July 2010, the Department of Health and Ageing requested NEHTA to undertake a consultation and engagement activity using its clinical leads and reference group members.

Since July 2010, NEHTA has arranged a number of reference group meetings and leveraged the experience and skills in each of its existing groups.

Each group has a mix of participants and includes clinical representatives, consumer representatives, state and territory representatives and representatives with other backgrounds.

NEHTA also periodically runs a series of roundtable sessions with specific groups, such as consumers, medical providers, nurses, allied health and ICT industry in order to review stakeholder specific issues.

NEHTA will continue to run reference group meetings and roundtable sessions throughout the length of the PCEHR Program.

A.8 Public consultation of the Concept of Operations

The Concept of Operations was made available for public feedback in April 2011. A total of 165 items were submitted by 157 individuals and entities. An analysis of the feedback has been prepared by Deloitte [DOHA2011b].

A.9 Legislation Issues

In July 2011, the Department released a Legislation Issues Paper for public consultation to seek feedback from the community on the appropriate settings to be included in the PCEHR legislation [DOHA2011b]. Feedback on the paper closed in August.
A.10 Future consultations

The Department of Health and Ageing will undertake additional rounds of consultation with consumers, healthcare providers and the ICT industry as the PCEHR Program progresses.
Appendix B  Current state

This appendix outlines the general trends around eHealth in Australia as well as lessons learned both locally and internationally in shared electronic health records.

B.1 General eHealth trends within Australia

Australia is one of the more information and communication technology enabled societies in the world. At the end of June 2009 there were 8.4 million active Internet subscribers in Australia, with 57% of subscribers having a download speed of 1.5Mbps or greater [ABS2009]. The existing Internet capability in Australia is able to support most current eHealth applications. Once implemented, the National Broadband Network will extend broadband support and facilitate new opportunities in eHealth.

The current healthcare system operates in a mixed mode of using paper-based and electronic-based systems for collecting and sharing health information. A number of different eHealth applications are in wide use in a number of different areas in the health sector including patient administration systems (PAS), clinical information systems (CIS), diagnostic imaging systems, pathology systems, practice management systems, etc.

The National E-Health Strategy noted during the consultation process that there is strong support for eHealth within Australia, and stakeholders recognise the potential efficiency, quality and many safety benefits it can deliver. Coupled with this widespread support, there was also a high degree of frustration with the pace of progress. In 2004, progress was too piecemeal and fragmented29, and lacked sufficient levels of investment and national coordination. This desire for a more nationally coordinated approach led to the creation of the National E-Health Strategy.

In terms of specific groupings, the following common themes are emerging across the community:

- **States and territories:** All state and territory governments are in the process of either defining or implementing some form of jurisdiction-wide eHealth strategy. These strategies typically involve substantial government investment on the upgrade of core IT infrastructure or the implementation of clinical information systems across the acute sector.

  Common classes of systems in use in the states and territories include simple PASs used in smaller regional facilities to fully developed CISs capable of interfacing with emergency department, theatre booking, hospital pathology, radiology and hospital pharmacy systems. Most States and Territories are somewhere in between and may have different mixes of capabilities from health service to health service.

  It should be noted that all states and territories are at different stages on their eHealth journeys. While they all use common classes of systems, they need to take specific approaches to solving their local challenges. However, these eHealth programs should result in the establishment of State and Territory eHealth platforms that provide the basis for integration with national infrastructure.

- **General Practice:** According to the Australian Medical Association (AMA), over 95% of GPs have computerised practice management systems. The majority of GPs with a computer at work used it for printing prescriptions,

29 This view was also reflected in a report by the Boston Consulting Group (BCG) in 2004 [BCG2004]. The BCG undertook a system wide review of eHealth related activities across all jurisdictions in Australia. The review identified over 360 current or planned eHealth initiatives. The large majority (more than 70%) of these initiatives were small localised initiatives with a budget of less than $500,000.
recording consultation notes, printing test requests and Referral letters and receiving results for pathology tests electronically. Roughly one third of GPs keep 100% of patient information in an electronic format and the remainder of general practices use a combination of paper and electronic records.

• **Community Pharmacy:** Anecdotal evidence indicates the uptake of systems within community pharmacies is quite high as it is a business necessity for pharmacists to manage their stock, dispense medicines, manage online claiming, create and maintain medication records and make use of evolving e-prescribing applications.

• **Allied Health:** Whilst there are some software packages available for managing allied health practices (e.g. around billing and bookings), anecdotal evidence indicates limited uptake of electronic health records in private allied health practices. Some public sector operated community health centres offer electronic health records for their allied health providers, but this is uncommon.

• **Specialists:** A Royal Australian College of Physicians survey of 1,266 Specialists found that 97.5% of respondents had access to computers at work [IMJ2009]. Most specialists are currently using practice management systems at their front desk for billing and booking; take-up of clinical systems within consulting rooms varies as much as 10% to 40% (depending on the speciality). A number of specialist systems are modified GP systems with additional modules added to support the needs of the specialist.

• **Private Hospitals:** There are a number of different products used across Private Hospitals, employed under different software implementations and underlying supported platforms. Their level of sophistication and function varies from simple PAS systems used to provide billing and booking in smaller day surgeries to fully developed CISs used in some of the not-for-profit groups. Outside of the not-for-profit hospitals, it is not uncommon for electronic health record systems to be operated mainly by specialists and the hospital mainly focuses on patient administration and theatre booking.

• **Diagnostic Services:** Private pathology and radiology providers have taken up ICT in order to be able to support their increasingly automated businesses and advanced diagnostic equipment. Pathology is one of the more advanced users of ICT and has a range of different vendors who supply systems into this space as well as supporting the delivery of electronic Pathology Result Reports. Similar levels of advanced usage are also seen in diagnostic imaging with a range of different vendors who supply both picture archive systems and radiology information systems into this space.

### B.2 The National E-Health Strategy

Australian governments have recognised, consistent with the experience of many other countries, that moving from a paper-based system to an electronic one requires a long-term plan with multiple staged goals that are linked to the experiences of patients as they journey through the health system.

The key lesson from analysis of comparable developed countries is that the success of an eHealth implementation depends on focused strategic plans [ECIS2007, DHC2004, MHSA2006]. These plans have been implemented with strong leadership by government and supported by appropriate investment over long lead times.

Australia has acknowledged this need for leadership through its collaborative approach between governments to address eHealth and through the development and public release by all Health Ministers of a National E-Health
The National E-Health Strategy proposes an incremental and staged approach to developing eHealth capabilities and supports the existing collaboration of Commonwealth, State and Territory governments. The Strategy also provides sufficient flexibility for individual jurisdictions and health sector participants to determine how they implement eHealth solutions within a common framework and set of priorities. It recognises the current eHealth work program to be delivered through NEHTA and the need for other investments over a ten-year timeframe to deliver a full national eHealth capability. It also recognises the significant role of the market in delivering eHealth solutions that will respond to a dynamic health sector.

The key principles that underpin the Strategy’s approach to deliver Australia’s national approach to eHealth are around creating the necessary national infrastructure; using an approach heavily informed by stakeholder engagement; an incremental approach to implementation and adoption; recognising that different stakeholders will have different starting points; leveraging existing systems where appropriate; striking a balance in national alignment and local independence; and fostering relevant skills in the community.

In order to deliver the vision for eHealth, the Strategy recommends work be conducted in four major work streams: Governance; Foundations; eHealth Solutions; and Change and Adoption.

The Strategy focuses on the development of eHealth solutions in priority health areas that will provide the greatest tangible benefit to all Australians and their healthcare providers. The three categories of solutions identified as high priority by the Strategy are:

- Electronic information sharing.
- Service delivery tools.
- Health information resources.

Much of the Strategy’s foundation work for information exchange is funded and delivery is underway. The NEHTA work program funded to June 2012 is focused on achieving the foundations for information exchange to support eHealth solutions.

The foundations for a National eHealth system include:

- A system for uniquely identifying individuals, healthcare providers and the organisations in which they work.
- Authentication services to ensure that transactions are private, traceable and only conducted by known identities.
- Healthcare providers using computer software that meets common standards for communicating information such as Prescriptions, Referrals, Discharge Summaries, Pathology Result Reports and Diagnostic Imaging Result Reports.
- A robust privacy framework for the handling of personal health information.

The Strategy identified a national Individual Electronic Health Record (IEHR) System as a high priority. The Strategy envisaged the IEHR as:

*A secure, private electronic record of an individual’s key health history and care information. The record would provide a consolidated and summarised record of an individual’s health information for consumers to access and for use as a mechanism for improving care coordination between care provider teams.* [AHMC2008]

Since the Strategy was originally developed, the term ‘PCEHR’ is now preferred as it better aligns with the recommendations from the National
Health and Hospitals Reform Commission which recommended that a national approach to electronic health records should be driven by ‘the principle of striving to achieve a person-centred health system.’ [NHRR2009].

In 2010, the Government has invested 466.7 million in the first release of a PCEHR System.

**B.3 Experiences with PCEHR Systems in Australia**

Prior to 2010, a number of shared electronic health record systems have been developed. Consideration of shared electronic health records in Australia started with the National Electronic Health Records Taskforce (NEHRT) in 2000, which was commissioned by the Australian Government to consider the potential for a network of electronic health records. The recommendations of the NEHRT led to the creation of the HealthConnect program and work on a range of trials on PCEHR progressed initially through HealthConnect and MediConnect programs in Tasmania, Queensland, New South Wales, South Australia, Western Australia and the Northern Territory. In 2005 it was recognised that for eHealth to progress further in Australia, key infrastructure and standards were required, and NEHTA was established.

Since the HealthConnect days, a number of regional Shared Electronic Health Record (SEHR) Systems have continued, including:

- **GP Partners in Brisbane Health eXchange** — GP Partners, one of the divisions of general practice in Australia offers a variety of services to GPs within its remit. One of these services is a health information exchange, offering connectivity between 166 of the 800 GPs in the area, six local hospitals, allied care providers and residential care facilities. The GP Partners Health eXchange offers automatic notification to GPs when a health record is checked or updated with results from an investigation by another care team member, and is integrated into GPs’ Clinical Systems to minimise the disruption to GP workflows [GPP2008].

- **eHealth NT Shared Electronic Health Record** — The Northern Territory Department of Health and Families has been progressively implementing a SEHR across the NT. In rural and remote communities implementation activities are being coordinated with the accelerated rollout of the Primary Care Information System (PCIS). In urban communities, activities are being focused on aboriginal medical services and clusters of urban private general practices. Feasibility is being assessed for expanding the SEHR into regions of Western Australia and South Australia. A major new initiative is the implementation of a current health profile, updated automatically when the individual attends their principal primary care GP or health centre. Future plans include provision to store and update Healthcare Management Plans and the capacity for an individual to access their SEHR via the Internet [NTH2008].

- **Goldfields Esperance GP Network** — The Goldfields Esperance GP Network has implemented a Regional SEHR. The SEHR is part of the GoldHealth Network and is used to support Kalgoorlie-Boulder patients and currently connects local general practices, specialist practices, aboriginal community controlled health services, a major regional hospital, a district hospital, and an aged care facility.

- **Healthelink in NSW** — Healthelink is a SEHR operated by NSW Health in Maitland (Hunter Valley) and Western Sydney. As of November 2009 it had over 90,000 individuals enrolled and allows health information to be shared between GPs, Community Providers and Hospital-Based Providers. NSW Health is currently reviewing the future of this program in light of the PCEHR System.

- **Smart Health** — Smart Health Solutions provide a SEHR alongside other chronic disease information management and secure online solutions. Smart Health has existing SEHR implementations at Royal Adelaide
Hospital, The Alfred, New England (Armidale, Tamworth, Inverell and Moree Hospitals), St Vincent’s and Mater Health (Sydney). Additional implementation sites are also proposed or under development.

From the earlier HealthConnect trials, a range of independent evaluation reports have been produced. The findings documented in these reports are brought together in the overarching ‘Lessons Learned Report’ [DOHA2005a]. In addition to the needs for national infrastructure and standards, the major lessons learned include:

- **Feasibility:**
  - A SEHR System is technically feasible, but the underlying infrastructure and connectivity (including the availability of CISs particularly in hospital, access at the point of care and network and communications infrastructure) limited the success of most implementations.
  - While community pharmacists and GPs are currently better positioned technically to move towards SEHR than hospitals, specialists and other private providers, there will be change management and business process challenges for all.

- **Registration:**
  - While the full process of registering individuals for a SEHR is too time-consuming for most healthcare providers, the trust between healthcare providers and their regular patients means that individuals will be strongly influenced in their decision to participate by the attitude of their healthcare providers towards eHealth.
  - Succinct and audience-specific information should be provided before registration, with further information available to those seeking it.
  - A Health Summary with key clinical information should be established as early as possible and appropriately funded/resourced.

- **Consent:**
  - Consent models need to be simple and practically workable at the point of care.
  - Individuals preferred voluntary participation based on an ‘opt-in’ model for participation.
  - Individuals prefer to provide some form of ‘standing’ consent to nominated healthcare providers to have ongoing access to their record (rather than consent at every episode of care).
  - The most popular consent model for when a healthcare provider sends an individual’s health information to a SEHR was for the healthcare provider to assume consent unless the individual says ‘no’.
  - Some individuals may never be sufficiently comfortable to participate, even with the most stringent controls.
  - Most healthcare providers were concerned about the completeness of the SEHR if individuals withhold information.

- **Drivers for Adoption and Change Management:**
  - A critical mass of both individuals and healthcare providers is needed to deliver benefits efficiently. It is important to complete the care chain wherever possible — gaps in the electronic health record reduce the healthcare provider’s perceptions of the utility of the record.
  - The key to provider healthcare participation will be demonstrable benefits and seamless interaction (such as the creation of Event Summaries) through integration with their normal business processes. Use of their clinical system is preferred over a separate web based Internet interface.
- Where it meets an existing business need, healthcare provider engagement and change management is significantly easier.
- Successfully engaging healthcare providers and the provision of effective change management support is a critical success factor. Clinical champions and the Divisions of General Practice are key change management facilitators.

• Governance and Stakeholder Management:
  - There is a need to effectively engage stakeholder groups at both national and local levels that will facilitate strong governance and engagement with the national approach.
  - The roles of funder and stakeholder need to be separated in the governance arrangements.
  - Early and ongoing vendor engagement is required to test, deliver and maintain functionality.

A number of lessons learned are also reported in an evaluation of the NSW Healthelink system [KPMG2008]. The report highlighted that building a SEHR is technically feasible and that there is support from both individuals and healthcare providers for such systems. However, the report also highlighted that uptake was slower than expected due to a number of reasons:
  - Healthelink had not yet reached a critical mass of patients, and therefore did not yet contain sufficient information for its potential to be realised.
  - The process of accessing and using Healthelink was not yet seamlessly integrated into clinicians’ routine system processes. This reflects the decision of NSW Health to contain the degree of sophisticated functionality as part of its pilot risk management strategy.
  - Healthelink has experienced difficulties with some independent vendor software products that were not originally designed to accommodate a SEHR. This will remain an issue until the software products used by GPs are able to accommodate the requirements to transmit information to a SEHR.

B.4 International experiences

eHealth has been viewed as an integral element of health sector reform in many countries. Prominent programs include:

• **England:** National Health Service (NHS) Connecting for Health is an agency of the UK Department of Health, which was formed in 2005 to modernise the NHS ageing IT infrastructure. As part of that program, there is a driver for the creation of a national ‘spine’, which includes a clinician-oriented summary care record (SCR) and a consumer-oriented ‘healthspace’ portal that complements locally held electronic health records.

• **Scotland:** The Scottish NHS in 2006 introduced a national ‘Emergency Care Summary’, which is available for all individuals and accessible by after-hour clinics and emergency departments.

• **USA:** Historically, the US has been the source of notable electronic health record (EHR) success stories, including large institutional EHRs in Kaiser Permanente, Veterans’ Affairs, Intermountain Health and the Mayo Clinic. More recently, in order to realise the anticipated benefits of eHealth, the US Centres for Medicare and Medicaid Services have announced a proposed rule to implement the HI TECH provisions of the American Recovery and Reinvestment Act of 2009 that provide incentive payments for the ‘meaningful use’ of certified EHR technology. This funding includes funding for hospital and physician uptake of EHRs in their practices, but also is complemented by additional funding for a National Health
Information Network to link regional Health Information Exchanges to enable sharing of healthcare information.

- Canada: In 2005 the Canadian government created Infoway, a not-for-profit organisation that collaborates with the provinces and territories, healthcare providers and technology solution providers to accelerate the use of EHRs in Canada. A key part of the Infoway approach is to drive the creation of a Health Information Access Layer (HIAL) in each province.

There are also other notable national EHR implementation and adoption programs in Denmark, Germany, Singapore and Hong Kong.

A review of European initiatives [CSC2009] highlighted a number of key lessons from these programs:

- Implementation and adoption is more likely to be successful if it is viewed as a healthcare reform initiative, supported by technology. In particular, it is essential that the healthcare value of the shared record be understood at the outset of the program, be designed into systems as early as possible and continuously be re-assessed. Furthermore, as with many IT systems, those who create the data often bear the most significant costs, whereas those who use the data gain the benefit. Therefore, funding models need to reflect this difference.

- Early communication regarding privacy options is essential.

- An effective shared record depends on an effective form of unique patient identification.

- Certification of systems against nationally agreed standards is a ‘must have’ element of any successful program.

- A comprehensive communication and engagement strategy is essential.

- The more the implementation and adoption is linked to policy, the more successful the adoption will be.

A consistent finding across a number of international studies suggests that a ‘middle out’ approach based on collaboration between government, the ICT industry, and healthcare providers to create an evolving set of standards and promote dialogue across sectors is more likely to be effective [IOSP2008, JAMI2009]. Large scale implementations based on centrally procured systems tend to receive greater levels of resistance from the community and end up being much more expensive than initially predicted due to the high levels of customisation required. In contrast, bottom-up approaches relying on organic growth, while initially being cost effective by preserving existing systems and infrastructure, can lead to limitations on the information that can be captured and shared for the benefit of broader health outcomes.

Additional findings from other reports include:

- A report on the Danish shared record scheme found that increasing the level of complexity does not bring a corresponding increase in benefits [GART2006]. The report recommended focusing on a simple, basic design and concluded getting the level of functionality right is essential.

- A report on the UK SCR reiterated that achieving critical mass is essential as clinicians will stop using a system if they fail to find shared records within it [BMJ2010a]. The same report also found that implementing a shared SCR is a major socio-technical challenge, and harvesting benefits will be highly contingent on the abilities of clinical champions and change agents. These champions and change agents need to be able to bridge different stakeholder groups, negotiate complex interdependencies and tensions between groups and mobilise implementation efforts.
Appendix C  Key changes to address feedback

Since the publication of this document for public comment, a substantial amount of feedback has been received. The feedback was independently reviewed by Deloitte Consulting [DOHA2011c], who found that a number of common themes had emerged.

The Department and NEHTA have reviewed the feedback and updated the document. This section explains how the common themes identified by Deloitte have been addressed.

A number of other key changes have also been included in this document as a result of ongoing work by the Department, NEHTA, and the Department of Human Services. These changes include:

- The Department has released a Legislation Issues Paper [DOHA2011b] to seek feedback on key proposals for the legislative framework, which will support the PCEHR System. This version of the Concept of Operations has been aligned with the Legislation Issues Paper.

- The role of the Department of Human Services and the Medicare program, in particular, has been clarified and added to the sourcing model (see Section 8.3). Changes made to the Concept of Operations as a result of stronger involvement by the Department of Human Services include:
  - The registration process has been further refined (see Section 3.2.2).
  - The nature of the Medicare information that can be included in a PCEHR has been clarified (see Section 4.3.8).
  - A range of proof of record ownership services have been added to facilitate online and assisted registration processes (see Section 6.5.1).

- The approach to change and adoption has been updated by the Change and Adoption Partner (see Section 8.4).

- The approach to benefits and evaluation has been updated by the Benefits and Evaluation Partner (see Section 9).

Table 7: Summary of feedback and key changes by theme

<table>
<thead>
<tr>
<th>Summary of feedback received</th>
<th>Key changes made</th>
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<tbody>
<tr>
<td><strong>Access control, security and privacy</strong></td>
<td>The previous version of the Concept of Operations allowed individuals to control access to specific documents by marking them as either ‘general access’ or ‘limited access’. This feature continues in this version. The ability to control access to within a clinical document (e.g. a ‘procedure’, ‘medicine’) has not been added as access control is at the whole document level.</td>
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<td>Interest was expressed in the functionality enabling PCEHR consumers to be able to hide particular data types.</td>
<td>Many submissions from healthcare bodies and healthcare professionals requested that critical health care information (e.g. allergies) be made always available to healthcare personnel; however, there were a number of submissions from</td>
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<td></td>
<td>The previous version of the Concept of Operations ensured that the Shared Health Summary was always accessible and could not be marked for ‘limited access’. This position has not changed.</td>
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## Summary of feedback received

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<th>Key changes made</th>
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<tr>
<td>members of the public that supported having the ability to keep some data private.</td>
<td>The ability to mark a clinical document as 'no access' has been removed to ensure that all clinical documents in an individual's PCEHR are available in an emergency. Individuals will still have the option to mark clinical documents at either a 'general access' or 'limited access' level to control access to clinical documents in their PCEHR (see Section 5.5). Individuals will also have the ability to 'effectively remove' a clinical document from their PCEHR (see Section 5.5). Once a clinical document has been effectively removed from a PCEHR it is no longer considered to be part of an individual's PCEHR and is not accessible by either the individual or healthcare providers (including using emergency access). The individual may at a future point in time ask to have the clinical document restored to their PCEHR.</td>
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<tr>
<td>Questions were raised in submissions from members of the public over the sharing of information, which is marked as hidden. Concerns were expressed by healthcare bodies over the potential inability of healthcare professionals to view hidden information in an emergency event. Many submissions stated the opinion that provisions must be made to make all PCEHR information available to healthcare personnel when it is in the patient's best interest.</td>
<td>The audit trail contents have been further refined to be more clear about the contents of the audit trail and the extent of content which different types of users are permitted to see (see Section 5.7).</td>
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<td>Comments were made on the need to have an audit logging function, capturing any changes or updates to a consumer's PCEHR. Clarification was sought concerning what information is captured in the audit log and how long such information is stored.</td>
<td>Other changes include:</td>
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<tr>
<td>Many responses listed other suggestions or requests for clarification of access control, security and privacy details listed in the Concept of Operations.</td>
<td>• An online interactive tutorial has been added to complement other educational material to educate individuals about their options around personal control (see Section 5.5). • Access controls have been grouped into two categories around 'basic' and 'advanced' access controls. Due to the nature of the advanced controls, individuals will be required to complete the online interactive tutorial before accessing the advanced access controls (see Section 5.5). • The 'include' and 'exclude' lists have been simplified into a single 'access list'. The access list now also includes a time limit. Healthcare organisations, which have not accessed an individual's PCEHR in a period of time, will be automatically removed from the individual's access list.</td>
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### Summary of feedback received

### Key changes made

(see Section 5.5).
- An option has been included for the individual to choose to make Medicare information available (see Section 3.2.6).

### General design suggestions

Clarification was sought regarding how nominated providers will be regulated and controlled by the Australian Government, including whether there will be definitive criteria to become a nominated provider.

Concerns were raised that if the nominated provider pool includes self-identified skillsets then the information in the Shared Health Summary may become unreliable.

Many questions were raised regarding the details of the architecture of the conformant repositories.

Questions were raised regarding the performance, responsiveness and reliability of having multiple conformant repositories located across Australia.

Questions were raised regarding the potential risk of having a PCEHR or Shared Health Summary located on another conformant repository, which may be unreachable due to system or network error. The safety and legal risks of this situation were highlighted.

Many responses listed general suggestions or requests for clarification of design

With regard to conformant repositories, the model has not changed. The expectation is service level agreements will be put in place to ensure that operators of conformant repositories meet a minimum level of performance.

The Legislation Issues Paper has also sought input around the need for tighter regulation of conformant repositories. This is turn may result in additional requirements on conformant repository operators.

With regard to the Shared Health Summary, the previous version of the Concept of Operations had proposed the Shared Health Summary be held on the national repositories service. This position has not changed.

Other changes include:
### Summary of feedback received

Details listed in the Concept of Operations.

### Key changes made

- An administration portal and a contact management service (see Sections 6.3.6 and 6.4.7) have been added to the system to help service and support agents, authorised registration agent and call centre agents better support individuals and healthcare providers with their access to the PCEHR System.

- The change history view has been removed and the index view now includes an option to find amended clinical documents (see Section 4.4.1).

### Information model

<table>
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<tr>
<th>Questions were raised concerning the standardisation and completeness of the data that is collected.</th>
<th>Section 4.2 has been added to elaborating the information model of the PCEHR System. It provides general information about information flows, clinical document conformance levels, data quality, managing changes to clinical documents and retention of records.</th>
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<tr>
<td>Concerns were raised over the quality of entered data, in particular in relation to patient entered data.</td>
<td>The source of any data loaded into the PCEHR will be clearly identified, so that users can form their own opinion on the quality of the information. Also, as per the previous version of the Concept of Operations, individuals will be limited to entering specific information for sharing with their healthcare providers, including their medicines and allergies. Future enhancements may be made once more experience has been obtained from lead eHealth sites.</td>
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<td>Some submissions noted that not all demographics had been considered in the data collection model.</td>
<td>The participant details has been updated to include additional information about emergency contacts, other contacts, interpreter needs, information about the custodian of advance care directives and preferences around notifications (see Section 3.2.3).</td>
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<td>A number of submissions questioned the appropriateness of some of the nominated providers who would be responsible for creating and updating Shared Health Summaries</td>
<td>The model for nominated provider has been refined. Please refer to the text above in the general design suggestions on how this issue has been addressed.</td>
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<td>Many submissions listed the critical importance of some fields being included in the PCEHR and the Shared Health Summary (e.g. allergies).</td>
<td>The information model for Shared Health Summary has remained the same and still includes allergies / adverse reactions, medical history, medications and immunisations. Future work has been proposed to look at...</td>
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<td>Summary of feedback received</td>
<td>Key changes made</td>
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<tr>
<td>A number of submissions raised questions regarding the level of detail of the information to be collected for the Event Summary, Shared Health Summary and the Consolidated View. Requests for additional clarification were received regarding the functionality, completeness and logistics of the Event Summary, Shared Health Summary, Consolidated View and the supporting national repositories.</td>
<td>The information model for Shared Health Summary and Event Summary has not been updated. The consolidated view has been refined (see Section 4.4.2).</td>
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<tr>
<td>Clarification was sought of the guidelines and the quality assurance relating to the creation and modification of structured and unstructured data.</td>
<td>Section 4.2 has been updated to describe the approach to management of data quality. The approach to managing data quality includes data validation, metrics for measuring data quality and a change and adoption strategy to help healthcare organisations improve the quality of the data within their systems that feed the PCEHR System. Support for unstructured data remains in the interim, and will be transitioned out in the future as source systems become more capable.</td>
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| Many responses listed additional suggestions or requests for clarification around the information model. | Additional changes include:  
- The model for releasing pathology result reports has been enhanced to allow release by a range of providers who have access to the report (see Section 4.3.7).  
- Diagnostic imaging has been removed from the scope of the 1 July 2012 release until more work can be done with diagnostic imaging providers on defining a model of access.  
- Custodian information about advance care directives is now included as participant information, rather than as a clinical document (see Section 3.2.3).  
- The impact of withdrawal and re-activation of a PCEHR has been clarified (see Section 3.2.7). |

**Long term governance and sustainability**

| Concerns were raised that the PCEHR will not be adequately supported post 30 June 2012. | Long term governance and sustainability is out of scope for this document. |
### Summary of feedback received

| Requests were made for further information regarding ongoing funding plans for the PCEHR system. |
| Consumer and Healthcare Professional support: |
| A number of submissions expressed interest in how the ongoing consumer support requirements (e.g. call centres, management systems etc.) will be managed post 30 June 2012. |
| Questions were raised about the potential ongoing funding allocated for the remuneration of healthcare professionals who will be impacted by the PCEHR. |
| Uncertainty was expressed about who will be managing the systems and services (including data management and ownership) of the PCEHR post 30 June 2012. |
| Additional detail was sought about plans for ongoing consultation by the Federal Government with stakeholder groups. |
| A number of submissions noted that most healthcare professionals already use a health information management system. The opinion was expressed that unless the PCEHR obtains a large consumer base, many of these healthcare professionals may choose not to participate in the PCEHR system. |

### Key changes made

| The approach to ongoing funding for adoption is out of scope for this document. |
| The change and adoption partner will review issues around training requirements. |
| The benefits evaluation partner will review issues around the potential benefits and drawbacks of the PCEHR System. |

### Business adoption

A number of submissions expressed concerns that creating and maintaining records for patients for the purposes of the PCEHR system and the training required to do this will create a significant administrative overhead for healthcare professionals. Some submissions also highlighted that this increase in administrative overhead could jeopardise the uptake of the PCEHR by healthcare professionals. Many submissions noted that the cumulative extra time spent per day on PCEHR administration will decrease the volume of patients seen per day by each healthcare professional. A large number of submissions suggested that remuneration should be provided as a key incentive for adoption by healthcare professionals and requested further details of a remuneration plan.
Summary of feedback received

Policy and legislation

Requests for additional detail were received concerning the specific standards and policies relating to key health information and summaries.

Questions were received concerning the timeframe for the policy development as well as the specific details of the policies that will be used.

Requests were received for additional details of the legislation applying to: parental access; family circumstances; and carer and palliative care.

A number of submissions requested additional detail regarding the authorisation of guardians and their capacity to act on behalf of an individual. Questions were raised about the legislative requirements that will apply to the disclosure of sensitive information.

Policy and legislation are out of scope for this document.

The Department will provide further information around the development of policy and legislation.

Adoption of the ‘opt in’ model

A number of submissions from the healthcare bodies and healthcare workers and researchers groups expressed concerns that if the PCEHR is optional, a large portion of the general public will not immediately create a PCEHR. Depending on the timeframe for desired uptake, this may result in low healthcare provider confidence in the system.

Some submissions stated the opinion that generating a value proposition for general public consumers will be difficult with an ‘opt in’ model.

‘Many submissions suggested that an ‘opt out’ model would be a much more effective way to achieve uptake than the ‘opt in’ model.

Rejection of the use of the PCEHR by healthcare professionals. If consumer participation is low, there is less incentive for healthcare professionals to take the time to consider the PCEHR for each of their patients, as it will not have been created for the majority of patients. This in turn lowers the motivation for healthcare professionals to use the PCEHR.

The opt-in approach to participation has not changed as opt in is part of the ‘Personally Controlled’ concept.

The change and adoption partner will review strategies for driving uptake of the PCEHR System.

Implementation planning and road map

Many submissions noted concerns

An outline of the implementation plan has
<table>
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<th>Summary of feedback received</th>
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<td>regarding the tight timeframe for implementation of the PCEHR system and the additional cost of developing and implementing the system by the proposed date of 1 July 2012. Concerns were expressed regarding the quality of the system if it is rushed through to production release to meet the proposed implementation date. Many submissions requested further detail regarding the roadmap and upcoming milestones of the PCEHR system. Several submissions requested a target roadmap showing milestones, which will be relevant specifically to healthcare providers. A number of submissions raised questions regarding the robustness of the implementation planning.</td>
<td>been added to section 8.2.</td>
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<tr>
<td>Clarification was sought of details regarding the eHealth sites.</td>
<td>The list of lead eHealth sites has been validated via an implementation planning study process (see Section 8.5)</td>
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<tr>
<td>Many of the submissions raised questions relating to the cost of updating or changing existing healthcare information systems or infrastructure to meet the needs of the PCEHR system. Concerns were raised regarding the capital expenditure required to build conformant repositories. Details were sought regarding the system architecture requirements for healthcare providers to adopt the PCEHR system.</td>
<td>The approach to ongoing funding for adoption is out of scope for this document. A change and adoption partner will review issues around adoption requirements.</td>
</tr>
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</table>

### Rural, aged care, disability and mental health provisions

| A number of submissions stated the opinion that many rural areas will not have the technology infrastructure in place to ensure access and adoption of the PCEHR system by 1 July 2012. Some submissions stressed the importance of a targeted marketing communication strategy to engage with rural areas. It was noted that healthcare professionals in rural areas are less likely to have the administrative support required to cope with the added administrative overhead of the PCEHR system. | A Change and Adoption Partner has recently been appointed. More information will be forthcoming in this area from the Change and Adoption Partner. Support for adoption in rural and remote areas has been added to the list of priorities (see Section 3.2.4). |

| A number of submissions noted that for | The previous version of the Concept of |
### Summary of feedback received

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<th>Concept of Operations</th>
<th>PCEHR System</th>
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<tr>
<td>many older people the PCEHR would not be easily accessible due to a lack of familiarity with or access to the required technology.</td>
<td>Operations highlighted a range of options available for individuals who may not have access to a computer or lack computer literacy (see Section 3.2.5).</td>
</tr>
<tr>
<td>Some submissions raised questions regarding the provisions for consumers who are unable to manage their PCEHR due to disability or illness. Many submissions highlighted the importance of privacy regarding mental health issues to avoid any potential stigmatism regarding mental health conditions.</td>
<td>The Department is currently reviewing provisions around representatives, to ensure that individuals who are unable to manage their PCEHR are appropriately represented. The change and adoption partner will review change and adoption support measures required to support individuals with disabilities or whom may have specific needs around mental health.</td>
</tr>
</tbody>
</table>

### Secondary use of data

Concerns were expressed that the use of secondary data for research or audit purposes may breach the privacy of consumers. Questions were raised regarding the regulation of any data used for research purposes. Questions were raised regarding the Government’s intent to use the PCEHR’s data for other purposes. A number of submissions highlighted the potential benefits that could be obtained from having a large amount of healthcare data available. Examples given included the support of clinical research, clinical registries and public health planning. Concerns were expressed that secondary data from the PCEHR might not be accurate and consistent enough to use for research or audit purposes. It was noted that there are potential benefits for the secondary use of data in relation to immediate and extended family members, in particular, with respect to providing an awareness of genetic diseases. The Concept of Operations has been updated to reflect the current position on research uses of the data and other approved uses (see Section 5.2.3).

### Legal and liability

A number of submissions highlighted the critical importance of clearly defining the legal and liability implications of the PCEHR System. Questions were raised regarding the liability implications of hidden data within a PCEHR. Some submissions asked if healthcare professionals would be legally obligated to Consideration of legal and liability is in general out of scope for this document, However, some positions have been clarified. In particular, as outlined in Section 2.3, the PCEHR System is defined as an ‘information system’ and not a ‘communication system’. Therefore there is no obligation for a healthcare provider to
<table>
<thead>
<tr>
<th>Summary of feedback received</th>
<th>Key changes made</th>
</tr>
</thead>
<tbody>
<tr>
<td>read all patient entered data in the PCEHR. Concerns were expressed that the healthcare professional would be held liable for any critical information missed in patient entered data.</td>
<td>review an individual’s PCEHR outside of a consultation. Furthermore, there is no obligation to review an individual’s PCEHR before uploading a clinical document (although, there is an obligation to review an individual’s PCEHR before uploading a new Shared Health Summary).</td>
</tr>
<tr>
<td>A number of submissions stated the opinion that patients cannot be trusted to enter reliable data and therefore healthcare professionals should not be held liable for any information contained in patient entered data.</td>
<td>The position on consumer-entered information has not changed. Consumer entered information, including allergies and medications, will be available for healthcare providers to access (see Section 4.3.9). Depending on the context, reviewing this information with the individual during a consultation may be part of the healthcare provider’s duty of care.</td>
</tr>
<tr>
<td>Legal guardian representation: Several submissions requested clarification about potential issues relating to the PCEHR for patients who are currently considered under the legal representation of another person (e.g. minors, mentally disabled persons etc.) Questions were raised regarding a legal guardian’s responsibility and legal liability in the management of another person’s PCEHR</td>
<td>The Department is currently reviewing provisions around representatives, to ensure that individuals who are unable to manage their PCEHR are appropriately represented, including in situations where they may not have an authorised representative.</td>
</tr>
</tbody>
</table>

### Education for stakeholders

Many submissions sought further details about the stakeholder education strategy and how and when it would be rolled out to the general public. A number of submissions requested confirmation of the funding allocated for stakeholder engagement and training. As the PCEHR will be utilised by a range of diverse stakeholder groups, many submissions sought clarification that any training programs would reflect the specific needs of the end user. Many submissions highlighted the importance of stakeholder involvement and acceptance, and suggested that this could be generated by targeted media campaigns and education workshops. A Change and Adoption Partner has recently been appointed. More information will be forthcoming in this area from the Change and Adoption Partner.

### Interest in being more involved with delivery of the eHealth system

Some submissions noted their interest in | A Change and Adoption and a Benefits
<table>
<thead>
<tr>
<th><strong>Summary of feedback received</strong></th>
<th><strong>Key changes made</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>being involved with the marketing, communication and stakeholder engagement to ensure that benefits are understood and to improve change and adoption processes</td>
<td>Realisation Partner have recently been appointed. More information will be forthcoming in this area from these partners.</td>
</tr>
<tr>
<td>Many submissions expressed an interest in being involved in future consultations</td>
<td></td>
</tr>
<tr>
<td>A number of the submissions noted an interest in being involved in unit testing, interface testing and user acceptance testing</td>
<td></td>
</tr>
</tbody>
</table>

**Accessibility / considerations for people with limited or no access to a compute**

| Additional details were requested about the usability provisions for disabled and aged members of the community. | Accessibility considerations have been updated to reflect the web accessibility guidelines from the Human Rights Commission (See Section 3.2.5). |
| Many of the submissions offered suggestions relating to usability considerations for the PCEHR system’s user interface. | |
| Questions were raised regarding the customisation of the PCEHR system’s user interface to meet the special needs of some consumers. | |
| Clarification was sought regarding the provisions for vision-impaired consumers. | |

| Several submissions expressed the opinion that the Concept of Operations does not clearly address alternative access methods for individuals with limited or no access to a computer. | The section outlining how the PCEHR may be accessed in situations where an individual may not have a computer or have sufficient computer literacy has been updated (see Section 3.2.5). |
| A number of submissions stated that rural area access was a particular area of concern to them. These submissions highlighted the importance of consumer education and alternative access arrangements for rural communities. | |

**Integration with existing health care systems**

<p>| A number of submissions raised questions regarding the level of integration between the PCEHR system and existing healthcare systems. Concerns were expressed about the cost of changes to existing healthcare systems required to integrate with the PCEHR system. | The approach to ongoing funding for adoption is out of scope for this document. A Change and Adoption Partner has recently been appointed. More information will be forthcoming in the area of integration of existing systems. The standards and specifications, which system suppliers will need to implement, have been updated to reflect the outcome of the standards review (see Section 6). |
| Some submissions requested clarification about whether the PCEHR will replace | As indicated in Section 2.3, the PCEHR System is intended to complement and not replace... |</p>
<table>
<thead>
<tr>
<th>Summary of feedback received</th>
<th>Key changes made</th>
</tr>
</thead>
<tbody>
<tr>
<td>current healthcare systems.</td>
<td>replace existing clinical information systems.</td>
</tr>
<tr>
<td>Several healthcare providers raised questions regarding any future PCEHR requirements that they will need to consider when scoping future projects for their existing healthcare systems.</td>
<td>The list of potential future enhancements has been updated to include a number of new areas of opportunity (see Section 2.8).</td>
</tr>
</tbody>
</table>

**Platform mobility**

Some submissions suggested that the marketing potential and convenience of mobile devices would greatly assist with the change and adoption of the PCEHR system.

Some submissions highlighted the convenience of being able to access the PCEHR from a mobile device.

Mobile device based support is currently out of scope and proposed as a future work item. The decision to leave mobile devices as a potential future work item, rather than having it included in the system build for 1 July 2012, is based on security concerns with such devices.
Appendix D  Scenarios

D.1  Introduction

The following scenario is intended to illustrate how the PCEHR System can be used, to highlight the benefits and identify key questions for consultation.

Some of the key features demonstrated by this scenario include:

• How a healthcare provider can gain access to a PCEHR (see Scene 1).
• The type of information a healthcare provider can access (see Scene 1).
• Access to records by the individual (see Scene 3).

The benefits illustrated in this scenario include:

• How access to prior information streamlines the collection of an individual’s medical history (see Scene 1).
• How the PCEHR facilitates better continuity of care (see Scenes 2 and 4).
• How the PCEHR facilitates improved consumer participation in their healthcare (see Scene 3).

Note that this is a simple scenario intended to highlight some of the basic features of the PCEHR System. Some of the more complex features around access control settings are not illustrated in this scenario.

D.2  Frank Harding

Frank is a 62-year-old retired schoolteacher, who has decided to travel around Australia. Frank and his wife Daphne have just purchased a 4WD and campervan and have headed north from their home in Croydon in Victoria. He had been diagnosed with Type II Diabetes (Non-Insulin Dependent Diabetes) and moderate depression. Both conditions require monitoring and treatment modification. His initial anti-depressant (Prozac) was ineffective and resulted in a rash and vomiting. He is now on Metformin to manage his diabetes.

Frank has consented to have a PCEHR and has opted to use ‘basic access controls’.

Scene 1: Frank visits the Emergency Department in Cairns

While on his holiday in Cairns, Frank presents to the Cairns Emergency Department (ED) complaining of chest pain and presenting with shortness of breath and cough.

In the current system, the Cairns ED would need to rely on Frank’s memory for his medical history. At best, if the ED had time and Frank’s GP was contactable, the ED would phone Frank’s GP to find out his medical history.

With access to the range of new eHealth capabilities, the Cairns ED can use the healthcare identifiers service to quickly locate Frank’s IHI by using Frank’s Medicare Card and other identifying details (name and date of birth).

After locating Frank’s IHI, the local clinical system also identifies that Frank has a PCEHR. As Frank’s access controls permit any healthcare provider involved in his care to have access to his PCEHR, the Cairns hospital adds itself to his ‘access list’.

From now on, the Cairns Hospital can use the PCEHR System to locate Frank’s health information in a range of different repositories. This authorisation will remain in place until Frank revokes it (or for 3 years).

When the doctor is able to see Frank, he/she can view a copy of Frank’s Consolidated View. The Consolidated View includes the Shared Health
Summary from his regular GP in Croydon and also shows any new information about Frank’s allergies/adverse reactions, medicines and medical history that may have been collected in his PCEHR on his travels (e.g. Event Summaries from visits to walk in GP practices).

At the conclusion of Frank’s consultation in the ED, the emergency physician diagnoses Frank with pneumonia and prescribes a course of antibiotics. Frank’s Liver Function Test (LFT) performed at the hospital showed a mild out of range result. The LFT results were explained to Frank by the ED physician and Frank was advised to have a follow up LFT in 2 weeks. Frank’s Discharge Summary is sent to Frank’s regular GP in Croydon and a copy is uploaded to Frank’s PCEHR.

**Scene 2: Frank in Port Douglas**

Two weeks later while in Port Douglas, Frank is feeling better and remembers that he needs to have a pathology test done. Frank attends a walk-in GP clinic in Port Douglas to have his pathology test organised.

In the current situation, Frank would need to remember the name of the pathology test and the details of his episode of care within Cairns for the Port Douglas GP to undertake the right course of action.

With access to the range of new eHealth capabilities, the Port Douglas GP can access Frank’s PCEHR to locate the Discharge Summary from the Cairns ED. Then using the information from Frank’s Discharge Summary, the Port Douglas GP can request a LFT for Frank electronically.

At the conclusion of this consultation, an Event Summary is sent by the GP to Frank’s PCEHR.

**Scene 3: Coffs Harbour**

After a day in Port Douglas, Frank is not feeling up to doing the full lap of Australia, so he and Daphne head home to Croydon. While in Coffs Harbour, the GP office in Port Douglas calls Frank requesting him to come back for a follow up visit to review his results. The GP has also released the pathology results to Frank’s PCEHR.

Frank is now too far away from Port Douglas to return for his follow up appointment, so the practice recommends that he should see his GP back in Croydon as soon as he returns.

Ordinarily in this case Frank would not have direct knowledge of his health records. Using the PCEHR System, Frank is able to become more involved in his own care. Frank is able to use the consumer portal to view his health information and then look up online resources such as HealthInsite and LabTestsOnline to help him understand his condition and lab test results.

**Scene 4: Croydon**

On return to Croydon, Frank books an appointment with his regular GP to review his results.

Ordinarily, Frank’s GP would need to request a copy of Frank’s results from the pathology laboratory in North Queensland or have the pathology test repeated. In this case, by using the PCEHR System, Frank’s GP is able to locate Frank’s results quickly. Frank’s GP can also easily see the entire medical history of his journey from the PCEHR index view, including visits to other healthcare providers.

Frank’s GP recommends that Frank undertake a new course of antibiotics and gets some rest before heading west to Broome and the Kimberly.
## Appendix E  Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Access List</td>
<td></td>
<td>A list of participating organisations the individual has authorised to access their PCEHR. Each organisation includes a level of access: ‘general access’, ‘limited access’ and ‘revoked’. Individuals which have opted for only basic access controls will not be able to set the level at ‘limited access’ or ‘revoked’. These are advanced features only.</td>
</tr>
<tr>
<td>Advance Care Directive</td>
<td></td>
<td>An advance care directive is a statement by a competent person expressing decisions about his or her future care should he or she become incapable of participating in medical treatment decisions.</td>
</tr>
<tr>
<td>Australian Childhood Immunisation Register</td>
<td>ACIR</td>
<td>The Australian Childhood Immunisation Register is a national register administered by the Department of Human Services Medicare program that records details of vaccinations given to children under seven years of age who live in Australia.</td>
</tr>
<tr>
<td>Australian Health Practitioner Regulation Agency</td>
<td>AHPRA</td>
<td>The organisation responsible for the registration and accreditation of a range of healthcare professions across Australia.</td>
</tr>
<tr>
<td>Australian Organ Donor Registry</td>
<td>AODR</td>
<td>The Donor Register is the only national register for organ and/or tissue donation for transplantation. It is administered by the Department of Human Services Medicare program. The Donor Register keeps a record of the individual's donation decision and of the organ and tissue the individual agrees to donate.</td>
</tr>
<tr>
<td>Authentication</td>
<td></td>
<td>Validating that the user wishing to access the PCEHR is who they claim to be. In electronic environments this is achieved by providing a user with a credential such as a user-id + password, a smart card or a one time password device.</td>
</tr>
<tr>
<td>Authorised Registration Agent</td>
<td>ARA</td>
<td>An authorised registration agent is a role designed to support assisted registrations. Authorised registration agents may for example work within a Medicare shop front or call centre, or work within participating healthcare provider organisations (for example, in a maternity ward, aged care facility or aboriginal healthcare service).</td>
</tr>
<tr>
<td>Authorised Representative</td>
<td></td>
<td>A person empowered under a law of the Commonwealth, a State, or Territory to act on behalf of an individual.</td>
</tr>
<tr>
<td>Authorised User</td>
<td></td>
<td>A person authorised by the healthcare organisation to access the PCEHR System on behalf of the participating organisation.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>Availability</td>
<td></td>
<td>A measure of how long the system is scheduled to be accessible by users of the system.</td>
</tr>
<tr>
<td>Carer</td>
<td></td>
<td>A carer is an individual who provides personal care, support and assistance to another individual who needs it because that other individual: has a disability; or has a medical condition (including a terminal or chronic illness); or has a mental illness; or is frail and aged. An individual is not a carer in respect of care, support and assistance he or she provides: under a contract of service or a contract for the provision of services; or in the course of doing voluntary work for a charitable, welfare or community organisation; or as part of the requirements of a course of education or training. From <em>Carer Recognition Act 2010 (Cth)</em>.</td>
</tr>
<tr>
<td>Clinical Document</td>
<td></td>
<td>A clinical document is a document that provides personal health information about an individual. Examples include a Shared Health Summary, Event Summary, Discharge Summary, Referral, pathology result report, etc. For the purposes of the PCEHR System, all clinical documents must have the IHI of the individual within it. A clinical document from a healthcare organisation must include the HPI-O of the organisation and the HPI-I of the author. Clinical documents may also come from other sources, such as consumer entered health summaries and Medicare.</td>
</tr>
<tr>
<td>Clinical Document Architecture</td>
<td>CDA</td>
<td>A HL7 standard intended to specify the encoding, structure and semantics of clinical documents for exchange.</td>
</tr>
<tr>
<td>Conformant Portal Provider</td>
<td>CPP</td>
<td>A supplier of a consumer-oriented portal that is capable of connecting to the PCEHR System.</td>
</tr>
<tr>
<td>Conformant Repository</td>
<td></td>
<td>A repository that conforms to the appropriate PCEHR standards and specifications required to ensure interoperability, privacy, integrity and long term availability of the healthcare information it holds.</td>
</tr>
<tr>
<td>Consolidated View</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Contracted Service Provider</td>
<td>CSP</td>
<td>A third-party organisation that supplies health software as a service to healthcare organisations.</td>
</tr>
<tr>
<td>Council of Australian Governments</td>
<td>COAG</td>
<td>An organisation consisting of the federal government, the governments of the six states and two mainland territories and the Australian Local Government Association.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>Data Quality</td>
<td></td>
<td>The result of ensuring that data held in PCEHR has the necessary attributes including: accuracy, completeness, consistency, currency, timeliness, fitness for use, provenance and compliance.</td>
</tr>
<tr>
<td>De-identified Data</td>
<td></td>
<td>Data is de-identified when it is not possible to reasonably ascertain the identity of a person from that data. It is context dependent.</td>
</tr>
<tr>
<td>Department of Health and Ageing</td>
<td>DOHA</td>
<td>An Australian Government department. The Department of Health and Ageing has a diverse set of responsibilities and aims to deliver better healthcare services and support active ageing for all Australians.</td>
</tr>
<tr>
<td>Detailed Clinical Model</td>
<td>DCM</td>
<td>A common underlying information model used to ensure consistency of structured information and clinical terminologies between different types of structured clinical document.</td>
</tr>
<tr>
<td>Electronic Health Record</td>
<td>EHR</td>
<td>A repository of personal health information in a computer processable form. Its primary purpose is the support of continuing, efficient and quality healthcare. (Definition adapted from [ISO 20514].)</td>
</tr>
<tr>
<td>Electronic Transfer of Prescription</td>
<td>ETP</td>
<td>A NEHTA specification for supporting transfer of electronic prescriptions between prescribers and dispensers.</td>
</tr>
<tr>
<td>Emergency Access</td>
<td></td>
<td>Access to an individual’s PCEHR that may be obtained without explicit consent, where the individual is unable to provide consent and there is serious threat to life, health or public safety in accordance with the provisions of the National privacy Principles.</td>
</tr>
<tr>
<td>End Point Location Service</td>
<td>ELS</td>
<td>A NEHTA specification for locating the address for where secure electronic messages should be delivered.</td>
</tr>
<tr>
<td>Event Summary</td>
<td></td>
<td>A clinical document summarising one or more healthcare events.</td>
</tr>
<tr>
<td>Health Level Seven</td>
<td>HL7</td>
<td>A non-profit organisation involved in development of international healthcare informatics interoperability standards.</td>
</tr>
<tr>
<td>Healthcare Identifier Provider Directory Service</td>
<td>HI PDS</td>
<td>A voluntary provider directory service provided as part of the HI Service.</td>
</tr>
<tr>
<td>Healthcare Identifier Service</td>
<td>HI Service</td>
<td>The HI (Healthcare Identifier) Service enables consistent identifiers to be created for individuals and healthcare providers across the Australian health system through the introduction of unique healthcare identifiers — see IHI, HPI-I and HPI-O.</td>
</tr>
<tr>
<td>Healthcare organisation</td>
<td></td>
<td>Organisations that participate in providing health services to individuals.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Definition</td>
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<td>-------------------------------------------</td>
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</tr>
<tr>
<td>Healthcare Provider</td>
<td></td>
<td>A person who is involved in or associated with healthcare delivery. A synonym for clinician.</td>
</tr>
<tr>
<td>Healthcare Provider Identifier for Individuals</td>
<td>HPI-I</td>
<td>The Healthcare Provider Identifier for individuals (HPI-I) is a 16 digit unique number used to identify providers who deliver healthcare in the Australian healthcare setting.</td>
</tr>
<tr>
<td>Healthcare Provider Identifier for Organisations</td>
<td>HPI-O</td>
<td>The Healthcare Provider Identifier for Organisations (HPI-O) is a 16 digit unique number used to identify organisations who deliver care in the Australian healthcare setting.</td>
</tr>
<tr>
<td>Index View</td>
<td></td>
<td>A view listing all clinical documents available in a PCEHR.</td>
</tr>
<tr>
<td>Individual</td>
<td></td>
<td>People who are, or could be, seeking care in Australia. Individuals are sometimes referred to as patients, clients and consumers. For the purposes of the PCEHR System, an individual must have an IHI.</td>
</tr>
<tr>
<td>Individual Healthcare Identifier</td>
<td>IHI</td>
<td>The Individual Healthcare Identifier (IHI) is a 16 digit unique number used to identify individuals who receive care in the Australian Health system.</td>
</tr>
<tr>
<td>Information and Communication Technology</td>
<td>ICT</td>
<td>A generic name for both information technologies and communication technologies, and their convergence.</td>
</tr>
<tr>
<td>Interoperability</td>
<td></td>
<td>The ability of two or more systems or components to exchange information and to use the information that has been exchanged [IEEE90].</td>
</tr>
<tr>
<td>National Authentication Service for Health</td>
<td>NASH</td>
<td>A national digital credential management service for healthcare providers and healthcare organisations.</td>
</tr>
<tr>
<td>Nominated Provider</td>
<td></td>
<td>A nominated provider is the author of a Shared Health Summary. Requirements for nominated providers are outlined in Section 4.3.1.</td>
</tr>
<tr>
<td>Nominated Representative</td>
<td></td>
<td>A representative nominated by the individual to be able to view their PCEHR.</td>
</tr>
<tr>
<td>Notice of Connection</td>
<td>NOC</td>
<td>A notice issued by the PCEHR System operator indicating that a system is ready to connect to the PCEHR System.</td>
</tr>
<tr>
<td>Organisation Maintenance Officer</td>
<td>OMO</td>
<td>The role within an organisation responsible for maintaining information about the organisation within the HI Service, as defined in the Healthcare Identifiers Act (2010) (Cth).</td>
</tr>
<tr>
<td>Participating Organisation</td>
<td></td>
<td>A healthcare organisation, which chooses participate in the PCEHR System and meets the participation criteria.</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Definition</td>
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</tr>
<tr>
<td>PCEHR System</td>
<td></td>
<td>A system of systems used to manage a collection of PCEHRs.</td>
</tr>
<tr>
<td>Personal Health Information</td>
<td></td>
<td>Health Information as defined in the Privacy Act (Cth).</td>
</tr>
<tr>
<td>Personal Health Record</td>
<td>PHR</td>
<td>A Personal Health Record (PHR) is a type of EHR that is initiated by and under the control of the individual. The personal health information it contains is at least partly entered by the individual. (Definition adapted from [ISO 20514].)</td>
</tr>
<tr>
<td>Personal Information</td>
<td></td>
<td>Information or an opinion recorded about an individual whose identity is apparent, or can reasonably be ascertained.</td>
</tr>
<tr>
<td>Personally Controlled Electronic Health Record</td>
<td>PCEHR</td>
<td>A type of EHR that is initiated and personally controlled by an individual. Personal controls are specifically as outlined in Section 3.2.1.</td>
</tr>
<tr>
<td>Pharmaceutical Benefits Scheme</td>
<td>PBS</td>
<td>An Australian Government scheme aimed at providing all Australians with affordable access to a wide range of prescription medicines.</td>
</tr>
<tr>
<td>Privacy</td>
<td></td>
<td>As used in the context of this report, privacy refers to the collection of rights and obligations contained in the National Privacy Principles and the related Information Privacy Principles. These cover matters to do with collection and use, access, security and data quality.</td>
</tr>
<tr>
<td>Proof of Record Ownership</td>
<td>PORO</td>
<td>A process used to validate evidence (e.g. in the form of shared knowledge/secrets or documentary) and used to substantiate that the presenting party has an existing relationship with the relying party (i.e. is already the “owner” of a digital identity on the relying party’s system).</td>
</tr>
<tr>
<td>Provider Access Consent Code</td>
<td>PACC</td>
<td>A code (i.e. PIN or passphrase) an individual can provide to an authorised user in order to have the participating organisation added to the access list.</td>
</tr>
<tr>
<td>Provider Access Consent Code (extended)</td>
<td>PACCX</td>
<td>A code (i.e. PIN or passphrase) an individual can provide to an authorised user in order to enable the participating organisation to have access to ‘limited access’ clinical documents.</td>
</tr>
<tr>
<td>Registration</td>
<td></td>
<td>The processes associated with the creation by an individual of their PCEHR. Registration will include processes covering verification of identity and evidence of entitlement (i.e. meeting the criteria for participation, such as having an IHI).</td>
</tr>
<tr>
<td>Report</td>
<td></td>
<td>Data extracted from one or more clinical documents from one or more PCEHRs for reporting purposes.</td>
</tr>
<tr>
<td>Responsible Officer</td>
<td>RO</td>
<td>A person with authority to act on behalf of a healthcare organisation with respect to the HI Service, as defined in the Healthcare Identifiers Act (2010) (Cth).</td>
</tr>
<tr>
<td>Term</td>
<td>Acronym</td>
<td>Definition</td>
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</tr>
<tr>
<td>Royal Australian College of General Practitioners</td>
<td>RACGP</td>
<td>The professional body for General Practitioners in Australia.</td>
</tr>
<tr>
<td>Shared Health Summary</td>
<td></td>
<td>A clinical document summarising an individual’s health status and includes important information such as allergies/adverse reactions, medicines, medical history and immunisations. Only a nominated provider can create or update the Shared Health Summary.</td>
</tr>
<tr>
<td>Software as a Service</td>
<td>SaaS</td>
<td>Software that is either supplied as a cloud based service or deployed over the Internet to run locally. Licenses and support for SaaS systems are commonly provided on a subscription basis, but other models are also used.</td>
</tr>
<tr>
<td>Transferrable Access Key</td>
<td>TAK</td>
<td>A cryptographic key included in Referrals to authorise the Referral recipient to be added to the access list.</td>
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<td>View</td>
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<td>Data extracted from one or more clinical documents within an individual’s PCEHR for the purposes of supporting the information needs of an individual or healthcare provider.</td>
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## Appendix F  References

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<td>NEHT2010a</td>
<td>National E-Health Transition Authority, <em>NEHTA Detailed Clinical Model Specifications</em>.</td>
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<td>OASIS, Security Assertion Markup Language (SAML), Version 2.0 OASIS Standard, (Published as 8 multi-document sets), 15 Mar 2005 Available at: <a href="http://docs.oasis-open.org/security/saml/v2.0/saml-2.0-os.zip">http://docs.oasis-open.org/security/saml/v2.0/saml-2.0-os.zip</a></td>
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All information in this publication is correct as of September 2011