



**Response to Request for Comment  
on the  
Electronic Health Records and  
Healthcare Identifiers:  
Legislation Discussion Paper**

**V1.1 - June 2015**

Authored by Fellows and Members of the

**Australasian College of Health Informatics**

[Secretary@ACHI.org.au](mailto:Secretary@ACHI.org.au) [www.ACHI.org.au](http://www.ACHI.org.au)

## Index

INDEX .....	2
RECOMMENDATION SUMMARY .....	4
EXECUTIVE SUMMARY .....	7
1. INTRODUCTION .....	9
1.1 PURPOSE OF THIS PAPER.....	9
1.2 What is not in scope .....	9
1.3 How to provide feedback .....	9
2. BACKGROUND .....	11
2.1 Personally controlled electronic health record system.....	11
2.2 Review of the PCEHR system.....	12
2.3 Healthcare Identifiers Service .....	13
2.4 Review of the HI Service.....	14
2.5 Proposed changes .....	14
2.6 Timeframes.....	15
2.7 Consultation to date.....	15
3. LEGISLATIVE PROPOSALS: PCEHR SYSTEM AND HI SERVICE .....	18
3.1 Preliminary.....	18
3.1.1 Name of the PCEHR system .....	18
3.1.2 Definitions.....	19
3.1.3 Timing of amendments.....	21
3.2 Governance .....	22
3.2.1 Establishment of ACeH .....	22
3.2.2 HI Service Operator.....	24
3.3 Participation .....	24
3.3.1 An opt-out PCEHR system?.....	24
3.4 Obligations of parties .....	28
3.4.1 Obligation to enter into participation agreement.....	28
3.4.2 Centralising and simplifying participant obligations .....	30
3.4.3 Obligation for organisations to have PCEHR policy .....	30
3.4.4 Obligations on authorised and nominated representatives.....	31
3.4.5 Application of obligations on different types of entities.....	31
3.4.6 Obligations to use PCEHR system .....	31
3.4.7 Obligation for System Operator to notify decisions .....	32
3.4.8 Obligation for System Operator to retain records.....	32
3.4.9 Obligation for System Operator to provide system testing.....	33
3.5 Privacy .....	33
3.5.1 Notification of PCEHR use.....	33
3.5.2 Temporary suspension of access to a PCEHR .....	33

3.5.3	Collection, use and disclosure of information .....	34
3.5.4	Penalties for misuse of information .....	37
3.6	Reviews.....	38
3.6.1	Review of the legislative changes .....	38
3.6.2	Privacy Assessments of AHPRA.....	38
4.	NEXT STEPS.....	39
	APPENDIX 1: ACRONYMS AND KEY DEFINITIONS .....	40
	Contributors .....	43

© 2015 Australasian College of Health Informatics

*Referencing, indexing and quoting is encouraged with appropriate attribution.*

## Recommendation Summary

The Australasian College of Health Informatics (ACHI) welcomes this opportunity to comment on the "Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper" as requested by the Minister of Health The Hon. Sussan Ley MP in May 2015.

The College is the professional body for Health Informatics in the Asia-Pacific Region. The credentialed Fellows and Members of the College are national and international experts, thought leaders and trusted advisers in Health Informatics. ACHI sets standards for professional practice and education in Health Informatics, supports initiatives, facilitates collaboration and mentors the community. The Fellows and Members of the College are widely involved in e-Health research, standards development, system design and implementation work in Australia, the region and globally.

ACHI supports the Australian government's national health reform agenda as informed by the National Health and Hospitals Reform Commission, the Primary Health Care Reform Report and the National Preventative Health Strategy Roadmap. We welcome an agenda that aims to create an improved healthcare system that is safe, of high quality and which is transparent, accountable, affordable and sustainable. We strongly support the Commonwealth's intentions to trial and deploy advanced Information and Communications Technology (ICT) in healthcare to accelerate these improvements.

The College agrees that an Electronic Health Record (EHR) that is defined by evidence-based criteria and executed following technical best-practice is a vital component of delivering effective universal healthcare to the Australian People.

Therefore, the College welcomes the Minister's request to review the proposed Electronic Health Records and Healthcare Identifiers legislation as part of the refresh of the Australian Government's healthcare delivery strategy. The Fellows and Members of the College have reviewed the Electronic Health Records and Healthcare Identifiers review paper and have identified areas that may - if mitigated - critically improve the former PCEHR's ability to start contributing to delivering quality, safe, equitable and sustainable healthcare to all Australians.

In summary, the College believes that the current implementation of the PCEHR does not realise the benefits originally sought and expected. We have identified a number of changes and improvements that we believe are necessary if the goals originally envisaged are to be achieved. There are a number of areas where the College believes substantial improvements are possible and has formulated the following **30 immediately actionable recommendations** for the Minister's consideration:

**ACHI Recommendation 1:** *That the communications strategy for the My Health Record be reviewed and refreshed to ensure it reflect the reality of the current implementation.*

**ACHI Recommendation 2:** *That the Individual Health Identifier (IHI) be included in the PCEHR communications strategy as there is little information available on the use nationally of the IHI for all members of the population.*

**ACHI Recommendation 3:** *That the Department consider a description similar to "The individual may have easier access to more information than was previously available about her or his health status and health care. This may enable the individual, depending on her/his health literacy and interest, to become more actively involved in caring for her or his health." to describe the core purpose and function of the PCEHR.*

**ACHI Recommendation 4:** *That the Department investigate and consider reliable methods for individuals to ensure their records are complete.*

**ACHI Recommendation 5:** That the Department clarify if healthcare providers are required to upload all relevant information to the PCEHR following each encounter

**ACHI Recommendation 6:** That the Department investigate and consider processes for individuals to add or upload their own medical history so that they do not need to remember and reiterate key historical facts multiple times.

**ACHI Recommendation 7:** . That the Department advise if the current implementation of the PCEHR complies with the following Australia Standards:

AS/ISO 18308-2005 Health Informatics – Requirements for an electronic health record architecture  
Standards Australia HB137-2013 e-Health Interoperability Framework  
Standards Australia HB 138-2013 e-Health Architecture Principles

**ACHI Recommendation 8:** That the Department advise if the proposed PCEHR "opt out" will be directly linked to "usability" or only the rights of access and if the new governance arrangements include 'data governance' to ensure data integrity, quality and security.

**ACHI Recommendation 9:** That the Department advise if the current PCEHR implementation complies with the following Australian standards:

Standards Australia HB222-2006 Australian Health Care Client and Provider Identification Handbook  
Standards Australia AS4846-2014 Person and Provider identification in healthcare

**ACHI Recommendation 10:** That the Department provide more detailed information and references regarding the statement "risks and issues emerging that may require enhancement and adjustment of current processes and the associated legislative and regulatory framework. Twenty-four recommendations were made for improving the HI Service".

**ACHI Recommendation 11:** That the Department provide more details how the legislative changes/amendments fit into the time-frames for "clinical implementations".

**ACHI Recommendation 12:** That the Department review if the current PCEHR implementation is appropriate to fulfil the requirement to support the provision of care across all health care domains including the private sector.

**ACHI Recommendation 13:** That the department investigate and mitigate the risks of a widespread disconnect and "passive opt out" without any deliberate action or thought process by individuals.

**ACHI Recommendation 14:** That the department investigate and mitigate the risks of mismatching PCEHR records as well as medical identity theft.

**ACHI Recommendation 15:** That the Department advise if and how the PIA stakeholder consultations in 2009 have been incorporated into existing and proposed PCEHR/IHI legislation and if further PIAs about the PCEHR Concept of Operations been conducted and if so, advise of the findings.

**ACHI Recommendation 16:** That the Department consider revising the PCEHR's approach to interoperability (national and international), mandating compliance to an agreed set of standards by a given date and a Health IT governance strategy.

**ACHI Recommendation 17:** That the Department establish a program to mitigate identification problems with the new IHI to minimise the risk of adding to the number of patients suffering clinical misadventure in Australian healthcare facilities and that do with errors involving the IHI should be considered part of, and reported to, a comprehensive clinical error reporting system.

**ACHI Recommendation 18:** *That the Department consider utilising the Australian Institute of Health and Welfare (AIHW) definitions and governance for data elements such as "healthcare" and "health information" to ensure consistency when used in any context, eg legislation.*

**ACHI Recommendation 19:** *That the Department undertake a review of all overlapping and parallel legislation relevant to the PCEHR to ensure that inconsistencies in terminology and responsibility are remedied.*

**ACHI Recommendation 20:** *That the Department ensure that if drivers' licence, passport, Immicard and other personal identification information is added to the PCEHR, any risks for misuse by hackers and identity theft is mitigated.*

**ACHI Recommendation 21:** *That the Department consider that ACeH's brief include data governance and mandating compliance with any one or sets of Australian technical standards by a given date and that Consumers also be represented.*

**ACHI Recommendation 22:** *That the Department ensure a suitably qualified statutory authority such as ACeH effectively advise the COAG Health Council on national eHealth policy.*

**ACHI Recommendation 23:** *That the Department consider including senior expertise in health informatics, system architecture, networking, semantic interoperability, health data, system evaluation/testing/credentialing, etc. in the governance of ACeH.*

**ACHI Recommendation 24:** *That the Department advise if during the period of the trials any further PCEHR funds will be expended on consumer sign-ups.*

**ACHI Recommendation 25:** *That the Department advise the details of the design of the proposed PCEHR trials including descriptions of methodology, representativeness, statistical significance and agreed success criteria.*

**ACHI Recommendation 26:** *That the Department confirm who would be legally liable if some clinically significant information in the PCEHR has been removed by the individual and a clinician relies on it and treats accordingly, but a misadventure occurs.*

**ACHI Recommendation 27:** *That the Department consider that the current approach where the System Operator has a statutory liability for any loss directly attributable to any act or omission by the System Operator is retained.*

**ACHI Recommendation 28:** *That the Department consider mandating that a data breach notification must occur in all instances that contain unintended patient care error.*

**ACHI Recommendation 29:** *That the department ensure that every healthcare provider needs to have a data governance protocol for key transferable data as well as agreed data standards for such key data.*

**ACHI Recommendation 30:** *That the Department clarify if the obligation to use the PCEHR means that there are implications for not using the PCEHR if a healthcare provider does not believe the system will benefit the care management activities/processes of his patient(s).*

**The Australasian College of Health Informatics looks forward to further working with the Minister and her Department on improvements to the former PCEHR that will enhance achieving the common goal of better healthcare for all Australians.**

*(Note: Parts of the content of the Discussion Paper is reproduced for convenience only)*



**Australian Government**  

---

**Department of Health**

# **Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper**

## **Executive summary**

The Australian Government is proposing changes to the personally controlled electronic health record (PCEHR) system and the Healthcare Identifiers (HI) Service to increase the number of individuals and healthcare providers participating in the PCEHR system, increase the clinical utility and usability of the PCEHR system to support meaningful use by healthcare providers, and improve the overall operation of the PCEHR system and HI Service, and eHealth more generally. This paper discusses the legislative changes that are proposed to support these changes.

The primary change being considered is to the participation arrangements for individuals. The PCEHR system currently operates on an opt-in basis where individuals who want a PCEHR register for one and give consent for their information to be uploaded to their PCEHR by healthcare providers and Medicare. From 2016, trials of different participation arrangements for individuals will be undertaken in order to inform Government about future approaches to increasing individual participation in the system. An opt-out model of participation, as recommended in a review of the PCEHR system, will be included as part of these trials, that is, individuals in certain trial regions will automatically be registered for an eHealth record unless they advise that they do not want an eHealth record.

While opt-out participation means that the PCEHR system will no longer be relying on the consent of individuals but on legal authority, the system will continue to offer the same level of personal control over a PCEHR and will continue to give information the same level of privacy and security protection.

The PCEHR is not intended to replace the usual and existing clinical information and processes that are expected to be applied in the course of an individual's healthcare. Moving to an opt-out system is not intended to change the responsibilities of healthcare providers and the individual to ensure that relevant information is available.

The scope of 'healthcare' is proposed to be clarified to remove any doubt that health-related aged care services, disability services and palliative care are considered part of healthcare. This would

better reflect the reality of health delivery in Australia and would facilitate integration of health-related services and support improved continuity of care for patients.

Proposed changes to eHealth governance arrangements will streamline the existing mechanisms across all eHealth development and implementation, and improve key stakeholder involvement with the establishment of the Australian Commission for eHealth.

Other proposed changes would:

- clarify the data breach notification requirements to remove ambiguities of what constitutes a data breach and when parties need to provide notification;
- clarify how healthcare providers and other entities can handle healthcare identifiers and other information, ensuring information can be obtained and used as is required to support safe and effective information sharing and recording; and
- provide alignment with Government measures to standardise regulatory powers (recognising the Government's 2014 legislation to establish a regulatory powers framework), and to better reflect the rights of people with disabilities (recognising the Australian Law Reform Commission's 2014 report *Equality, Capacity and Disability in Commonwealth Laws*).

Finally, it is proposed that the PCEHR be renamed the My Health Record. It is considered that this name will better reflect the partnership between individuals and healthcare providers. There will be no reduction of the personal controls available for individuals to manage their PCEHR, and the system will continue to support the principle of placing individuals at the centre of their healthcare.

The Government is also considering whether changes to PCEHR system's penalty framework are necessary.

# 1. Introduction

## 1.1 Purpose of this paper

This paper is intended to provide a plain English description of the proposed changes to the legislative framework for the personally controlled electronic health record (PCEHR) system and Healthcare Identifiers Service (HI Service), and a brief analysis of why the changes are needed.

The purpose of the paper is to encourage discussion and support public consultation.

These proposed changes should not be considered final. During the process of legislative development further changes can arise as the result of consultation with the public and government agencies, privacy impact assessments and legislative constraints. The proposals are also subject to Government decision and Parliamentary agreement.

Particular issues are brought to the attention of readers using coloured breakout boxes, as follows:

**Example:** Yellow boxes provide examples of how particular changes would work in practice or the types of circumstances the changes are intended to address.

**Consider:** Green boxes identify matters on which stakeholder input is of particular interest due to legal and/or practical ramifications.

**Note:** Red boxes are provided to alert readers to important matters.

Acronyms and terms used in this paper are described at **Appendix 1**.

This paper does not discuss technical, administrative or other changes that may be made to the PCEHR system or HI Service.

This paper refers to an eHealth record as a PCEHR and not by its proposed new name My Health Record.

## 1.2 What is not in scope

This paper is intended to describe those components of the PCEHR system which require legislative support. It does not include information about the architecture and design of the PCEHR system.

Many aspects of the PCEHR system are determined by operational and technical requirements which do not need to be set out in the legislation.

## 1.3 How to provide feedback

Submissions must be provided in writing, and must identify the name/s of the party/ies and/or organisation/s they represent (if any), as well as contact details.

Submissions can be made by any of the following ways:

1. mail it to PCEHR/HI Discussion Paper Feedback  
Department of Health  
MDP 1003  
GPO Box 9848

CANBERRA ACT 2601

2. email it to [ehealth.legislation@health.gov.au](mailto:ehealth.legislation@health.gov.au)
3. upload it at [the eHealth website](#)
4. fax it to (02) 6289 5673.

Submissions will be made public and shared with other Commonwealth, state and territory government agencies to inform the development of the legislative changes. If you want your submission to remain confidential please mark the submission as such, and submitters should be aware that confidential submissions may still be subject to access under Freedom of Information law.

The closing date for submissions is **5 p.m. (Australian Eastern Standard Time), Wednesday, 24 June 2015.**

**Note:** Readers should note that submissions or comments will generally be subject to freedom of information provisions under the *Freedom of Information Act 1982*.

## 2. Background

### 2.1 Personally controlled electronic health record system

The PCEHR system was established by the *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act) and became available to the public on 1 July 2012. It is a national system for providing access to individuals' key health information, intended to:

- help overcome the fragmentation of health information in Australia;
- improve the availability and quality of health information;
- reduce the occurrence of adverse medical events and the duplication of treatment; and
- improve the coordination and quality of healthcare provided to individuals by different healthcare providers.

The PCEHR system builds on the foundation laid by the introduction of healthcare identifiers.

A PCEHR is an electronic summary of a person's key health information, assembled from information held by distributed participating organisations, known as registered repository operators, and the National Repositories Service operated by the PCEHR System Operator.

**ACHI Comment 1:** *The College notes that the current implementation of the PCEHR is a collection of documents and other bits of information rather than an "electronic summary of a person's key health information". We are concerned that this - in our view - false idea that the contents of the PCEHR have been summarised has been repeatedly promulgated and may indeed be one of the causes of widespread disappointment and resulting non-use of the PCEHR by clinicians. We recommend that the communications strategy for the My Health Record be reviewed and refreshed to ensure it reflect the reality of the current implementation.*

**ACHI Comment 2:** *The College notes that there is little information available on the use nationally of the Individual Health Identifier (IHI) for all members of the population and recommends that the IHI be included in the PCEHR communications strategy.*

The PCEHR system places the individual at the centre of their own healthcare by enabling access to important health information where and when it is needed by individuals and their healthcare providers. The individual can choose to limit access to their PCEHR and to particular documents in their PCEHR, can add their own health notes, and can remove documents from their PCEHR if they choose.

**ACHI Comment 3:** *The meaning of this statement is questionable and certainly not based on evidence. If patients are not at "the centre" of their health care now, who or what "is" at the centre of a person's health care? Does or can a person's health care even have a "centre"?*

*The College believes this claim is superficial, maybe even grossly overstated. It implies that having a collection of bits and pieces of data in their PCEHR in itself puts the patient much more in the driving seat and somehow enables the patient to know what she or he needs to do next. This ill-informed idea is deeply concerning. Simply having whatever information has been uploaded to a person's PCEHR is not enough in itself to "place the individual at the centre of their own health-care", because patients to widely varying degrees may need help from their regular GP and from other health professionals to interpret the (often "raw") clinical data in their PCEHR and to understand what it means for them.*

*The Department may wish to consider a description similar to "The individual may have easier access to more information than was previously available about her or his health status and health*

*care. This may enable the individual, depending on her/his health literacy and interest, to become more actively involved in caring for her or his health."*

*In essence, the current implementation of the PCEHR enables the person to view some of her or his own records that have been made by various health professionals and organisations (and uploaded by them), and it enables the person to allow other people, including health professionals who may be caring for them, also to view that information.*

*In this context, the College notes that there is lack of evidence regarding the reliability of sources and mechanisms of establishing an individual's health information, as the current implementation of the PCEHR does not guarantee the fidelity of uploads to the original clinical data, but relies on the reliability of data extracts and clinical systems vendor certification testing. We also note that currently there are no reliable methods for individuals to ensure their records are complete. In addition, it is unclear if healthcare providers are required to upload all relevant information to the PCEHR following each encounter at which the individual agrees to the upload.*

*The College notes that in the current implementation of the PCEHR, it does not appear to be possible for individuals to easily add or upload their own medical history so that they do not need to remember and reiterate key historical facts multiple times.*

Since it began operating, the PCEHR system has evolved and grown, providing new and enhanced capabilities, such as the Child eHealth Record and prescription/dispense records which were implemented in May 2013, and the capacity to include pathology and diagnostic imaging reports that were implemented in December 2014.

The PCEHR System Operator is the Secretary of the Department of Health.

**ACHI Comment 4:** *The College notes that the current implementation of the PCEHR has the characteristics of a document storage system and not those of a data/information management system. For example, is it possible for any emergency health care provider to view via the PCEHR a list of all prescribed medications, take up and compliance by any individual presenting in a hospital emergency department?*

## 2.2 Review of the PCEHR system

On 3 November 2013 the then Minister for Health and Minister for Sport, the Hon Peter Dutton MP, announced a review of the PCEHR system. The report, *Review of the Personally Controlled Electronic Health Record – December 2013* (PCEHR Review)<sup>1</sup>, was publicly released in May 2014.

The PCEHR Review found that there was overwhelming support for continuing the path of implementing a consistent eHealth record system for all Australians, but that a change in approach was needed to correct early implementation issues. The PCEHR Review made thirty-eight recommendations aimed at making the system more usable and able to deliver the expected benefits in a shorter period, including new governance arrangements, moving to an opt-out system, and improving usability for healthcare providers and individuals.

The Australian Government is responding to the recommendations of the PCEHR Review.

**ACHI Comment 5:** *THE College has identified that the current implementation of the PCEHR utilises standards developed by NEHTA in parallel to the work of Standards Australia IT-14 Committees as well as existing international standards which have long been incorporated into widely used software used by General Practitioners, hospital and the healthcare sector generally.*

<sup>1</sup> The report is on the [Department of Health website](#)

*The College queries if the current implementation of the PCEHR complies with the following Australia Standards:*

*AS/ISO 18308-2005 Health Informatics - Requirements for an electronic health record architecture*

*Standards Australia HB137-2013 e-Health Interoperability Framework*

*Standards Australia HB 138-2013 e-Health Architecture Principles*

**ACHI Comment 6:** *The College views The current PCEHR registration and uploading process appears to be cumbersome and time-consuming which not surprisingly led to a great reluctance for participation by GPs and other clinicians.*

*The College queries if the proposed PCEHR "opt out" will be directly linked to "usability" or only the rights of access? "Usability" relates to the core functionalities underlying "information management" not "document storage". Do these new governance arrangements include 'data governance' to ensure data integrity?*

*Refer to:*

*1: Hovenga & Grain, Health Information Systems in: Hovenga & Grain (Eds) Health Information Governance in a Digital Environment, IOS Press Amsterdam 2013*

*2: Leao BF. Terms of Reference for Designing the Requirements of the Health Information System of the Maputo Central Hospital and Preparation of the Tender Specifications. Geneva: World Health Organization. 2007*

*3: Hannan TJ, Celia C. Are doctors the structural weakness in the e-health building? Intern Med J. 2013;43(10):1155-64. Epub 2013/10/19*

*4: Tierney WM., Kanter AS., Fraser HSF., C. B. A Toolkit For eHealth Partnerships in Low-Income Nations. Health Affairs. 2010;29(2):268-73*

## 2.3 Healthcare Identifiers Service

The HI Service was established by the *Healthcare Identifiers Act 2010* (HI Act) and commenced on 29 June 2010. It is a national system for consistently identifying individuals, healthcare providers and healthcare provider organisations.

The HI Service is an initiative of the Council of Australian Governments as part of accelerating work on a national electronic health record system to improve safety for patients, to support safe and efficient sharing and storage of health information and increase efficiency for healthcare providers. It is jointly funded by the Commonwealth, states and territories.

As a foundation service to other eHealth measures, the HI Service is an important step in realising the benefits expected to be derived from eHealth. Communication of health information is a vital part of effective healthcare, and the accurate identification of individuals, individual healthcare providers and healthcare provider organisations is critical in all health communication. Mismatching of patients with their records and results is a documented problem for the health system and a clear link has been established between avoidable harm to patients and poor medical records management.

Using an individual healthcare identifier provides a way for healthcare providers to more accurately match the right records to the person they are treating and improve accuracy when communicating information with other healthcare providers. This helps to avoid medical mix-ups or one person's information being recorded on another patient's file.

Using healthcare identifiers for healthcare providers and organisations supports secure messaging between providers by providing a consistent identifier for e-communication; facilitates electronic

communications between providers by providing a way for providers to look up contact details of other providers; and supports implementation of a security and access framework to ensure authentication of providers who access national eHealth infrastructure.

Healthcare identifiers are part of the core national infrastructure required to support secure electronic communications across Australia's healthcare system.

The HI Service Operator is the Chief Executive Medicare.

**ACHI Comment 7:** *The College queries if the current PCEHR implementation complies with the following Australian standards:*

*Standards Australia HB222-2006 Australian Health Care Client and Provider Identification Handbook*

*Standards Australia AS4846-2014 Person and Provider identification in healthcare*

*Refer "The Unique Health Identifier. Essential to Australian health care.....or not?" The Informatics Insider, June 2010 No. 1*

## 2.4 Review of the HI Service

Section 35 of the HI Act requires that an independent review of the HI Act and regulations be conducted after two years of operation, and this review commenced in October 2012. The *Healthcare Identifiers Act and Service Review – Final Report, June 2013* (HI Review)<sup>2</sup> was delivered on 25 June 2013.

The HI Review found that the core functionality of the HI Service is operating and working effectively. It acknowledged that the development and implementation of a national HI Service is a significant achievement given its scale, complexity and importance to the delivery of a national eHealth system. The HI Review noted that, as the system is being implemented and is now impacting directly on clinical workflow, there are some risks and issues emerging that may require enhancement and adjustment of current processes and the associated legislative and regulatory framework. Twenty-four recommendations were made for improving the HI Service.

The Commonwealth, states and territories are responding jointly to the recommendations of the HI Review.

**ACHI Comment 8:** *Can the Department provide more detailed information and references regarding the statement "risks and issues emerging that may require enhancement and adjustment of current processes and the associated legislative and regulatory framework? Twenty-four recommendations were made for improving the HI Service"*

## 2.5 Proposed changes

The changes proposed in this paper are primarily the result of recommendations made by the HI Review and PCEHR Review. Changes have also been identified through administrative and operational experience with the HI Service and PCEHR system by government and non-government entities.

The changes proposed will require amendment to legislation to have effect, namely:

<sup>2</sup> The report is on the [Department of Health website](#)

- *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act);
- *Personally Controlled Electronic Health Records Regulation 2012* (PCEHR Regulations);
- *PCEHR Rules 2012, PCEHR (Participations Agreements) Rules 2012* and *PCEHR (Assisted Registration) Rules 2012*, collectively referred to as the PCEHR Rules;
- *Healthcare Identifiers Act 2010* (HI Act); and
- *Healthcare Identifiers Regulations 2010* (HI Regulations).

Consequential amendments are also proposed to be made to the *Privacy Act 1988* (Privacy Act), *Health Insurance Act 1973* and *National Health Act 1953*.

## 2.6 Timeframes

The amendments to legislation are proposed to be made in late 2015, subject to Parliamentary passage.

**ACHI Comment 9:** *The College queries where these changes/amendments fit into the timeframes for "clinical implementations".*

## 2.7 Consultation to date

Stakeholder consultation on the recommendations of the PCEHR Review was undertaken in July to September 2014. The key objectives of the consultation were to understand stakeholder views in order to inform system design, implementation and communications planning, risk management planning for the implementation of the key PCEHR Review recommendations, and to identify what needs to be changed to prepare the PCEHR system for national and ubiquitous adoption and use.

Consultations were conducted using thirty-seven face-to-face workshops with large and small groups. This was supplemented with a small number of group teleconferences with selected stakeholder groups who were not easily able to attend the workshop sessions. Workshops had a diversity of stakeholder groups including:

- individuals;
- healthcare providers (including general practitioners, specialists, allied health practitioners, pharmacists and nurses) working in primary and acute care settings;
- health software vendors;
- private health insurance providers;
- medical indemnity insurance providers;
- private hospital representatives; and
- healthcare providers and community workers working with Indigenous and remote communities.

Stakeholders expressed strong support for the continued operation of a national shared electronic health record system and for the findings of the PCEHR Review. In particular, there was strong support for the move to an opt-out system accompanied by an effective public awareness and education campaign, and for retention of the current personally controlled nature of the record.

Key learnings from the consultations are described below:

- Individuals and clinicians want to see more representation of their voices and experiences in the ongoing design and implementation of the PCEHR system. They don't necessarily

want a seat on the board of the governing body but do want to ensure that there are mechanisms by which different perspectives, impacts and expertise can be fed into the governance process through effective consultation.

- There is considerable uncertainty in the clinical and vendor community about the future of the PCEHR system. More concrete actions are required to get stakeholders involved in progressing the adoption of the PCEHR system as an ongoing element of the Australian health system.
- Consultations highlighted that knowledge and understanding of the PCEHR system is patchy at best across all stakeholder groups and is particularly poor amongst the general public. While awareness is better amongst healthcare providers, the perception of the PCEHR system is quite poor, and its benefits are not generally understood nor accepted at the current time. Awareness raising will be particularly important ahead of any proposed introduction of an opt-out model.

**ACHI Comment 10:** *The College notes that these statements are incongruent with this opening statement regarding "overwhelming support" for the PCEHR. The College further notes that according to DoH statistics, clinicians have the lowest uptake/involvement in the PCEHR.*

*The PCEHR can only be effective if all healthcare providers participate. Consumer experience indicates that the PCEHR is currently often ineffective, as healthcare providers cannot rely\*on information previously uploaded to an individual's PCEHR being complete.*

\* Refer: <http://aushealthit.blogspot.com.au/2015/06/there-are-large-number-of-attributes-of.html>

- In general, individuals understand when the purpose and intent of the PCEHR system is carefully explained. This suggests that an information campaign that is benefits-focused and clear about what they need to do will be necessary.
- Like the general public, clinicians need to see the benefits of the PCEHR system and they need to understand that there is a pathway to improving the functionality and utility of the existing system. They also need supporting materials in order to assist them in discussing the impact of the opt-out model with individuals because the consultation suggests that many individuals will turn to their general practitioner for advice.
- While the majority of stakeholders strongly supported the move to an opt-out model, concern was raised about precisely how an opt-out model might be designed and implemented. Careful design of the opt-out model will be required to manage stakeholder concerns and to ensure stakeholders clearly understand how and why the opt-out model will be introduced.
- While many individuals did not consider that they would necessarily use the access controls and notifications provided in the PCEHR system, they all acknowledged the need for these controls to be retained. Individuals stressed the need for simple mechanisms.
- Meaningful use of the PCEHR system for healthcare providers will be driven by the utility and content of the PCEHR. This will require a focus on improving the usability of the PCEHR system, addressing accessibility issues for those segments of the healthcare provider community such as allied health practitioners who aren't well served with PCEHR compliant software solutions, and a concerted effort to drive provider participation.
- Most stakeholders were comfortable with the types of content that the PCEHR system can currently hold, however there was concern that very little of this content is being uploaded. It is therefore important to drive population of PCEHRs.

- The introduction of the PCEHR system into clinical practice requires a complex registration process, implementation of new software capabilities and changes to clinical practice. To enable individuals and healthcare providers to start using the PCEHR system they will need access to local support capabilities that will provide the on-the-ground help they need.
- The current roll-out of the PCEHR system seems to have bypassed the private hospital sector. Getting this sector more involved, understanding its drivers and involving its representation in clinical advisory committees will be necessary to ensure completeness of coverage and benefit for individuals.

**ACHI Comment 11:** *The College queries if there is a problem with how the implementation was planned as care should be delivered across all health care domains. The question is not one of whether the private sector should be involved (it must be) but if the current PCEHR implementation is appropriate to fulfil this requirement.*

- Vendors consider that greater use can be made of international standards rather than having to adopt standards specifically designed in Australia. They also want more stability around standards, and want to know in advance when they will be introduced or changed and what they will contain so they can plan their business accordingly.

**ACHI Comment 12:** *The College believes that there are very few incentives for patients to engage with the current implementation of the PCEHR, as there is no meaningful patient engagement in the system to make this worth their effort. The current implementation is an adjunct record to clinical notes, consumes ongoing resources with few demonstrable outcomes and the current PCEHR patient portal provides access to information that is generally of little value to improve health outcomes. So what is in it for patients?*

*The College observes that there is increasing anecdotal evidence that "passive opt out" will increase, e.g. as government-sourced patient data (MBS, PBS, etc.) populates the record and patients do not engage with their record, any errors will persist in the PCEHR system\*.*

*Most Australians are still unaware that they have a national healthcare identifier (Individual Health Identifier - IHI), are not aware of the national eHealth record system (PCEHR) despite the past promotional activity and may therefore not understand that it is planned that they will be automatically opted into a PCEHR trial. The College is concerned that this lack of understanding may result in a widespread disconnect and "passive opt out" without any deliberate action or thought process by individuals.\*\**

*The learnings listed above appear to rely on "information sessions" and a "marketing" approach rather than solid research querying the fundamental issues. While an effective information and education approach is needed, fixing the technical usability and confusion surrounding the current situation would seem to be a priority.*

*Mismatching records is poor medical record management. Therefore, other identifying elements such as date of birth, mother's maiden name or a similar set of identifying questions as banking uses would be essential to confidently identify the individual receiving healthcare services. However, medical identity theft becomes an issue. A repository containing such a rich source of identifying information would need to be extremely secure. One would expect that the security levels needed and the time to navigate this to ensure the safe management of this data may well discourage legitimate users.*

*Medical identity theft is a huge problem. Research indicates that in the US there were 1.3 million occurrences of this in 2009\*\*\*. This has risen to 2.3 million in 2011 and criminal attacks on this data up 125% in five years. Victims pay an average of \$13500 each to amend and fix these attacks on their personal data.*

\* Paul Madden, DoH, 18/6/15

\*\* The Australian general public's perceptions of having a personally controlled electronic health record (PCEHR), Andrews L., Gajanyake R., Sahama T., International Journal of Medical Informatics, Volume 83, Issue 12

\*\*\* Dr Ashish Jha (Harvard), Healthcare IT News 4/6/2015

**ACHI Comment 13:** *The College queries how the PIA stakeholder consultations in 2009\* been incorporated into relevant PCEHR/IHI legislation. Have further PIAs about the PCEHR Concept of Operations been conducted and if so, where are the findings? What evidence was produced and how were these PIA findings incorporated into relevant legislation?*

\* 2009 NEHTA IHI PIA Consult; Galexia PIS Consult 2009; Mallesons PIA Consult 2009; Clayton Utz 2009)

**ACHI Comment 14:** *The College notes that fundamental issues relating to interoperability (national and international) are relevant but may not have been considered. There also needs to be mandated compliance to an agreed set of standards by a given date and a Health IT governance strategy. The College believes that system designers and software developers will not create standards-compliant systems otherwise.*

**ACHI Comment 15:** *Consideration should also be given to who should be able to upload information to the PCEHR. Are "health practitioners" limited to persons with recognised clinical qualifications and who may be registered by the Australian Health Practitioner Regulation Agency (AHPRA)? There are other practitioners in healthcare who may expect to be able to upload information to their "patient/client's" PCEHR. The College seeks clarification how recognised health professional groups who are not under AHPRA can more easily gain access to the PCEHR for their members.*

### 3. Legislative proposals: PCEHR system and HI Service

#### 3.1 Preliminary

##### 3.1.1 Name of the PCEHR system

As recommended in the PCEHR Review<sup>3</sup>, the name of the electronic record should better reflect the partnership between individuals and their healthcare providers, and recognise that there is a shrinking need to differentiate between digital and physical sources.

The Department undertook consultations and focus group testing which indicated that My Health Record is generally considered to be a simple and easily remembered name.

It is proposed that the PCEHR be renamed the My Health Record. All references to "PCEHR" and "PCEHR system" in legislation will be amended accordingly.

Further, to remove any risk of confusion, the name of the PCEHR Act will be renamed the My Health Record Act.

This paper will continue to refer to the PCEHR system.

<sup>3</sup> PCEHR Review, recommendation 1

### 3.1.2 Definitions

#### Alignment between HI and PCEHR Acts

Currently, “consumers” in the PCEHR Act and “healthcare recipients” in the HI Act are defined to mean the same thing. That is, “an individual who has received, receives or may receive, health-care”. The policy is to align this terminology in both Acts and subordinate legislation, using either “healthcare recipient” or “individual”.

#### Clarification of “healthcare”

Currently, “healthcare” in the PCEHR Act and the HI Act and “health service” in the *Privacy Act 1988* (Privacy Act) are defined to mean the same thing.

The Australian Law Reform Commission (ALRC) report of August 2008 recommended that the meaning of “health service” be amended to, among other things, include “a health-related disability, palliative care or aged service”.<sup>4</sup>

The HI Review recommended that the scope of the use and disclosure of healthcare identifiers make clear that it includes aged care and disability programs.<sup>5</sup>

To give effect to the HI Review recommendation and consistent with the ALRC recommendation, the definition of “healthcare” in both the HI Act and the PCEHR Act is proposed to be amended to cover health-related disability, palliative care or aged care services.<sup>6</sup> Further, it is proposed to make a number of other minor changes, such as including assessment and treatment of “injury” (in addition to the existing “illness and disability”), and allowing regulations to be made to exclude activities from being “healthcare” because they are performed for reasons other than care or treatment, such as for the purpose of life, health or other insurance. This would ensure the range of entities that fall within the definition of a “healthcare provider organisation” includes aged care, palliative care and disability service providers.

Given the need to have consistent definitions of “healthcare” in the PCEHR Act and HI Act, and “health service” in the Privacy Act, it is proposed to make consequential changes to the Privacy Act so that the current alignment of definitions between the three Acts continues. This would ensure that common definitions apply regardless of whether a healthcare provider is using the PCEHR system or is providing services other than by way of the PCEHR system.

The definition of “health information” in both the PCEHR Act and the HI Act is also proposed to be clarified by expressly providing that health information includes information about the *physical, mental or psychological* health or disability of an individual, and is not limited to just information about physical matters.<sup>7</sup>

Minor changes would be made to the definition of “health information” in both the HI Act and the PCEHR Act to reflect the changes being made to the definition of “healthcare”.

---

<sup>4</sup> Recommendation 62-2, Australian Law Reform Commission Report 108, *For Your Information: Australian Privacy Law and Practice*, May 2008

<sup>5</sup> HI Review, recommendation 14(h)

<sup>6</sup> By qualifying “disability, palliative care or aged care services” with the words “health-related”, the ALRC accepted the Privacy Commissioner’s views that not all disability, palliative care or aged care services are concerned with an individual’s health, injury or disability and, as a result, only health-related services should fall within the definition of “health service” (or “healthcare” under the PCEHR Act and HI Act)

<sup>7</sup> This change was also recommended by the ALRC and was accepted by the previous Government

**Consider:** The PCEHR Act definitions for “healthcare” and “health information” should align as closely as possible to those equivalent terms in the Privacy Act to ensure the PCEHR system is consistent with the operation of the Commonwealth privacy framework. If we do not amend the Privacy Act, inconsistencies would arise and healthcare providers could be subject to different privacy arrangements depending on whether or not they are using the PCEHR system.

**ACHI Comment 16:** *Regarding identification problems with the new IHI, the College understands that these are now substantially reduced.\* However, there is still a concern about a residual risk of misidentification that may add to the number of patients suffering clinical misadventure in Australian healthcare facilities.*

**ACHI Comment 17:** *The College notes that the Australian Institute of Health and Welfare (AIHW) provides definitions and governance for data elements such as “healthcare” and “health information” to ensure consistency when used in any context, eg legislation.*

**ACHI Comment 18:** *The College suggest a review of all overlapping and parallel legislation to ensure that inconsistencies in terminology and responsibility are amended would seem well overdue. The States and Territories should also be encouraged to review legislation that governs healthcare, privacy and other related matters. Commonwealth legislation affects the PCEHR, but State based legislation also governs the way information is handled in each State.*

### Distinguishing between healthcare providers and organisations

The HI Act currently defines “healthcare provider” to include both healthcare provider organisations and individual healthcare providers. As a result both information and identifiers of organisations are given the same level of privacy protection as individuals. This differs from the treatment of organisations under the Privacy Act which does not consider information about organisations to be personal and, as a result, does not regulate information about organisations.

The HI Review recommended that healthcare provider organisations be distinguished from individual healthcare providers, and that healthcare provider organisations’ healthcare identifiers not be given the same privacy protections as those for individual healthcare providers and individuals.<sup>8</sup>

It is proposed that all provisions make clear whether they apply to healthcare provider organisations and/or individual healthcare providers, and that information about healthcare provider organisations, including their healthcare identifier, no longer be treated as personal information.

**Example:** This change would make it easier to promote organisations that are registered with the PCEHR system. The PCEHR System Operator could publish a list of healthcare provider organisations that participate in the PCEHR system. This would inform individuals who want to receive healthcare by a healthcare provider who can include information in their PCEHR.

<sup>8</sup> HI Review, recommendations 12(a) and 14(f), respectively

**ACHI Comment 19:** *The Australian Institute of Health and Welfare (AIHW) has identified and defined terms such as "healthcare provider" standard data elements in its METeOR data dictionary. The College recommends that these data standards be used in any relevant legislation. The College also recommends that the PCEHR and related systems be compliant with standard data elements as published in METeOR.*

*The College supports that the registration of organisations and health care providers would help weed out the non-clinical "health provider organisations" which may see access to individuals' records as a marketing opportunity.*

### Expanding "identifying information"

The PCEHR Act and HI Act both prescribe information that is considered "identifying information" of individuals, healthcare providers and healthcare provider organisations, such as name and address. Identifying information can only be collected, used or disclosed in certain situations, and improper collection, use or disclosure of identifying information can incur a criminal penalty.

A telephone number is defined to be identifying information of an individual healthcare provider but not an individual. Further, the definition of "identifying information" in relation to individual healthcare providers and healthcare provider organisations allows regulations to be made to prescribe additional information that is identifying information. However, it is not possible to make regulations prescribing additional identifying information for individuals. These restrictions are preventing the handling of information in ways that would enhance the utility of the PCEHR system. For example, it is not currently possible to collect and use individuals' mobile telephone numbers or email addresses to enable the PCEHR System Operator to send them messages.

It is proposed that the definition of "identifying information" in relation to an individual include this regulation-making power. Such a regulation-making power would provide flexibility for the PCEHR System Operator and/or the HI Service Operator to collect additional information if it is necessary. For example, it is intended that regulations be made that would prescribe the following information as identifying information:

- a mobile telephone number and email address – this would allow the System Operator to collect and use this information to notify individuals of access to their PCEHR or other matters by email or SMS, rather than by post, in accordance with the individual's preferences;
- the status of an individual's healthcare identifier (IHI) – this would improve the ability of the HI Service Operator to manage an individual's choice to opt-out;
- the unique reference number of the individual's driver licence, passport or Immicard, and the type of credential (driver licence, passport or Immicard) – this would allow the PCEHR System Operator to collect this information, and disclose it to the Document Verification Service, in order to verify the identity of an individual who chooses to opt-out. The System Operator will not store this information once it has been used to verify the individual's identity.

**ACHI Comment 20:** *The College is concerned regarding the "scope creep" of the PCEHR as detailed above.*

*Whilst including telephone numbers to verify and contact individuals properly the prospect of adding drivers' licence, passport, Immicard or whatever provides a potentially rich source for hacking and identity theft.*

### 3.1.3 Timing of amendments

The amendments to the PCEHR Act and HI Act are generally proposed to commence upon Royal Assent, except where otherwise specified in this paper.

## 3.2 Governance

The PCEHR Review identified serious concerns with current eHealth governance arrangements. It found that significant change is needed on the basis that existing arrangements:

- (a) do not reflect the representation of the expected users of the system, including clinicians and healthcare providers, within the governance framework;
- (b) do not have the confidence of the sector;
- (c) are duplicative, overly complicated and bureaucratic in nature; and
- (d) do not effectively balance the needs of government and private sector health organisations.

To address these issues, it is proposed that new eHealth governance arrangements be established. From July 2016 a new organisation, the Australian Commission for Electronic Health (ACeH), will be responsible for all national eHealth systems including the PCEHR system. ACeH will be a separate legal entity to the Commonwealth reporting to health ministers. ACeH will be governed by a skills-based board supported by a number of advisory committees with appropriate technical expertise and representation from jurisdictions and the sector. ACeH will assume responsibility for the governance and operation of all eHealth across Australia.

These proposed changes will enhance national eHealth governance arrangements to simplify structures, strengthen accountability, improve transparency, and more appropriately represent key eHealth stakeholders.

**ACHI Comment 21:** *The College suggests that ACeH's brief include data governance and mandating compliance with any one or sets of Australian technical standards by a given date. The College recommends that Consumers also be represented. Appropriate, accountable governance as well as appropriate representation is also essential*

*Refer "Designing Health IT: From Health Systems Design to User Interfaces", GHDonline Expert Panel, Harvard University, <http://www.ghdonline.org/designing-health-it/discussion/designing-health-it-from-health-systems-design-to/>*

### 3.2.1 Establishment of ACeH

ACeH will be established as a new corporate Commonwealth entity through rules made under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and the PGPA Rules.

#### Timing of ACeH establishment

ACeH is proposed to commence operations from July 2016.

#### Disbanding current arrangements

The PCEHR Act currently provides that the System Operator must have regard to advice and recommendations provided by the Jurisdictional Advisory Committee (JAC) and the Independent Advisory Council (IAC), and that the Minister must consult IAC and JAC before making any PCEHR Rules.

JAC and IAC will be abolished as part of the new governance arrangements and this will require amendments to the PCEHR Act and PCEHR Regulations to remove all provisions associated with their establishment, operation and the need for the Minister to consult with JAC and IAC before making PCEHR Rules.

Under the new governance arrangements, the roles of JAC and IAC will respectively be performed by the new ACeH Jurisdictional Advisory Committee as recommended by the PCEHR Review<sup>9</sup>, and an independent assurer reporting directly to the Minister.

### Transition to new arrangements

As recommended by the PCEHR Review, an implementation taskforce will be established (administratively) from July 2015 to oversee and advise on the design, establishment and transition to the new national eHealth governance arrangements, including transitioning functions from NEHTA.<sup>10</sup>

### ACeH functions

ACeH will assume responsibility for governance of all national eHealth operations and functions, including:

- (a) responsibility for PCEHR system operational activities as the PCEHR System Operator, currently undertaken by the Department of Health; and
- (b) broader eHealth system operations now managed by NEHTA.

The Department of Health will retain responsibility for national eHealth policy.

**ACHI Comment 22:** *While the COAG Health Council has the mandate to be the ultimate policy-maker for healthcare, the College seeks reassurance that a suitably qualified statutory authority such as ACeH effectively advise the Council on national eHealth policy.*

*The support and co-operation of the State Health and Legislative authorities is essential.*

### ACeH Board

To achieve broader eHealth end-user representation in the governance of eHealth, it is proposed the ACeH Board and its advisory committees will include individuals with expertise such as:

- (a) healthcare provision;
- (b) consumer of health services;
- (c) IT systems and innovation including health informatics;
- (d) governance;
- (e) clinical safety; and
- (f) privacy and security.

Representatives of jurisdictions and the Commonwealth will also be included on the Board. The Commonwealth Minister will appoint an independent chair in consultation with all states and territories.

**ACHI Comment 23:** *The College understands that the constitution of the ACeH Board has already been decided. The College is concerned that while the ACeH Board will involve the Federal government, the state/territory jurisdictions, medical representatives, consumer stakeholders, etc. specific expertise is also required including system architecture, networking, semantic interoperability, health data, system evaluation/testing/credentialing, etc.*

<sup>9</sup> PCEHR Review, recommendations 3-6

<sup>10</sup> PCEHR Review, recommendation 7

## ACeH staff

It is anticipated that ACeH would employ some staff under Australian Public Service (APS) conditions and other staff under non-APS conditions. The Rules establishing ACeH could make provisions for such employment arrangements.

The CEO, with the approval of the ACeH Board, would determine employees' terms and conditions, as well as the engagement of consultants to assist in ACeH performing its functions.

### 3.2.2 HI Service Operator

The HI Act currently defines the HI Service Operator as the Chief Executive Medicare. Unlike the PCEHR Act there is no ability to prescribe a different entity to be the HI Service Operator.

While there is no intention at this time to change who is the HI Service Operator, it is proposed that amendments be made that, like the PCEHR Act, allow regulations to be made to prescribe a different entity to be the HI Service Operator, to provide future flexibility.

Parliament would be able to disallow any proposed changes if it did not agree. The provision would limit the identity of any proposed new HI Service Operator to entities established by Commonwealth law. This would prevent private sector bodies being prescribed and would effectively limit the HI Service Operator to public sector bodies such as statutory authorities.

*ACHI Comment 24: None*

## 3.3 Participation

### 3.3.1 An opt-out PCEHR system?

The PCEHR system currently operates on an opt-in basis for individuals and participants in the PCEHR system (i.e. healthcare provider organisations, contracted service providers, repository operators and portal operators). This means that an individual (or their representative) needs to take steps to apply to the System Operator and have their identity verified (and, if a representative is applying, provide evidence of their relationship to the individual) so that a PCEHR can be created for them.

The PCEHR Review recommended that the system transition to operate on an opt-out participation model for individuals in order to increase uptake of the PCEHR system and increase its value to, and encourage its use by, healthcare providers.<sup>11</sup> Any decision to move to a national opt-out participation model for the PCEHR system would be a significant decision and Government would need to examine its ramifications before implementing such a model.

**Note:** Opt-out participation means that instead of enabling individuals (or their representatives) to choose to have a PCEHR, the system automatically creates a PCEHR for individuals unless they (or their representatives) choose **not** to have one.

It is therefore proposed to undertake a number of trials of different participation models for the PCEHR system in selected regions of Australia in 2016, including opt-out trials. The purpose of these trials is to:

<sup>11</sup> PCEHR Review, recommendation 13

- identify appropriate methods of targeting and delivering critical information to key audiences;
- assess the effectiveness of targeted communications, and education and training for healthcare providers; and
- test implementation approaches.

These trials will inform future decisions about, and the optimal approaches for, maximising participation in the PCEHR system, including the possible adoption of an opt-out system for individuals.

While the trials are being undertaken the system will continue to operate on an opt-in basis across the rest of Australia.

**ACHI Comment 25:** *The College assumes that during the period of the trials there will be no further PCEHR funds expended on consumer sign-ups. The College is concerned that there may be PCEHR resources applied to bundled consent sign up, although this process will be streamlined, before the findings of the trial have been published and reviewed*

**Note:** Amendments will need to be made to the PCEHR Act and HI Act to enable opt-out trials to operate while the system continues to operate on an opt-in basis elsewhere.

**ACHI Comment 26:** *To achieve reliable recommendations, the design of the proposed PCEHR trials needs to follow a sound methodology, be representative, statistically significant and have prior agreed success criteria.*

It is proposed that a mechanism be included in the PCEHR legislation that would allow the Minister or the Governor-General to determine the areas of Australia where the system would operate on an opt-out basis. The Minister would be required to consult (or the Governor-General would need to be satisfied that consultations have occurred) with the state or territory concerned and have the proposal considered by the Council of Australian Governments (COAG) Health Council before any such determination was made.

**In practice:** The Minister may make a declaration similar to those made under the *Quarantine Act 1908* in relation to quarantine zones. The declaration would identify the boundaries of each trial region and specify the date/s on which the trials would commence and conclude, subject to agreement by the state or territory concerned. Such an instrument would be subject to Parliamentary scrutiny and would be disallowable.

If, following the trials, there is a subsequent Government decision to implement an opt-out participation model nationally, there would be a mechanism to enable the Minister or Governor-General to expand the coverage of opt-out to cover all of Australia (and its external territories). This would include the date from which opt-out would commence nationally.

### Opting out in trial regions

Individuals choosing to opt-out of the PCEHR system would need to verify their identity with the System Operator. This is necessary so that the System Operator can be certain that they are opting-out the correct person. The System Operator would subsequently write to that person at the

latest address held by Medicare confirming that they have opted out. This is designed to prevent third parties being able to opt-out individuals when they have no authority to do so.

Minors and people with limited or no capacity to make their own decisions may be opted out by a representative. The representative would need to demonstrate to the System Operator that they have the authority to act on behalf of the individual (e.g. they are a parent, guardian or have a power of attorney) and have their identity verified by the System Operator. The person would then be recognised by the System Operator as the individual's representative and could opt the individual out of registration.

Individuals who opt-out and later change their mind will be able to register for a PCEHR, and all people will retain the right to cancel their PCEHR at any time.

**ACHI Comment 27:** *It appears to be unclear how 'newcomers' to the PCEHR will be informed about the trial and encouraged to opt in.*

### Opt-out transition in trial regions

There will be a period of two months in which individuals in trial regions will be able to notify the System Operator that they do not want a PCEHR. At the end of this period, PCEHRs will be created for everyone in the trial regions, except those who opted out (or were opted out by a representative) during the transition period and those who had previously been registered but who have cancelled their PCEHR. Any person who becomes eligible for a PCEHR after this two month period, such as newborns, will not automatically get a PCEHR and if they want a PCEHR they will need to apply to register under the opt-in process.

The proposed timing for the opt-out trials is as follows:

- (a) opt-out period – two months: individuals in trial regions may choose to opt-out, or may be opted out by a representative;
- (b) trial registration period – two weeks: registration of eligible individuals in trial regions – that is, PCEHRs are created;
- (c) transition period – six weeks: records will be available to individuals (but not healthcare providers) and individuals or representatives will be able to set access controls. This will ensure that individuals and/or representatives in trial regions are able to set access controls in relation to their PCEHR before documents start to be uploaded by their healthcare providers and before healthcare providers are able to access PCEHRs;
- (d) provider access – around July 2016: healthcare providers can access PCEHRs created for individuals in the trial regions and will be able to upload records.

It is envisaged that the legislation would contain a mechanism allowing some changes to this timing if necessary. Individuals in trial regions will be able to continue registering for a PCEHR leading up to the start of the trials. In areas outside of trial areas, opt-in registrations will continue to be accepted by the System Operator.

### Individual consent

Under the current opt-in regime, an individual must give standing consent at the time of registering for a PCEHR for healthcare provider organisations to upload documents to their PCEHR, subject to some exceptions<sup>12</sup>, and can choose whether or not to consent to their Medicare data (Medicare

<sup>12</sup> The current exceptions to standing consent, set out in paragraphs 41(3)(a) and (b) of the PCEHR Act, are that:

- (i) the individual can tell a healthcare provider not to upload a document; and
- (ii) if the document to be uploaded relates to certain matters prescribed in state and territory laws that have been preserved by PCEHR Regulation 3.1.1 (known as preserved privacy laws). For example laws relating to the disclosure of HIV/AIDS or communicable diseases in-

Benefits Schedule (MBS) claims information, Pharmaceutical Benefits Scheme (PBS) claims information, Australian Childhood Immunisation Register (ACIR) information and Australian Organ Donation Register (AODR) details) being uploaded. Outside the opt-out trial areas, the need for individual consent at the time of registering will continue.

It will not be practical for the System Operator to obtain the consent of all individuals in trial areas who do not opt out. Therefore, in opt-out trial areas it is proposed that, in place of consent, for those who do not choose to opt-out, the legislation would authorise the registration of individuals and uploading of records by healthcare provider organisations and Medicare (including up to two years of historical Medicare data). The authorisation in relation to uploading records to an individual's PCEHR would be subject to the same exceptions that currently exist – for example, the individual would still be able to tell a healthcare provider to not upload a particular record and would still be able to stop their Medicare data being uploaded. Authorisation is required because individuals won't have the opportunity to give consent.

Privacy concerns associated with registration of individuals who don't opt-out, and the uploading of documents to a registered individual's PCEHR, will be addressed by allowing individuals to:

- set access controls to control who can access what information in their PCEHR, including restricting access to their Medicare data and removing documents;
- tell healthcare providers on a case-by-case basis to not upload certain documents;
- monitor activity in their PCEHR using the audit log or via messages alerting them that someone has viewed or used their PCEHR;
- make a complaint if they consider that there has been a breach of their privacy; and
- cancel their registration if they wish, that is, cancelling their PCEHR.

**Note:** As with the current arrangements, the Chief Executive Medicare would have the discretion not to upload or make available Medicare data – for example, in relation to children aged between 14 and 18 years.

**ACHI Comment 28:** *It appears to be unclear if all health practitioners and health organisations, whether private or public, are to be included in the proposed "opt-out" provisions of the legislation or is it planned for health practitioners and health organisations to opt in to the PCEHR using financial incentives, such as the PIP, a purpose designed fund or through other incentives.*

## Secondary use of information

The PCEHR System Operator is currently authorised to prepare and provide de-identified information in the PCEHR system for research and public health purposes. Information in the PCEHR system is not currently used for this purpose but as the volume of information grows, arrangements and capability will be implemented for this to occur. Appropriate protections around the preparation and disclosure of de-identified information will be implemented to ensure individuals' privacy is safeguarded.

The processes and systems to allow this to occur still need to be developed, subject to consultation.

---

formation. In these cases, the provider will still need to obtain consent from the individual before uploading a record, in accordance with the relevant state or territory law.

An individual can also provide consent for a researcher to collect and use the information in their PCEHR. The existing arrangements in place for such activities, such as ethics approval, apply to use of information in the PCEHR system.

There are no proposed changes to how information in the system can be used for secondary purposes.

**ACHI Comment 29:** *The College acknowledges the value of the PCEHR as useful source of rich clinical data. This needs to be carefully overseen by a responsible body with sound research/ethical and academic resources and responsibilities. The input from experts in "de-identifying" data to an appropriate level while maintaining its usefulness would also be essential.*

### Registering individuals in opt-out trials

In the opt-out trial areas, at the end of the opt-out period, the System Operator will register (that is, create a PCEHR for) all individuals who have an active and verified Individual Healthcare Identifier (IHI) except:

- individuals who are already registered for a PCEHR;
- individuals who opted out during the transition period; and
- individuals who had a PCEHR but who have cancelled it before the transition period.

Individuals who have opted out may subsequently decide they want a PCEHR. If this occurs, they will be able to register and have a PCEHR created for them. This registration process will be the same as the current registration process under the PCEHR Act.

An individual (or their representative) will continue to be able to cancel their registration at any time. The System Operator would write to the individual to confirm that registration will be cancelled. This is designed to prevent third parties from being able to cancel other individuals' PCEHRs.

**ACHI Comment 30:** *The College notes that "opt-out" is widely acknowledged to be the most effective approach to broad-based participation of a largely disengaged population therefore it is not clear what parameters will be measured and which hypotheses will be tested in the trials. The College encourages the Department to outline the proposed methodology of the trials as soon as possible.*

### Registering healthcare provider organisations and other entities in opt-out trials

Healthcare provider organisations, contracted service providers, repository operators and portal operators will continue to participate on an opt-in basis. Healthcare provider organisations will be encouraged to use the system through revised incentives, and education and training services.

**ACHI Comment 31:** *None*

## 3.4 Obligations of parties

### 3.4.1 Obligation to enter into participation agreement

To help reduce red-tape and rationalise core obligations for participants in the PCEHR system, it is proposed to remove the need for healthcare provider organisations, contracted service providers, repository operators and portal operators to enter into participation agreements.

Where necessary, requirements in participation agreements would be transferred into the legislation. The proposed approach to handling key obligations currently in participation agreements are discussed below.

### Intellectual property

Participation agreements currently contain licensing provisions which enable information uploaded by healthcare provider organisations to be shared between participants in the PCEHR system (for example, as part of storing a record in a repository), and to be supplied to and used by other healthcare provider organisations, without infringing any copyright which might exist in the record.<sup>13</sup>

With the proposed abolition of participation agreements, it is proposed that the PCEHR Act provide that any use of a document in the PCEHR system or downloaded from the PCEHR system does not infringe copyright.

This would not affect ownership of the copyright. It would merely allow health records to be appropriately shared between participants in the PCEHR system, as currently occurs in the normal course of providing healthcare to individuals.

### Liability

Participation agreements for some types of participants in the PCEHR system currently include liability provisions.<sup>14</sup> Those provisions state that the System Operator is liable for any loss the entity suffers in using the PCEHR system, where that loss is a direct result of the System Operator's acts or omissions. The provisions currently exclude System Operator liability for any indirect or consequential loss suffered.

With the removal of the need for participation agreements, it is proposed that the liability provisions be disposed of rather than be transferred to the legislation. This would mean that the System Operator would be subject to the common law and would not expressly try to exclude any particular type of loss in the PCEHR Act.

**Note:** The common law applies limits to loss and damage that can be recovered.

**ACHI Comment 32:** *The College is concerned that the common law process is tedious, long-winded and expensive and it expects that only large organisations will be able to afford to take action. The College recommends that the current approach where the System Operator has a statutory liability for any loss directly attributable to any act or omission by the System Operator is retained.*

### Data breach notifications

The PCEHR Act requires the System Operator, repository operators and portal operators to notify the Australian Information Commissioner if they become aware that:

- a person has, or may have, contravened the PCEHR Act in a manner involving the unauthorised collection, use or disclosure of health information included in an individual's PCEHR; or

<sup>13</sup> For example, see clause 7 of the healthcare provider organisation participation agreement

<sup>14</sup> For example, see clause 11 of the healthcare provider organisation participation agreement and clause 13 of the contracted service provider participation agreement

- an event has occurred or circumstances have arisen that compromise, or may compromise, the security or integrity of the PCEHR system;

and the contravention, event or circumstances directly involved, or may involve, the entity.

Affected individuals must be notified of a breach, and affected participants in the PCEHR system must take steps to address the breach and to minimise the risk of it reoccurring.

The obligation to report data breaches is important for personal control as it allows individuals to take steps to protect themselves and their information if a breach occurs. It is also important so the System Operator can address any security or integrity issues with the PCEHR system as quickly as possible. Without notification, individuals and the System Operator would not know that they need to take action.

While the PCEHR Act does not currently impose this obligation on healthcare provider organisations and contracted service providers, the participation agreements do.<sup>15</sup> Given the proposal to abolish participation agreements, it is proposed to amend the PCEHR Act requirement to report data breaches to include healthcare provider organisations and contracted service providers. This would help standardise the response of participants in the PCEHR system should there be a breach and would rationalise obligations for healthcare provider organisations and contracted service providers.

Amendments would also be made to clarify when data breach notification must occur.

**ACHI Comment 33:** *The College believes that a data breach notification must occur in all instances to contain unintended patient care error.*

### 3.4.2 Centralising and simplifying participant obligations

It is important that the PCEHR Act apply equally to all participants in the PCEHR system, particularly given the proposal to abolish participation agreements. For example, section 78 of the PCEHR Act (which requires compliance with the PCEHR Rules) currently only applies to registered repository operators and registered portal operators. It is proposed to make a number of minor amendments, including to section 78, so that the PCEHR legislation applies appropriately to all participants in the PCEHR system.

### 3.4.3 Obligation for organisations to have PCEHR policy

The PCEHR Rules currently require registered healthcare provider organisations to have in place a policy that addresses certain PCEHR matters, such as security measures they will take and training they will provide to staff (rule 25). However, there is no requirement for this policy to address how the organisation will ensure data quality so it is proposed that this requirement be included. Requirements for other participants in the PCEHR system to also have policies would be introduced. This is to ensure that all participants in the PCEHR system have appropriate security and information handling practices in place.

**ACHI Comment 34:** *The College is concerned how it will be insured that this approach is independent and factual. The College believes that every healthcare provider needs to have a data governance protocol for key transferable data as well as agreed data standards for such key data.*

*Note: "all participants" can be understood to mean including the individual - does that mean that everyone with a PCEHR will have to have a documented "security & information handling practice in place."?*

<sup>15</sup> Clause 4.4(ii) of the healthcare provider organisation participation agreement and clause 7.2(b) of the contracted service provider participation agreement

### 3.4.4 Obligations on authorised and nominated representatives

The PCEHR Act currently provides for authorised representatives and nominated representatives to assist individuals to manage their PCEHR. The responsibilities of authorised and nominated representatives would be clarified to align them with the proposed new Australian supported decision-making regime.<sup>16</sup> These changes would include replacing the current obligation in the PCEHR Act for representatives to act in the best interests of the individual with obligations to:

- consider the will, preferences and rights of the individual when making a decision; and
- perform the role of authorised representative or nominated representative diligently and in good faith.

### 3.4.5 Application of obligations on different types of entities

The HI Review noted that there was some confusion around the legal status required of healthcare provider organisations.<sup>17</sup> Under the HI Act and the PCEHR Act, a healthcare provider organisation does not need to be a separate legal entity. This is made clear by the definition of “entity” in each Act that encompasses “trusts”, “partnerships” and “unincorporated associations”, none of which are separate legal entities.

While the PCEHR Act specifies how obligations apply to organisations that are trusts, partnerships and unincorporated associations<sup>18</sup>, the HI Act does not and this has caused some confusion. It is therefore proposed to include in the HI Act application provisions along the lines of those in the PCEHR Act.

**ACHI Comment 35:** *The College believes that this needs to be in accordance with the standard definitions as per the relevant identifier standard and documented in METeOR.*

### 3.4.6 Obligations to use PCEHR system

The PCEHR Review recommended that payment for Medicare items relating to health assessments, comprehensive assessments, mental healthcare plans, medication management reviews and chronic disease planning items depend on the uploading of specific documents to the PCEHR system.<sup>19</sup> It is therefore proposed that changes be made to the *Health Insurance Regulations 1975* to give effect to these requirements. For example, a healthcare provider undertaking a medication review in a patient’s home may be required to upload to the individual’s PCEHR the report of that review. Some exceptions would need to be provided, such as where the individual does not have a PCEHR or has directed the healthcare provider not to upload that document.

These changes are not intended to have any adverse impact on individuals so care would need to be taken in the development of such changes.

<sup>16</sup> Recommendation 6-3, Australian Law Reform Commission Report 124, *Equality, Capacity and Disability in Commonwealth Laws*, August 2014

<sup>17</sup> HI Review, section 3.4.2

<sup>18</sup> Sections 100-102 of the PCEHR Act

<sup>19</sup> PCEHR Review, recommendation 38

**Consider:** In what circumstances should healthcare providers not be required to upload a health assessment, comprehensive assessment, mental health plan, medication review report or chronic disease plan?

*ACHI Comment 36: The College queries if the obligation to use the PCEHR means that there are implications for not using the PCEHR if a healthcare provider does not believe the system will benefit the care management activities/processes of his patient(s).*

### 3.4.7 Obligation for System Operator to notify decisions

The PCEHR Act currently requires the System Operator to notify individuals and entities about decisions to cancel, suspend or vary an individual's or an entity's registration (section 51 and 53). The PCEHR Act states that a decision to cancel or suspend registration of an individual or other entity takes effect when the decision is made (subsection 571(7)), however it also states that the earliest time a suspension or cancellation can take effect is when the individual is notified by the System Operator of the decision (subsection 53(5)).

It is proposed to amend the PCEHR Act to clarify when a suspension or cancellation takes effect.

Notification of these decisions must be given in writing. Giving decisions in writing can take time which affects when the decision can take effect. This is particularly problematic in urgent circumstances such as when ongoing registration of an entity could pose a risk to the PCEHR system.

It is proposed to give the System Operator greater flexibility by allowing the System Operator to choose how notifications would be made. The System Operator would be obliged to notify individuals and entities about these decisions using the most appropriate form of communication. For example, electronic notification (e.g. by email) would be the preferred method if it is practical and the System Operator was authorised to communicate in this manner. In other cases, it may be appropriate to communicate by phone. Written notification (non-electronic) would only be used if no other forms of communication are practical or appropriate.

### 3.4.8 Obligation for System Operator to retain records

The System Operator operates the National Repositories Service which stores a minimum critical set of health information about registered individuals, including shared health summaries, event summaries, discharge summaries, and consumer-only notes.

The PCEHR Act currently specifies that any record about an individual that is uploaded to the National Repositories Service (NRS) must be retained for 30 years after the death of the individual or, if the date of death is not known, for 130 years after the record was uploaded (section 17).

In order to help minimise the volume of records retained by the NRS, while still ensuring that records are retained for appropriate periods for clinical and other authorised purposes, it is proposed to amend this requirement so that records are retained for the longer of:

- (a) 30 years after date of death; or
- (b) if date of death not known, 130 years from the individual's date of birth.

### 3.4.9 Obligation for System Operator to provide system testing

It is helpful for test environments to be available to vendors and other stakeholders so they have an opportunity to test how systems operate and interact before they are implemented.

It is proposed that the PCEHR System Operator be given a function to develop and implement a test environment. The test environment would not use any real information and would be isolated from the live system.

## 3.5 Privacy

### 3.5.1 Notification of PCEHR use

A function of the System Operator is to provide access control mechanisms that enable registered individuals to set controls, regulating access by healthcare provider organisations and nominated representatives who can access their PCEHR. These access control mechanisms must provide default settings if an individual chooses not to set any controls. The access control mechanisms are currently prescribed in the PCEHR Rules (Part 2).

The PCEHR system also allows individuals to elect to be notified (by email or by SMS) when certain activities occur in relation to their PCEHR, including when a healthcare provider accesses their PCEHR by asserting an emergency exists or when their nominated healthcare provider uploads a new shared health summary.

The PCEHR Review recommended that a new notification be provided that would allow an individual to be notified when their PCEHR is opened or used.<sup>20</sup>

It is proposed to amend the legislation to require the System Operator to add an optional access control that alerts individuals by SMS or email each time their PCEHR is opened. This access control would only be available to individuals who wish to receive the alert and who have given their mobile number or email address to the System Operator. The legislation would be amended to allow this information to be collected, used and disclosed as necessary to give effect to this access control.

### 3.5.2 Temporary suspension of access to a PCEHR

While there are provisions allowing the System Operator to suspend access to a PCEHR in specified circumstances, the legislation does not currently allow this to occur immediately if:

- a threat to the security of the record or the PCEHR system or the System Operator is concerned that such a risk may exist. This risk could occur, for example, where the System Operator becomes aware that a person (not the individual) is trying to cancel the registration of an individual's registration, or access an individual's PCEHR, without authority; or
- an issue or suspected issue with the individual's (or their representatives') identity or other technical or operational issue.

It is therefore proposed to allow suspension of access to a PCEHR by representatives if there is a risk to the individual, and by participants in the PCEHR system in the circumstances outlined above. This change would not affect the registration of an individual or an individual's access to their PCEHR.

---

<sup>20</sup> PCEHR Review, recommendation 28

### 3.5.3 Collection, use and disclosure of information

The HI Act and PCEHR Act are currently very prescriptive in specifying the particular entities that may collect, use or disclose information for and for what purposes. In some cases different steps in the HI or PCEHR process are authorised by different provisions in different legislation. Given the degree of complexity in the information flows in the PCEHR system and HI Service, this prescriptive approach has left some entities confused about what they can and can't do, and has created barriers to the effective operation of the HI Service and PCEHR system.

It is proposed to simplify these authorisations by moving from a prescriptive approach, which specifies how an entity carries out an activity, to a principles-based approach, which would list the information that is protected, the entities who are authorised to collect, use and disclose, and the purposes for which information can be collected, used and disclosed. This will not change the nature of the authorisations simply their representation in legislation.

It is also proposed to clarify certain authorisations that have been identified as ambiguous in the PCEHR Review, HI Review and in day-to-day management of the HI Service and PCEHR system, and to provide some new authorisations to improve the effectiveness of the PCEHR system and HI Service. These other changes are described below.

These changes do not relax the privacy framework for the PCEHR system or HI Service. They provide clarity to help entities know what they can and cannot do with information and healthcare identifiers, and help the HI Service Operator and PCEHR System Operator to meet their obligations.

#### Third party information

There is some question about whether healthcare providers are authorised to include third party personal information in a document to be uploaded to the PCEHR system, and whether the System Operator is authorised to collect such records and include them in PCEHRs.

It is proposed that the clarification be made through legislation to remove any doubt that healthcare providers may include relevant third party personal information in a record uploaded to the PCEHR system, and that the System Operator is authorised to collect the information in the record for inclusion in the individual's PCEHR.

#### Healthcare Provider Directory (HPD)

The HI Act established the HPD which lists the details of individual healthcare providers and healthcare provider organisations that have a healthcare identifier, with their consent (section 31). The purpose of the HPD is to facilitate communication between providers by providing a reliable way to identify providers and listing contact information.

The HI Review found that the opt-in basis of the HPD is a barrier to effective communications and this is adversely affecting other eHealth services that depend on the HPD, such as secure messaging.<sup>21</sup>

Given that the information about a healthcare provider organisation is not personal information, it is proposed to remove the need for organisations to provide consent before they are listed in the HPD. Any organisation that has an HPI-O would automatically be listed in the HPD. Organisations would need to ensure their information is kept up to date.

Individual healthcare providers would continue to be listed in the HPD only if they give consent.

---

<sup>21</sup> HI Review, recommendation 12(b)

## Handling of healthcare identifiers by prescribed entities

As recommended by the HI Review, it is proposed to include a mechanism which would allow health-related organisations to be listed in Regulations so that they are permitted to handle healthcare identifiers and associated information as part of assisting organisations in their registration and participation in the PCEHR system.<sup>22</sup> This was a function undertaken by Medicare Locals in the past and may be relevant to Primary Healthcare Networks.

Recent changes to the HI Act have allowed healthcare identifiers to be associated with aged care records in certain limited circumstances. This is to ensure that the aged care record is associated with the correct individual.

Consideration is being given to allowing certain other records to use healthcare identifiers to ensure the owners of the records are accurately identified. Any additional use of healthcare identifiers would be tightly restricted – for example, for use in records relating to the provision of healthcare or for closely-related purposes.

**Example:** The National Disability Insurance Scheme (NDIS) records could be allowed to make use of healthcare identifiers to ensure NDIS records are associated with the correct individual. This use would be consistent with the changes to the definition of “healthcare” to include “health-related disability, palliative care or aged care services” – see section 3.1.2 for further details.

It is proposed to allow regulations to be made prescribing additional uses of healthcare identifiers in closely restricted areas. Parliament would be able to disallow any proposed additional uses if it did not agree.

## Information Commissioner’s use of healthcare identifiers

The Office of the Information Commissioner is the privacy regulator for the HI Service. Any breach of the HI Act or in relation to an individual’s or healthcare provider’s healthcare identifier is an interference with privacy (section 29 of the HI Act), thereby triggering the powers of the Information Commissioner under the Privacy Act.

The HI Review found there is some uncertainty about whether the Information Commissioner is permitted to handle healthcare identifiers for the purpose of investigating complaints.<sup>23</sup> To remove any doubt that might exist, the Information Commissioner would be expressly authorised to handle healthcare identifiers and associated information as part of carrying out her or his functions under the Privacy Act and the HI Act.

---

<sup>22</sup> HI Review, recommendation 14(a)

<sup>23</sup> HI Review, recommendation 14(b)

**Note:** Legislation to disband the Office of the Information Commissioner is currently before Parliament. If that occurs, privacy functions under the Privacy Act will be performed by the Commonwealth Privacy Commissioner.

### Healthcare provider organisations' use of healthcare identifiers

The HI Review identified limitations on the HI Service Operator disclosing, to a healthcare provider organisation, healthcare identifiers and identifying information of individual healthcare providers in that organisation. This is adversely affecting the utility of the HI Service.<sup>24</sup>

To clarify this situation, it is proposed to authorise the HI Service Operator to disclose the status of individual healthcare providers' healthcare identifiers (such as whether it has been suspended) and the type of provider (such as whether they are a general practitioner).

### Healthcare identifier searching capabilities

Healthcare providers can search the HI Service for an individual's healthcare identifier when they accurately provide certain key information about the individual. When the information submitted exactly matches the information held by the HI Service, the individual's healthcare identifier is disclosed to the healthcare provider. Without a perfect match, the healthcare identifier is not disclosed. The HI Review found that this is causing problems because very minor data quality issues, such as minor spelling or punctuation differences, cause a mismatch, and these types of errors occur frequently.<sup>25</sup> This means the healthcare provider cannot attach the individual's healthcare identifier to their records, undermining the objectives of the HI Service.

It is proposed that, in instances of mismatches, the HI Service Operator be permitted to undertake actions which would enable resolution of the identity without disclosing personal information about third parties. This would help the HI Service Operator verify the identity of the correct individual in order to disclose the healthcare identifier.

### Retaining information for security purposes

The PCEHR System Operator is only permitted to collect, use or disclose information that is necessary to carry out its functions. At present this means that there are certain security activities that the PCEHR System Operator cannot undertake. In order to improve its ability to detect fraudulent activity or activities that pose a risk to the security of the PCEHR system, it is proposed to clarify that personal information can be collected, used and disclosed for the purposes of detection, prevention and enforcement activities for the PCEHR system.

### Handling by Australian Health Practitioner Regulation Agency (AHPRA)

AHPRA is responsible for assigning healthcare identifiers to most individual healthcare providers. Once this occurs identifying information about the provider and the healthcare identifier is provided to the HI Service Operator in order to maintain the HI Service and inform the PCEHR system. This information flow is one way which is problematic because sometimes the HI Service Operator identifies errors in this information and needs to notify AHPRA so the information can be corrected at its source. It is therefore proposed to allow the HI Service Operator to disclose this information to AHPRA in order to ensure data quality and accuracy.

In considering AHPRA's role, the HI Review considered that AHPRA could play a role in improving healthcare providers' adoption of healthcare identifiers, such as making it more accessible

<sup>24</sup> HI Review, recommendation 14(d)

<sup>25</sup> HI Review, recommendations 8(b) and 11

to providers and including it as part of regular professional registration renewal activities.<sup>26</sup> It is proposed to ensure that AHPRA can disclose HPI-Is to healthcare providers to improve adoption and encourage greater uptake of eHealth.

### 3.5.4 Penalties for misuse of information

The HI Act and PCEHR Act, together with the Privacy Act, currently provide penalties for misuse of information and healthcare identifiers.

- The HI Act imposes criminal penalties for unauthorised collection, use or disclosure of healthcare identifiers (imprisonment for up to two years or up to 120 penalty units (i.e. \$20,400 for individuals and \$102,000 for bodies corporate) or both).
- The PCEHR Act imposes civil penalties for unauthorised collection, use or disclosure of health information in a PCEHR, and for a range of other breaches of the Act such as taking PCEHR information outside Australia or failing to report data breaches (penalties vary, but they range up to 120 penalty units (i.e. up to \$20,400 for individuals and \$102,000 for bodies corporate)).
- The Privacy Act imposes civil penalties for interferences with privacy (up to 2,000 penalty units (i.e. up to \$340,000 for individuals and \$1.7 million for bodies corporate)).

Consideration is being given to increasing the range of enforcement and penalty options available should a person breach the PCEHR Act. For example, consideration is being given to introducing criminal offences in relation to the PCEHR system for serious breaches, while retaining the ability to impose civil penalties. This would establish a more graduated framework for better responding to inappropriate behaviour in a way that is more proportional to the severity of the breach.

**Consider – in relation to PCEHRs:** A PCEHR contains sensitive information about an individual.

Do you consider that more serious misuses of PCEHR information should be subject to criminal penalties (including the possibility of imprisonment), as well as retaining civil penalties (monetary fines, injunctions, etc.) for less serious breaches?

Or should misuses of PCEHR information incur only civil penalties?

**ACHI Comment 37:** *The same approach to deterrence and punishment should be taken as is currently in place for other acts of premeditated harm or acts for personal gain within the medical domain and other domains.*

<sup>26</sup> HI Review, recommendation 14(c)

**Consider – in relation to healthcare identifiers:** As well as health information, PCEHRs may also contain an individual’s healthcare identifier.

Healthcare identifiers are simply a number. They do not contain any health information. At present, the HI Act imposes criminal offences only for misuse of healthcare identifiers.

Do you consider that misuse of individuals’ healthcare identifiers should continue to be a criminal offence?

Would it be more useful to introduce civil penalties for less serious misuses of healthcare identifiers for individuals? For example, to allow a more graduated range of enforcement options.

***ACHI Comment 38:** The approach to deterrence and punishment should be determined based on the possible harm and achievable personal gain.*

## 3.6 Reviews

### 3.6.1 Review of the legislative changes

Two years after the proposed changes to the HI Act and PCEHR Act are made, it is proposed that an independent review be conducted to ascertain whether the changes have achieved the desired results and to identify whether there are any other issues that need to be addressed. The report of this review would need to be provided to health ministers and be tabled in Parliament.

### 3.6.2 Privacy Assessments of AHPRA

The Privacy Act allows the Information Commissioner to assess agencies’ and organisations’ handling of information in accordance with the Australian Privacy Principles (section 33C), however the HI Review identified that AHPRA is outside of the Commissioner’s jurisdiction because it is neither an agency nor an organisation.<sup>27</sup> Given AHPRA’s role in assigning healthcare identifiers to individual healthcare providers and as a source of critical information for the HI Service Operator, it is proposed that changes be made to ensure that the Commissioner can conduct assessments and carry out investigations of AHPRA in respect of its handling of healthcare identifiers.

---

<sup>27</sup> HI Review, recommendation 14(e)

#### **4. Next steps**

After consultation on this paper closes on 24 June 2015, submissions and all other forms of feedback received on the paper will be collated and considered. All input will inform the drafting of legislative changes to the PCEHR system and HI Service.

Legislation is proposed to be introduced into Parliament in August 2015.

Further public consultation on subordinate legislation (regulations and rules) may be undertaken after August 2015.

## Appendix 1: Acronyms and key definitions

Acronym/term	Definition
ACeH	Australian Commission for Electronic Health
ACIR	Australian Childhood Immunisation Register
AHPRA	Australian Health Practitioner Regulation Agency
ALRC	Australian Law Reform Commission
AODR	Australian Organisation Donation Register
APP	Australian Privacy Principle
APS	Australian Public Service
ASQCHC	Australian Safety and Quality Commission in Health Care
COAG	Council of Australian Governments
DHS	Department of Human Services
Document Verification Service	The Document Verification Service is a national online system that allows organisations to compare a customer's identifying information with a government record. It is a secure system that operates 24 hours a day, seven days a week, and matches key details contained on Australian-issued identifying credentials to provide verification (or not) of a person's identity. This service is managed by the Attorney-General's Department.
Health	Department of Health
Healthcare identifier	A unique 16 digit number assigned by the HI Service Operator to individuals, healthcare providers and healthcare provider organisations. It is a government related identifier for the purposes of the <i>Privacy Act 1988</i> .
HI Act	<i>Healthcare Identifiers Act 2010</i>
HI Regulations	<i>Healthcare Identifiers Regulations 2010</i>
HI Review	A review of the HI Service was undertaken in accordance with section 35 of the HI Act and was delivered in June 2013. The report is available on the <a href="#">Department of Health website</a> .
HI Service	Healthcare Identifiers Service
HPD	Healthcare Provider Directory
HPI-I	Healthcare Provider Identifier—Individual A healthcare identifier assigned to an individual healthcare provider who is registered as a member of a health profession.
HPI-O	Healthcare Provider Identifier—Organisation A healthcare identifier assigned to an entity that provides healthcare and employs a healthcare provider with an HPI-I who provides healthcare as part of their duties.
IAC	Independent Advisory Council An advisory body that comprises individuals with specific expertise that makes recommendations to the System Operator in respect of the operation

Acronym/term	Definition
	of, participation in, and clinical, privacy and security matters relating to, the PCEHR system.
IHI	Individual Healthcare Identifier A healthcare identifier assigned to an individual who has received, receives or may receive healthcare.
JAC	Jurisdictional Advisory Committee An advisory body that comprises representatives from Commonwealth, state and territory health departments that makes recommendations to the System Operator in respect of matters relating to government interests in the PCEHR system.
MBS	Medicare Benefits Schedule
MHR	My Health Record
Ministerial Council	The Ministerial Council means the Council of Australian Governments council (however described) that is responsible for health matters. At present this is the COAG Health Council, comprising the Commonwealth and state and territory health ministers.
NASH	National Authentication Service for Health
NDIS	National Disability Insurance Scheme
NEHTA	National E-Health Transition Authority
NRS	National Repositories Service
OAIC	Office of the Australian Information Commissioner
OMO	Organisation Maintenance Officer The OMO of a healthcare provider organisation has responsibilities in the HI Service and the PCEHR system. An OMO's responsibilities include registering new seed organisations, maintaining a list of employees within their organisation who can access the HI Service and PCEHR system, and managing their organisation's access flags.
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally controlled electronic health record The PCEHR of an individual means the record of information that is created and maintained by the System Operator in relation to the individual, and information that can be obtained by means of that record, including health information associated with the individual and audit information associated with that record.
PCEHR Act	<i>Personally Controlled Electronic Health Records Act 2012</i>
PCEHR system	The personally controlled electronic health record system is operated by the Secretary to the Department of Health for the: collection, use and disclosure of information from many sources, and the holding of that information, in accordance with individuals' or as required by law; and assembly of that information as relevant to a particular individual so that it can be made available in accordance with the individual's wishes or as re-

Acronym/term	Definition
	quired by law, to facilitate the provision of healthcare to the individual or for other lawful purposes.
PCEHR Review	A review of the PCEHR system was commissioned by the Government and was completed in December 2013. The report is available on the <a href="#">Department of Health website</a> .
PGPA Act	<i>Public Governance, Performance and Accountability Act 2013</i>
PIA	Privacy impact assessment
Privacy Act	<i>Privacy Act 1988</i>
RO	Responsible Officer The RO of a healthcare provider organisation has responsibilities in the HI Service and the PCEHR system. An RO's responsibilities include managing the registration of a seed organisations and notifying changes of ownership.
Service Operator	The Chief Executive Medicare is specified by the HI Act to be the Service Operator and she or he is responsible for operating the HI Service.
SMS	Short Message Service
System Operator	The Secretary to the Department of Health is specified by the PCEHR Act to be the System Operator and he or she is responsible for operating the PCEHR system. Regulations may specify a different entity to be the System Operator, following consultation with the Ministerial Council.

## **Contributors**

Lead Author: Klaus Veil

Contributors: Juanita Fernando, Oliver Frank, Terry Hannan, Evelyn Hovenga, Robina McCarthy, Chris Pearce, etc.

Review and other contributions: Fellows and Members of ACHI