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5 January 2012

Mr Ian Holland
Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Mr Holland,

Thank you for the invitation to provide a submission to the Standing Committee on Community Affairs to assist its inquiry into the provisions of the *Personally Controlled Electronic Health Records Bill 2011* and a related bill.

NEHTA is the lead organisation supporting the national vision for eHealth in Australia; working with consumers, healthcare providers, the ICT industry, and governments to enable safer, higher quality and sustainable healthcare. NEHTA is the managing agent for the development of the PCEHR on behalf of the Department of Health and Ageing.

NEHTA's submission provides information on four interests of the Committee:

- What the PCEHR will do
- Who will be able to participate
- How people's privacy will be protected
- How security will be managed

NEHTA has consulted extensively on these issues since the PCEHR design commenced in 2010, with input from over 200 organisations in over 140 workshops and events led by NEHTA, supplemented by 170 workshops and events led by the Department of Health and Ageing and the national change and adoption partner. This input formed the basis of the *PCEHR Concept of Operations* which is the key design document for the system.

What the PCEHR will do

> Ruth is 88 years old, and was admitted into a Sydney hospital in November 2011. She was discharged from hospital after her condition had stabilised, but on arriving back in residential care, her health deteriorated. Ruth was admitted back into the same hospital two days after she had been discharged.
>
> Records of Ruth's previous admission could not be located within the hospital, so the full admission process had to be carried out again, including contacting her carers to capture information about her many medications.
>
> Having a central place with information about Ruth's medications and hospital visits would reduce the duplication for healthcare workers collecting this information and would make the hospital admission less distressing for Ruth.

National E-Health Transition Authority

The PCEHR will enable better access to important health information currently held in dispersed records around the country. It will do this by displaying clinical information such as a person's:

- Medical history
- Medicines
- Allergies and adverse reactions
- Immunisations

Information will be entered by a person's healthcare provider, in addition to Medicare information from the Pharmaceutical Benefits Scheme, Medicare Benefits Scheme, Australian Organ Donor Register and Australian Childhood Immunisation Register.

A consumer will also be able to enter information on:

- over the counter medications
- allergies and adverse reactions
- the location and custodian of an advance care directive[1] (if they have one)

The following information will also be available through the PCEHR:

- hospital discharge summaries
- referrals
- specialist letters
- event summaries

Screen designs at Appendix A show how this information will be presented to authorised healthcare providers within a clinical workflow.

> I have a blue folder that I carry with me. It contains all my health information. What's really needed is a single drop box where you can keep all your information, and it's accessible by whoever you give permission to.
> *Rachel De Sain, healthcare consumer*
>
> To have just that basic information, especially medications, will be really, really helpful.
> *Dr John W. Bennett, General practitioner, Brisbane*
>
> I often see in my practice patients with memory problems. You can imagine what it's like trying to get a good history out of them.
> *Dr David L. Stokes, Clinical Neuropsychologist, Melbourne*

Who will be able to participate

Consumers who would like to participate in the PCEHR will be able to register from July 2012. Unlike healthcare identifiers which do not require a consumer's consent, only those consumers who actively choose to register for a PCEHR will have one created.

Consumers will need to have an individual healthcare identifier to register. All healthcare consumers in Australia are eligible for a healthcare identifier, even if they are not eligible for Medicare benefits. The Chief Executive of the Department of Human Services Medicare is the Healthcare Identifiers Service Operator (HI Service Operator) and has issued individual healthcare identifiers to 98% of Australians, automatically created by virtue of their Medicare or Department of Veterans' Affairs relationship and permitted by the *Healthcare Identifiers Act 2010*. Consumers who are not automatically assigned an individual healthcare identifier can apply for one through the HI Service Operator.

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[1] An advance care directive is a statement by a competent person expressing the intention to refuse medical treatment in the future, at a time when he/she may no longer be competent to make a treatment decision. An advance care directive may relate to a specific medical condition, or be aimed towards all future possibilities.

Consumers who choose to participate will be able to:

- Access all the health information stored in their PCEHR
- Control who has access to their PCEHR and view an audit trail to see who else has accessed their PCEHR
- Share information with their healthcare providers, such as allergies and over the counter medications
- Improve the quality of their health information by highlighting potential errors in their records and requesting the potential error be reviewed

Healthcare provider organisations who would like to participate will need to have a Healthcare Identifier Provider – Organisation (HPI-O), which they can obtain by applying to the Healthcare Identifiers Service Operator. Eligibility is defined in the *Healthcare Identifiers Act 2010* and *Regulations*, and includes a requirement that the organisation has conducted, conducts or will conduct an enterprise that provides healthcare, and employ a healthcare provider[2]. Over 600 healthcare organisations have already applied for and received a HPI-O.

Authorised healthcare providers will be able to view information in the PCEHR in line with the access controls the consumer has set. For example, if a consumer marks some information as available only in a medical emergency, this will not be visible to healthcare providers outside an emergency. The PCEHR will clearly notify providers that it may not represent a complete set of health information about a consumer. This is no different to the current situation where consumers make choices about the information they disclose to their GP, pharmacist, dentist or specialist.

> If you're in the hospital, new staff come along and they'll ask you the same questions over and over again. It just gets frustrating.
> *Cherie Thompson, Consumer involved in lead eHealth implementation, Sydney*
>
> My patients can go to hospital and not have to carry bits of paper that I've had to print out, and that they often lose en route, or they can't decipher at the other end.
> *Dr Ray Seidler, GP in eHealth lead implementation site, Sydney*
>
> In my 20 years of practice, I've administered around 20,000 anaesthetics and I can count on one hand the number of times I have seen GP information before my pre-operative assessment.
> *Dr Rowan Thomas, Anaesthetist, Melbourne*
>
> To have a record that is mobile is actually a key issue, particularly for Aboriginal people living in remote communities.
> *Dr Trevor Lord, Senior Medical Officer, Kimberly WA*

How people's privacy will be protected

Security and privacy go hand in hand. Security is about being in control of the data; controlling who has it and ensuring nobody can steal it. Privacy is about making sure that people authorised to use data are acting responsibly; using the data in the right way and not abusing the privilege of their access. Both elements are required if people are to trust their information will be safe in the PCEHR.

NEHTA's approach to privacy is based on the concept of having many complementary layers of protection. This includes technical controls, effective and transparent governance arrangements including enquiry and complaint processes, legal protections and penalties, and regulatory oversight.

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[2] Healthcare is defined in the *Privacy Act 1988*.

Technical access controls include:

- Controlling who to give access – a consumer can control how an organisation is added (or removed) from the list of organisations that are permitted to access a consumer's PCEHR.
- Setting basic access controls – these controls enable all healthcare organisations involved in providing healthcare to the consumer to access the consumer's PCEHR. A consumer can choose to be notified when a new organisation has accessed their PCEHR.
- Setting advanced access controls – these controls include setting up a Provider Access Consent Code (PACC) without which access to the consumer's PCEHR is not possible, except in an emergency; restricting organisations from being on the access list; and managing document level access.
- Emergency access - access controls may also be overridden in situations where the consumer requires emergency care, in line with current laws and practices.

Access controls can allow those documents considered sensitive by the consumer to only been seen by a limited group of healthcare providers chosen by that consumer. If a consumer does not wish to restrict their PCEHR in any way, access will be open to any healthcare providers legitimately involved in their care. In addition to these controls, a consumer may ask their healthcare provider to not upload a specific document into their PCEHR.

Some medical professionals have raised concerns that if consumers are able to restrict access to information in their PCEHR, this will create clinical risk because healthcare providers will be basing their decisions on only part of the story. NEHTA acknowledges the importance of access to accurate clinical information for good clinical decision making. However, consumers currently exercise choice in the information they provide to different healthcare providers. The PCEHR is intended to increase the control that consumers have over their information, not to reduce it. Therefore, the option to withhold information in some circumstances remains in the design. It is important to note that the PCEHR will not change the current processes by which healthcare providers communicate directly with each other about a consumer's healthcare.

Governance arrangements include:

- The System Operator defined in legislation – this will initially be the Secretary of the Department of Health and Ageing or another body established by the regulations. This is consistent with the approach taken to the HI Service Operator, with the CEO of Medicare defined in legislation as the Service Operator.
- Establishing a jurisdictional advisory committee to advise the System Operator on matters relating to the interests of the Commonwealth, states and territories. The jurisdictional advisory committee will ensure state and territory involvement in the operation of the PCEHR system.
- Establishing an independent advisory council to advise the System Operator on matters relating to the operation of the system, and in particular consumer security, privacy and clinical matters relating to its operation. It will ensure the involvement of key stakeholders, including consumers and healthcare providers.
- The role of the Ministerial Council defined in legislation – the Minister must consult with the Ministerial Council on various matters, such as making regulations, providing reports on system operations and privacy management, and appointing a person to review the operation of the Act. This is consistent with the role of the Ministerial Council in overseeing the operation of the HI Service defined in the *Healthcare Identifiers Act 2010*.
- Operating enquiry and complaint processes – the System Operator will provide a call centre to allow consumers to register or withdraw from the PCEHR system, manage their access controls, or make an enquiry or complaint.

Legal protections include:

- Civil penalties for any unauthorised collection, use and disclosure of health information contained in a person's PCEHR.
- Some penalties incorporate fault elements. For example, the fault element in section 51 is designed to ensure that liability does not arise where there is inadvertent or mistaken access to a person's PCEHR. The Draft Bill does not affect any existing criminal laws.

- In addition, an act or practice that contravenes the Draft Bill in connection with a consumer's health information included in a consumer's PCEHR would be taken to be an interference with privacy for the purposes of the *Privacy Act 1988*. This would enable complaints to be made to the Office of the Australian Information Commissioner and penalties applied through that process.

Regulatory oversight includes:

- The Information Commissioner is given enforcement powers in the legislation, in addition to power within the *Privacy Act 1998*. The PCEHR System Operator will routinely report to the Information Commissioner, and the Office has an ongoing role in the review of the legislation.
- A range of regulatory responses are provided, including penalty regimes, enforceable undertakings and injunctions.
- Mandatory breach reporting to the System Operator and Information Commissioner.

Overarching all these protections is the ultimate choice for consumers – whether to have a PCEHR or not. If a consumer does not want to share their information with healthcare providers through the PCEHR then they have the choice to abstain. The legislation provides that a consumer not be discriminated against or refused healthcare if they do not have a PCEHR.

Managing privacy – how will it work?

Christine Lee has decided to register for a PCEHR. She will authenticate her identity in line with the Commonwealth Government's standard for electronic authentication of the identity of consumers dealing with the government, possibly through the Australian Government Online Service Point[3].

Christine chooses to provide some basic information about herself (contact details, emergency contact), her current medications, her allergies and details of her solicitor who holds her advance care directive. She then decides to set 'basic' access controls, which authorises any healthcare provider involved in her care to access information in her PCEHR.

Six months on, Christine logs in to her PCEHR and views the audit trail which shows who else has viewed her record. Among several entries from her local GP, she notes access by an interstate GP practice she has not had contact with.

Christine phones the PCEHR System Operator and makes an enquiry about this entry. The system operator investigates the claim and contacts the GP practice, which has no record of Christine ever attending the practice. The system operator contacts Christine to advise her of this outcome, and following a discussion about Christine's options, a complaint is referred to the Information Commissioner.

The Information Commissioner conducts an investigation into the potential privacy breach. If found, it has powers under Privacy legislation, the PCEHR legislation, and Healthcare Identifiers legislation, with criminal penalties of up to two years imprisonment and fines of up to $66,000 per offence.

How security will be managed

As stated earlier, security goes hand in hand with privacy, and is about being in control of the data; controlling who has it and ensuring nobody can steal it.

The PCEHR system will not replace or hold all the information contained in healthcare providers' records. Instead, the PCEHR system will draw upon information held in registered

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[3] This mechanism is still being confirmed as the appropriate solution for consumer authentication.

repositories (held in Australia only) to provide a summary view of a consumer's key health information. This architecture avoids consolidating health records wherever possible, addressing increased security risks in merging databases (the 'honeypot' effect).

An organisation which operates a repository will be required to apply to the PCEHR system operator to register as a repository operator and will be subject to security requirements to be set out in regulation. The system operator, repository operators or portal operators have mandatory notification obligations in the event of:

- unauthorised collection, use or disclosure of health information included in a consumer's PCEHR
- an event that compromised, or may compromise, the security or integrity of the PCEHR system
- Any change to their conditions of registration, including whether the organisation changes such that it is no longer mostly owned and managed in Australia.

This level of mandatory breach reporting is over and above reporting obligations in existing privacy legislation.

> We see the effect of rapid communication in other areas of our life, and we're getting to a point now where we expect that in healthcare. When I see you in an emergency department, in a general practice setting, in a specialist room, I'll have more rapid access to up to date information about what's happened to you in the past.
>
> *Dr John Zorbas, Resident Medical Officer, Perth*
>
> I'm looking forward to the day when people are empowered through the PCEHR to change their own health outcomes.
>
> *Dr Chris Mitchell, General Practitioner, Lennox Head NSW*
>
> PCEHRs that meet the needs of consumers can build consumer confidence and trust in the health system … they can empower consumers to be active partners in their health and make informed decisions about their healthcare.
>
> *Consumers Health Forum of Australia*

NEHTA has made significant progress in finalising the design and specifications for the PCEHR. The legislation before parliament complements the technical design by setting out governance arrangements and the rights and responsibilities of participating parties. It is NEHTA's view that the system design and legislation appropriately respond to the issues communicated by consumers, healthcare providers, the ICT industry and policy makers and will deliver a system that will improve healthcare outcomes for all Australians.

Yours sincerely

Peter Fleming
Chief Executive Officer

Screen samples[4] – PCEHR use in a clinical workflow

A person's PCEHR will show a consolidated view of information as shown below. This could be used by a healthcare provider as shown in the steps on the following pages.

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[4] At the time of submission, consultation was complete on these screen samples, and had been provided to the National Infrastructure Partner. They were subject to final review and testing, so the final PCEHR system design may vary from the screens shown here.

Step 1

A provider looks at a consumer's PCEHR on 14-Aug-2011 and can see that there have been no new documents since the last Shared Health Summary (18-Apr-2011).

An individual's PCEHR may not represent a complete set of health information. *more*

Overview Download

18-Apr-2011 Shared Health Summary

Author: Dr Adam Jones, General Medical Practitioner, Croyden General Practice *contact details*

Current & Past Medical History

27-May-2008	Endogenous depression
13-Nov-2005	Non insulin dependent Diabetes Mellitus

Medicines

Citalopram 20mg Tablet
1 Daily (Oral)

Metformin 500mg Tablet extended release
3 Daily (Oral)

Allergies & Adverse Reactions

Prozac - Rash (Moderate)

⊙ **Immunisations** *1 item*

Consumer Entered Information

This view allows you to see Medicines and Allergies & Adverse Reactions recorded by the consumer or their authorized representatives.

View consumer entered information

Medicare

Pharmaceutical Benefits Scheme

Australian Childhood Immunisation Register

- Medical Benefits Scheme *Activate*

- Australian Organ Donor Registry *Activate*

Recent Diagnostic Reports *Sent to the PCEHR in the last 12 months View all*   COMPARE

05-Mar-2011 Pathology - IMM, HEM, SER Nth Queensland Pathology Services

18-Jan-2011 Pathology - HEM Pathology organisation name

Recent Documents *Sent to the PCEHR in the last 12 months View all*   COMPARE

18-Apr-2011 Shared Health Summary General Medical Practitioner, Croydon Family Practice

27-Jan-2011 Referral General Medical Practitioner, Croydon Family Practice

12-Dec-2010 Shared Health Summary General Medical Practitioner, Croydon Family Practice

Step 2

A GP looks at the consumer's record on 12-Oct-2011. They note that there have been a number of new documents since the last Shared Health Summary the entered.

An individual's PCEHR may not represent a complete set of health information. *more*

Overview Download

Advance Care Directive

NEW! *4 new documents sent to the PCEHR since the Shared Health Summary* COMPARE

11-Oct-2011 Pathology - ABG, IMM, HEM, SER LargePath Services
10-Oct-2011 Event Summary Specialist General Practitioner, Port Douglas Clinic
05-Oct-2011 Discharge Summary Resident Medical Officer, Bay Hill Hospital
02-Oct-2011 Specialist letter Renal Medical Specialist, Port Moresby Hospital

The Compare option provides more detail on what has changed

18-Apr-2011 Shared Health Summary
Author: Dr Adam Jones, General Medical Practitioner, Croyden General Practice *contact details*

Current & Past Medical History

27-May-2008 Endogenous depression

13-Nov-2005 Non insulin dependent Diabetes Mellitus

Allergies & Adverse Reactions

Prozac - Rash (Moderate)

Medicines

Citalopram 20mg Tablet
1 Daily (Oral)

Metformin 500mg Tablet extended release
3 Daily (Oral)

Immunisations *1 item*

Consumer Entered Information

This view allows you to see Medicines and Allergies & Adverse Reactions recorded by the consumer or their authorized representatives.

View consumer entered information

Medicare

Pharmaceutical Benefits Scheme

Australian Childhood Immunisation Register

- Medical Benefits Scheme *Activate*

- Australian Organ Donor Registry *Activate*

Recent Diagnostic Reports *Sent to the PCEHR in the last 12 months View all*   COMPARE

11-Oct-2011 Pathology - ABG, IMM, HEM, SER LargePath Services
05-Mar-2011 Pathology - IMM, HEM, SER Nth Queensland Pathology Services
18-Jan-2011 Pathology - HEM Pathology organisation name

Recent Documents *Sent to the PCEHR in the last 12 months View all*   COMPARE

10-Oct-2011 Event Summary General Medical Practitioner, Bay Hill Hospital
05-Oct-2011 Discharge Summary Resident Medical Officer, Bay Hill Hospital
02-Oct-2011 Specialist letter Renal Medical Specialist, Croydon Family Practice
18-Apr-2011 Shared Health Summary General Medical Practitioner, Croydon Family Practice
27-Jan-2011 Referral General Medical Practitioner, Croydon Family Practice
12-Dec-2010 Shared Health Summary General Medical Practitioner, Croydon Family Practice

Step 3

The GP uses the 'Compare' view to better understand how the new documents relate to the last Shared Health Summary.

Step 4

Having read the new documents, the GP updates and posts a new Shared Health Summary. This clears out the newer documents list, though the documents are still shown in the 'Recent documents' list.

An individual's PCEHR may not represent a complete set of health information. *more*

Overview Download

Advance Care Directive

12-Oct-2011 Shared Health Summary
Author: Dr Adam Jones, General Medical Practitioner, Croyden General Practice *contact details*

Current & Past Medical History

12-Oct-2011	COPD
27-May-2008	Endogenous depression
13-Nov-2005	Non insulin dependent Diabetes Mellitus

Allergies & Adverse Reactions

Prozac - Rash (Moderate)

Medicines

Salbutamol inhaler
    2 puffs 4 hourly PRN

Citalopram 20mg Tablet
    1 Daily (Oral)

Metformin 500mg Tablet extended release
    2 tabs daily

▶ **Immunisations** *1 item*

Consumer Entered Information

This view allows you to see Medicines and Allergies & Adverse Reactions recorded by the consumer or their authorized representatives.

View consumer entered information

Medicare

Pharmaceutical Benefits Scheme

Australian Childhood Immunisation Register

- Medical Benefits Scheme *Activate*

- Australian Organ Donor Registry *Activate*

Recent Diagnostic Reports *Sent to the PCEHR in the last 12 months View all*   COMPARE

11-Oct-2011	Pathology - ABG, IMM, HEM, SER	LargePath Services
05-Mar-2011	Pathology - IMM, HEM, SER	Nth Queensland Pathology Services
18-Jan-2011	Pathology - HEM	Pathology organisation name

Recent Documents *Sent to the PCEHR in the last 12 months View all*   COMPARE

12-Oct-2011	Shared Health Summary	General Medical Practitioner, Croydon Family Practice
10-Oct-2011	Event Summary	General Medical Practitioner, Bay Hill Hospital
05-Oct-2011	Discharge Summary	Resident Medical Officer, Bay Hill Hospital
02-Oct-2011	Specialist letter	Renal Medical Specialist, Croydon Family Practice
18-Apr-2011	Shared Health Summary	General Medical Practitioner, Croydon Family Practice
27-Jan-2011	Referral	General Medical Practitioner, Croydon Family Practice
12-Dec-2010	Shared Health Summary	General Medical Practitioner, Croydon Family Practice