Mr Ian Holland
Committee Secretary
Standing Committee on Community Affairs Legislative Committee
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 Provision of the Personally Controlled Electronic Health Records Bill 2011 and the Personally Controlled Electronic Health Records (Consequential Amendments) Bill 2011. My submission relates to the function of the PCEHR, participants in the system, privacy and other broad legislative provisions, the management of security and the sustainability and functionality of the system.

I have an interest given my previous membership of NHMRC's Privacy Working Committee, National Health Committee and Health Advisory Committee and in leading the implementation of Evidence Based Medicine (EBM) in Victorian Local Hospital Networks of Western Health and Bayside Health (now Alfred Health). I was Chair of a committee of Bayside Health's Clinical Pathways Working Group (CPWG) which undertook a Cost Benefit Analysis of IT platforms for EBM implementation by clinical pathways. The legislation includes provisions for national emergencies and public threats. This could include pandemics and bioterrorism threats. I undertook a consultancy as part of a consortium on *Potential Avian Influenza Induced Pandemics* for the Federal Government and was Chair of Bayside Health's EBM Committee on Bioterrorism Preparedness. As Deputy Chair, Guidelines and Economists Network International (GENI) I have a keen interest in IT applications for EBM. I previously project managed the Corporate Services Review in the Victorian Department of Human Services, which included a review of State-wide IT systems.

My comments build on my previous submissions to Senate Inquiries relating to the National Health Reform Amendment (National Health Performance Authority) Bill 2011, COAG Reforms Relating to Health and Hospitals, the National Health and Hospital Network Bill 2010, the Federal Financial Relations Amendment (National Health and Hospitals Network) Bill 2010 and the Pricing Authority legislation in 2011. It also builds on the issues and recommendations by the Senate Committees in their final reports that related to my submissions [1] [2] [3] [4] [5] [6] [7] In particular it builds on recommendations relating to the implementation of EBM through *State Centres of EBM, Health Services and Workforce Redesign*. I strongly support the intent of both Bills which can facilitate Australia to achieve international leadership in IT platforms within an EBM framework. However, I have made recommendations to facilitate use of data in EBM implementation and in circumstances to assist in mitigating national and international public health threats.

Participants

The PCEHR will enable better access to information in dispersed records by displaying clinical information including an individual's medial history, drugs, adverse reactions and allergies and immunization. The health care provider will enter information and PBS, MBS, Australian Childhood Immunization Register and the Organ Donor Register information is also included. The consumer can include information on the custodian and location of an advance care directive which expresses the intention to refuse treatment in the future when she/he may not be competent to decide on treatment.

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[1] http://www.aph.gov.au/Senate/committee/economics_ctte/health_finance_10/submissions.htm (Antioch KM: submission 1)
[2] http://www.aph.gov.au/Senate/committee/clac_ctte/Nat_hlth_hospital_network_43/submissions.htm (Antioch KM: submission 10)
[3] http://www.aph.gov.au/senate/committee/fapa_ctte/coag_health_reforms/submissions.htm (Antioch KM: submission 20)
[4] http://www.aph.gov.au/senate/committee/clac_ctte/nhpa/submissions.htm (Antioch KM Submission 14)
[5] http://www.aph.gov.au/Senate/committee/economics_ctte/health_finance_10/report/index.htm
[6] http://www.aph.gov.au/senate/committee/clac_ctte/Nat_hlth_hospital_network_43/report/report.pdf
[7] http://www.aph.gov.au/senate/committee/clac_ctte/nhpa/report/index.htm

The PCEHR will also make available hospital discharge summaries, referrals, specialist letters and event summaries. Consumers who choose to participate in PCEHR can register from July 2012. They can then access all health information in their PCEHR, control who has access and view an audit trail. They can highlight potential errors and request reviews in their records. They can share information such as allergies and over the counter drugs with their health care providers. Health care organisations can apply to their Health Care Identifiers Service Operator for a Health Care Identifier Provider – Organisation (HPI-O). Such providers can view PCEHR information in accordance with access controls specified by the consumer. The PCEHR will notify providers that it may not represent a complete set of consumer health information (NEHTA, 2012)[8].

Privacy Protection

NEHTA's privacy approach is based on many layers of protection including technical controls, effective and transparent governance for complaints and enquiry, legal protections, penalties and regulatory oversight. NEHTA (2012)[8] specifies several technical controls:

- The consumer can control which organizations can have access
- Basic access controls can be set to enable all healthcare organizations providing health care to the consumer to have access.
- Advanced access controls can be set using a Provider Access Consent Code (PACC) which is required for access (except in an emergency); document level access can be managed and organizations can be restricted from inclusion in the access list.
- Controls can be overridden in *emergency care requirements for the consumer* to enable emergency access.

However, some medical professionals have expressed concern that if consumers restricts access it can increase clinical risk as providers will only have limited information for decision making (NEHTA, 2012)[8]

Recommendations:

1. *The Federal Government to develop mechanisms to reduce and manage this general clinical risk identified by medical professionals, especially in the case of emergency situations for consumers and during national threats to public health, which may require access to the entire records included on the PCEHR to mitigate the threat.*
2. *Consumers, practitioners and health service organizations to be fully informed of the access implications of the legislation in scenarios of both consumer and public health emergencies. A case study of access issues during a Pandemic could be used to clarify access implications in a public health emergency.*
3. *Given the potential complexities of Information Technology interface with health service provision and the variation of consumer and practitioner expertise in using IT systems, the Federal Government to give thorough consideration to the training implications of the implementation of the legislation including a Cost Benefit Analysis of various training programs for both consumers and practitioners. This should include costing the known limitations of uptake of new IT clinical systems and the effectiveness of such IT training programs.*

Governance

The System Operator will initially be the Secretary of the Department of Health and Ageing or another body established by the regulation. A Jurisdictional Advisory Committee will advise the System Operator on matters relating to Commonwealth, States and Territories. An Independent Advisory Council will be established to advise the System Operator to ensure providers and consumers are involved. The Council will advise on operations, security, privacy and clinical matters.

[8] National E-Health Transition Authority (2012) Submission to the Standing Committee on Community Affairs on the Inquiry in to the provision of Personally Controlled Electronic Health Records Bill 2011 and a related Bill

A Ministerial Council will be established. Operating enquiry and complaint processes will be provided by the System Operator (NEHTA, 2012)[8]. Division 3, Subdivision B, Clause 27 of the Bill specifies membership knowledge and experience of the Independent Advisory Council. Three members must represent consumers' interests. The remaining members must, between them, have experience or knowledge in a range of areas specified in 27(2)(b)(i) to (vii) such as law and/or privacy etc.

Recommendation

4. *The category of 'Evidence Based Medicine' (EBM) be added to the current list of expertise required by a member of the Independent Advisory Council at paragraph 27(2)(b) of the Bill. Expertise of a member in EBM is essential given the use of the information for clinical decision making and its possible utilization over time in Information Technology platforms for Decision Support in local quality instruments such as clinical pathways, clinical protocols and within the broader patient journey scenarios. Given the likely evolution of the PCEHR information for these purposes it is <u>essential</u> that a member has demonstrated expertise in the implementation of Evidence Based Medicine at the point of health care provision. This should be made explicit at paragraph 27(2)(b). It should <u>not</u> simply be assumed that other members in the membership categories will likely have this skill set.*

The rationale for this recommendation is outlined below. The Explanatory Memorandum[9] on the Bill states that "The PCEHR system, by drawing together health information about a consumer from many different sources, will create a much richer data source about consumers than an existing system" (Parliament of the Commonwealth of Australia, 2010-2011 Explanatory Memorandum[9], pg 44). The Explanatory Memorandum states at page 46 that information can be downloaded from the PECHR system into the local Clinical records system of a health care provider organization and the information can be subsequently obtained from the local clinical system. Sub clause 71(4) provides that obtaining information from that other system even though originally from PCEHR is taken <u>not</u> to be obtained using the PCEHR system. Authorizations and prohibition in Part 4 of the PCEHR Bill do not apply where the information is accessed using the local clinical records system and existing Commonwealth, State and Territory privacy and health information laws and professional obligations apply (Parliament of the Commonwealth of Australia, 2010-2011, Explanatory Memorandum, pg 46[9]). Given the provisions of the sub-clause, it is possible that information could be used for EBM implementation in health facilities for pathways, protocols and Clinical Practice Guideline implementation.

Legislative protections

There are civil penalties for any unauthorized collection, use, disclosure of health information in the PCEHR. The fault element in Section 51 ensures liability does not arise where there is inadvertent access. The Draft Bill does not affect any existing criminal laws. Any interference with privacy for the purposes of the Privacy Act 1988 could enable complaints to the Office of the Australian Information Commissioner and associated penalties (NEHTA 2012)[8]. Paragraph 41(3)(b) and sub-clause 41(4) are designed to ensure that state and territory requirements can be preserved in relation to the disclosure and uploading of certain health information such as HIV and other notifiable disease. Such laws must be prescribed in the regulations and health care providers must not upload a record unless they meet the requirements in the prescribed laws as specified in the Explanatory Memorandum at page 23.

Public health emergencies are important considerations in the application of the Bill, especially issues relating to access to the information for PCEHR data. The Department of Health and Ageing (2011)[10] states that Australia is a signatory of the International Health Regulations 2005 (IHR) whereby Australia has agreed to report incidence and maintain good surveillance and response capacity to prevent the international spread of disease.

[9] Parliament of the Commonwealth of Australia, House of Representatives 2010-2011 'Personally controlled electronic health records Bill 2011:Explanatory Memorandum' circulated with authority of the Minister for Health and Ageing, the Honorable Nicola Roxon, MP)

[10] Australian Government Department of Health and Ageing (2011) 'Review of Australia's Health Sector Response to Pandemic (H1N1) 2009: Lessons Identified'.

Department of Health and Ageing's national Incident Room (NIR) is Australia's National Focal Point (NFP). The NFP notifies and reports public health events of international significance to the WHO within 24 hours of event assessment and responds to national public health risks and national public health emergencies. In the event of a pandemic, the NFP would receive and distribute information critical to decision makers in Australia and *internationally*. The Quarantine Act 1908 provides very broad powers regarding, inter alia, the examination of humans, detention, isolation and the prevention or control of the spread of the disease etc. The National Health Security Agreement under the National Health Security Act 2007 establishes a national coordination framework for rapid decision making and health sector response to public health emergencies.

This includes the sharing of information between the Australian Government and States and Territories in relation to Communicable diseases in order to enhance understanding of epidemiology threats and the ability within Australia to respond to those diseases. The States and Territories also have broad public health and emergency response powers which provide the legislative framework to support actions that may be required at jurisdictional level to respond to a pandemic (Department of Health and Ageing, 2011) [10].

Division 6 Clause 58 states that identifying information may be used and disclosed by, inter alia, the Department of Defence (Parliament of the Commonwealth of Australia, 2010-2011, Explanatory Memorandum[9] pg 34). In national emergency issues relating to bioterrorism (biological, radiological and chemical) there could be an urgent imperative to access PCEHR data. Sub-clause 64(2) covers the collection, use and disclosure in a consumer's PCEHR where the information is needed to prevent a serious threat to public health or public safety. An example is a circumstance where a dangerous infection is detected in a hospital and it is necessary to identify the source of the infection to prevent its spread. Here the PCEHRs of recent arrivals to hospital may be accessed to assist in identify the infection source. This authorization does not extend to consumer only notes. (Parliament of the Commonwealth of Australia, 2010-2011, Explanatory memorandum[9] pg 41).

In clause 66, the Bill only allows access to identified health information for *research* where the consumer has consented (unlike the current position under the National Privacy Principles) (Parliament of the Commonwealth of Australia, 2010-2011, Explanatory memorandum[9] page 42). However urgent *epidemiological research* investigations in public health emergencies for the 'public interest' would be greatly facilitated by access to 'consumer only notes', along with the 'identified health information' even in circumstances where the consumer has not consented. Clause 77 places obligations on entities that hold records for PCEHR purposes to not hold or take the records outside Australia, nor to process or handle information relating to the records outside Australia, or to cause or permit another person to do the above outside Australia. Division 5, sub-clause 105(6) deals with Australia's obligations under international agreements and this takes account of International Covenant on Civil and Political Rights under which Australia has obligations in relation to privacy,

Recommendation

5. *The Department of Health and Ageing give careful consideration to the implications of the International Health Regulations 2005, The Quarantine Act 1908, the National Health Security Act 2007 and the International Covenant on Civil and Political Rights for the proposed legislation and whether the provisions of the new legislation can take full advantage of the data contained in, and derived from, the PCEHR in mitigating national and international threats to public health.*

Regulatory oversight

The legislation gives enforcement powers to the Information Commissioner in addition to the power within the Privacy Act 1998. Regulatory responses include penalty regimes, enforceable undertakings and injunctions. There is mandatory breach reporting to the System Operator and Information Commissioner. The legislation provides that a consumer not be discriminated against or refuse health care if they do not have a PCEHR. Therefore overarching the legal protections, the consumer chooses whether to have a PCEHR (NEHTA 2012) [8].

Security management

"The PCEHR system will not replace or hold all the information contained in health care providers records. Instead, the PCEHR system will draw upon information held in registered repositories (held in Australia only) to provide a summary view of the consumers' key health information. This architecture ***avoids consolidating*** health records wherever possible adding increased security risk in merging data bases (the honey pot effect)" (NEHTA, 2012 pg 5, 6) [8]. However, as outlined above, the Explanatory Memorandum states *"The PCEHR system, by **drawing together** health information about a consumer from many different sources, **will create a much richer data source** about consumers than an existing system"* (Parliament of the Commonwealth of Australia, 2010-2011, Explanatory Memorandum[i] page 44).

This clarification in the Explanatory Memorandum is insightful and I refer again to recommendation 4 above about the need for an expert in EBM to be appointed to the Independent Advisory Council at paragraph 27(2)(b) of the Bill, given the potential for this information to be used at the health provider level for decision making and in IT decision support and clinical pathway, clinical protocol and patient journey scenarios.

An organization operating a repository will be subject to the regulations security arrangements. There will be mandatory notification obligations if there is unauthorized collection use or disclosure of information, an event that compromises the security of the PCEHR and where the organization's registration changes eg no longer mostly owned and managed in Australia. This mandatory report breaching level is beyond reporting legislation in privacy legislation (NEHTA, 2012) [8].

PCEHR (Consequential Amendments) Bill 2011

The Personally Controlled Electronic Health Records (Consequential Amendments) Bill 2011 is strongly supported as it ensures that the PCEHR Bill, once enacted, operates effectively and appropriately. The Consequential Bill amends the Healthcare Identifiers Act 2010 (HI Act) to allow healthcare identifiers to play a central role in the integrity, security and safety of the PCEHR system. The Consequential Bill will also make amendments to the Health Insurance Act 1973 and the National Health Act 1953 to enable a range of health records created by Medicare to be included in a consumer's PCEHR where the consumer wants that information included[11].

Recommendation:

6 That the PCEHR (Consequential Amendments) Bill 2011 be approved given it will facilitate excellent Evidence Based Policy and EBM implementation to occur once the PCEHR Bill is enacted.

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[11] Parliament of the Commonwealth of Australia, House of Representatives 2010-2011 'Personally controlled electronic health records (Consequential Amendments) Bill 2011:Explanatory Memorandum' circulated with authority of the Minister for Health and Ageing, the Honorable Nicola Roxon, MP)