Australian Privacy Foundation

.

enquiries@privacy.org.au

http://www.privacy.org.au/

APF feedback about the Draft Concept of Operations (ConOps): Relating to the introduction of a Personally Controlled Electronic Health Record (PCEHR) system.

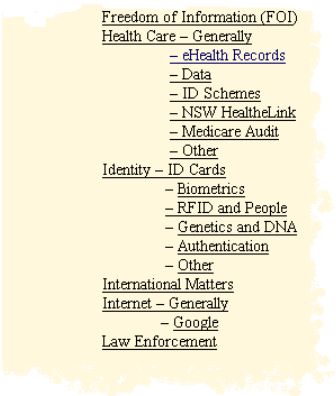
30 May 2011

The Australian Privacy Foundation (APF) is the country's leading privacy advocacy organisation. I write as Chair of the Health Sub Committee of the APF. I refer to "the Draft Concept of Operations (ConOps): relating to the introduction of a Personally Controlled Electronic Health Record (PCEHR) system".

Experts have long indicated that a systematic and transparent approach must be taken to privacy compliance in order to achieve a trustworthy PCEHR system upon which Australians can rely (1). The APF has made many attempts to communicate with NEHTA and the Department of Health and Ageing in systematic and transparent ways over several years, as the partial screenshot from our website illustrates. Despite claims to the contrary, effective consultation (i.e. meaningful two way communication) with consumer advocacy NGOs began to occur in 2011. In this context, the "Draft ConOps: relating to the introduction of a PCEHR system" is disappointing.

Selected APF Papers Sorted by Policy Topic

http://www.privacy.org.au/Papers/indexPolicies.html



Screenshot 1: Section of more than 2 e-pages of APF letters, submissions and papers sorted by "Health Care"

This submission comprises 2 sections. Section 1 outlines fundamental problems with the National E-Health Transitional Authorities' (NEHTA's) approach to the ConOps. Section 2 details key deficiencies of the proposals contained within the Draft.

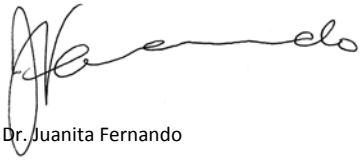
The APF submission does not explicitly respond to all concerns although we do raise several broad issues that may concern other stakeholders. The primary focus is to analyse privacy issues from the individual citizen's perspective. Our clear impression is that health authorities are resisting the need to embrace the broader informed community with anything but public relations projects; we await continued and meaningful consultation.

The APF is disconcerted by the lack of a governance framework in the draft ConOps. Work on the framework will occur throughout the third quarter of 2011, after enabling legislation has been introduced to Parliament (2). Key questions need a response prior to introducing the legislation. These concern:

1. Who will hold what type of health and personal information?
2. Who will be authorised to send, read, write, print, download and otherwise access the information? How will such authorisation occur?
3. How will data quality be assured?
4. How will private information be protected?
5. What evidence suggests the draft PCEHR system will make a difference to community concerns about answers to these questions?
6. Who is ultimately responsible and accountable for the draft PCEHR system?

The draft ConOps and accompanying Consumer Booklet do not explicitly address community unease about the baseline of all information government authorities may hold on citizens although many of these may be indexed in future system builds, as illustrated in Figure 1. The draft PCEHR system is unlikely to improve community health outcomes although, as the figure does show, it looks likely to prove useful to government agencies, insurers and researchers.

Yours sincerely



Dr. Juanita Fernando

Chair, Health Sub Committee
Australian Privacy Foundation

Dr Fernando is in Medicine, Nursing & Health Sciences
Monash University 03 9905 8537 or 0408 131 535
mailto:Juanita.Fernando@monash.edu

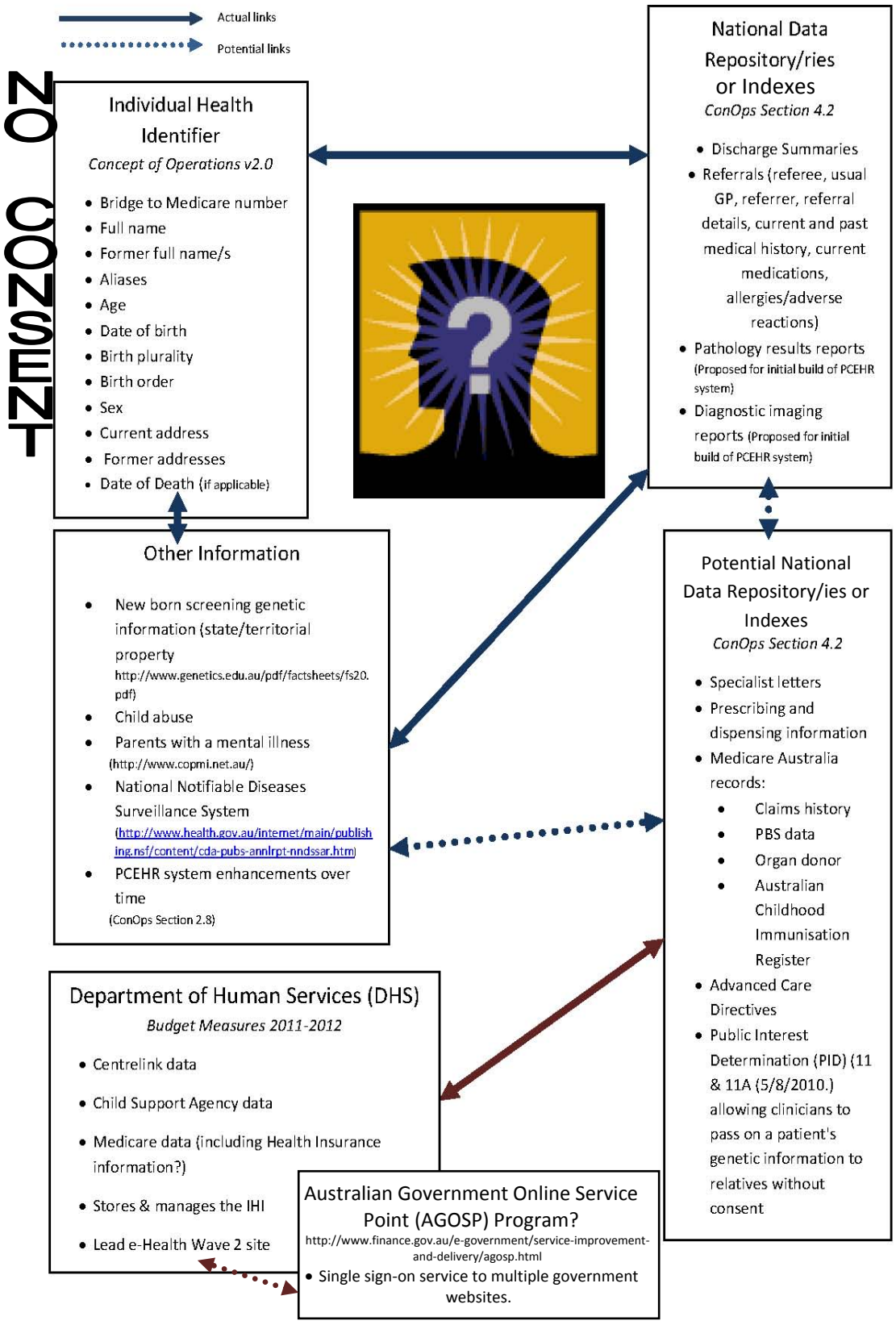
Dr Fernando is a councillor of the Australasian College of Health Informatics. http://www.achi.org.au/
Contact Details for the APF and its Board Members are at:
http://www.privacy.org.au/About/Contacts.html

REFERENCES

1. NHHRC, "A healthier future for all Australians - Final Report June 2009" (http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report)
2. Draft Concept of Operations relating to the introduction of a personally controlled electronic health record (PCEHR) system. Consumer, Healthcare, Provider, ICT Industry, and Policy Consultation Report January to April 2011, NEHTA.

Figure 1: Identified information about citizens held and/or indexed by Australian government health authorities in PCEHR system May 2011.

© J. Fernando 2011



Section 1: The ConOps approach

The lack of a coherent governance framework in the document lies at the heart of the APF submission on the draft ConOps. The development of such a framework would address the key privacy issues that are likely to influence individual enrolments into the system. It would also provide an opportunity to depoliticize various stakeholder discussions about the PCEHR system. Our health authorities seem to have learned nothing from the largely unsuccessful British national electronic health record system (1). Plans to design our PCEHR system without embedding it into a plain-English and transparent governance framework need urgent reassessment if we hope to create safer, more efficient and sustainable health care services for all Australians.

These governance shortcomings indicate that the draft PCEHR ConOps does not achieve our understanding of the key aim of a Concept of Operations document. A Concept of Operations is a document describing the characteristics of a proposed system from the viewpoint of an individual who will use that system (3). The PCEHR ConOps does not achieve this aim and stakeholders are not made aware of prospective system characteristics that will inform the outcomes they actually need from an electronic health record. The ConOps is confusing to read and obscures important issues. Document sections and sub-sections are supported by important information embedded in figures and tables only and by a bewildering multitude of cross-references to other parts of the same document. Rather than an informative Concept of Operations document, the draft PCEHR ConOps is excessively complex and seems intelligible only to "insiders".

The ConOps seems to prime Australians to re-set their expectations as to the deliverables funded by their investment of the $467 million in the PCEHR system. We are very concerned where patient control and consent will actually start and stop in relation to using the initial build of the PCEHR system. Government control of all personal and health information about citizens, some of this consensual, is depicted in. "*Figure 1: Identified information about citizens held and/or indexed by Australian government health authorities in the PCEHR system May 2011*". The APF is disturbed by the breadth and depth of information about individuals the PCEHR system plans to store or index without a clear governance framework upon which to base informed consent processes.

We can't see how the draft ConOps resembles or relates to the PCEHR system described in the National E-Health Strategy (2). The ConOps indicates that the range of citizen data stored in the PCEHR system may expand in unknown ways using unspecified methods for future undefined refinements. We have no access information about actual PCEHR pilot project plans, protocols, data models or evaluations. The draft ConOps for the PCEHR system signals an even more confusing era of access to private citizen information by clinicians, health organisations and many authorities than at present. While some attention is paid to clinical governance matters in isolation, such as accreditation, the overall governance framework for the PCEHR system and e-health nationally has not been devised. Work on an overarching governance framework, rather than the much needed detailed plan, will occur during a few months in late 2011, after enabling legislation has been introduced to Parliament. In short the Draft ConOps seems to be hastily conceived in such as way as to meet the scheduled implementation date of July 2012 rather than to inform stakeholders about how the system will function in real life.

REFERENCES

1. iHealthBeat, "Audit Slams British EHR Program for Being Largely Unsuccessful" http://www.ihealthbeat.org/articles/2011/5/18/audit-slams-british-ehr-program-for-being-largely-unsuccessful.aspx
2. National E-Health Strategy, http://www.health.gov.au/internet/main/publishing.nsf/content/national+Ehealth+strategy
3. Concept of Operations, http://en.wikipedia.org/wiki/Concept_of_Operations
4. Draft Concept of Operations relating to the introduction of a personally controlled electronic health record (PCEHR) system. Consumer, Healthcare, Provider, ICT Industry, and Policy Consultation Report January to April 2011, NEHTA.

Section 2: Privacy issues

This section lists the important elements overlooked or euphemized by the draft ConOps.

1. *Enabling legislation*

   At a recent Roundtable meeting in Melbourne, the APF asked for further information about the national repository service, including potential data sources, from both private and public health organisations, and enabling legislation to support the repositories. NEHTA has advised that:

   > "*Legislative issues relating to repositories are currently being assessed by Australian governments (i.e. Commonwealth and States and Territories). Proposed legislative approaches to these issues will be the subject of public consultation." (12)*

   The APF and other stakeholders were advised that a legislative issues paper is due in June 2011, with four week turn-around for comment. The exposure draft of legislation to support the creation of the PCEHR, the national repository service and consequential legislative amendments by July 2012 is scheduled for August to September2011. At least one public meeting will be scheduled before the PCEHR system legislation is introduced to Parliament, scheduled around October 2011. Consumer feedback will be drawn from patients at lead e-health implementation sites to inform PCEHR system design. State and federal law harmonization will not occur in time for initial PCEHR system build. **While not directly related to the draft ConOps document, the APF maintains the rushed implementation schedule and lack of access to hard data will impede the ability of individuals and organisations to provide meaningful, reflective and considered feedback to health authorities.**

2. *System governance*

   Evidently, "*the PCEHR long term governance framework will be agreed and in place through the last quarter of 2011/2012*" (13). Plans to design a governance framework after enabling legislation has been introduced to Parliament are disturbing. We raised the urgent need for an inclusive, formal and long-term governance framework for consultation at the recent Four Corners Roundtable in Sydney (5). The draft ConOps describes an advanced state of the PCEHR system design, lead sites are already working with the system (in the context of patient care) and the legislative implementation schedule is proceeding rapidly. The health authorities will spend only a few months devising the governance framework for a system that hopes to change the face of Australian healthcare forever. The community are unlikely to have faith in, or trust, the PCEHR system without a methodical, well planned governance framework at its heart. **In line with the APF's Policy Statement, the PCEHR system is not likely to attain key aims stated in the draft ConOps unless a detailed, formal governance framework that includes representation from NGO consumer advocacy groups occurs before the draft system and consequential amendment bills are tabled in Parliament**.

3. *Trial methods and outcomes*

   We are surprised to note that the scheduled implementation date evidently takes precedence over establishing the solid governance framework that ought to have been decided before the IHI and other PCEHR system building blocks were established. A key outcome from the Melbourne roundtable indicates several matters fundamental to ensuring a practical PCEHR system are currently under discussion. Important information about patient and clinician analyses of the system at lead sites will not be publicly available. The APF and other organisations and individuals will be denied access to real data to inform decisions about PCEHR system analyses. **The APF is concerned that keeping information about fundamental matters from the public domain will hamper community trust in the PCEHR system and may actually jeopardise the entirety of Australian national e-health efforts.**

4. *National repository service*

   The national repository service referred to throughout the ConOps is not explicitly discussed in the document. The current draft may be interpreted to indicate the repositories will store information about the community without their consent. The APF put this question to NEHTA at the Melbourne Roundtable and has been formally advised:

"*The PCEHR National Repositories will only hold information on behalf of the PCEHR System in relation to enrolled individuals*" (12).

We suggest this matter be more clearly addressed in future iterations of the ConOps, brochures and material designed to support community enrolments into the PCEHR system.

5. *Data fragmentation and extra work*

On the one hand the ConOps indicates that PCEHRs will address data fragmentation as a business driver. Data fragmentation is linked with adverse health outcomes and refers to silos of de-contextualised information that is stored in a variety of locations fostering uncoordinated decision-making processes (1). On the other hand the draft states the PCEHR system will not replace existing fragmented health information and communication (ICT) systems. Evidently it will impose additional layers on existing local and Territory and State based health information infrastructure. Recent comment from an Australian Medical Association (AMA) representative at the Clinician-Consumer Roundtable meeting in Melbourne suggested that workflow issues have not been considered in the draft ConOps. The representative said that if the PCEHR system added to time constraints between doctor and patient (i.e. if a clinician is forced to see fewer patients per work shift due to PCEHR system demands) then doctors won't use the system at all (12). The imposition of additional work is unlikely to be embraced by clinicians, especially those in private practice, so that – as experienced in the UK – many clinicians may ultimately ignore the system completely and health information will remain as fragmented as it was previously (2).**In the absence of workflow information in the draft ConOps, the APF maintains that models describing the PCEHR system in the context of clinical workflow and patient care outcomes should be urgently addressed by NEHTA prior to the initial system build.**

A review of the Con Ops shows the PCEHR is not intended to replace local patient identifiers and practice records and so ensure the right treatment is given to the right patient at the right time (3**).** Local health services will continue to rely on same, fragmented combination of information technology used presently. **The APF submits that the ConOps needs to state how the introduction of a parallel system will end data fragmentation and ensure the right treatment is given to the right patient at the right time.**

6. *Personal control*

Section 3.2.1 of the draft ConOps indicates that patients will be able to view all elements in their PCEHR and can tailor clinician views according to authorisation. Section 2.8 of the draft and recent stakeholder meetings suggests much of this control will occur during future refinements scheduled at unspecified points of time (12). Unless people have some control of data on entry, they are being treated as 'dumb terminals' themselves. Equally, the quality of the 'original' data in this context is unchecked and therefore unverified: it is dangerous to assume that existing data is accurate when establishing an entirely new data regime. **The ConOps should explain in plain-English what level of personal control consumers will actually have in the initial build of the PCEHR, that is, as of July 2012.**

7. *Error correction*

Error correction, enquiry and complaints arrangements outlined in the Draft ConOps are very dangerous to the health and wellbeing of the Australian community. The arrangements are manual and depend upon the individual affected reporting their concerns to a PCEHR Operator. The Operator will then initiate an enquiry and redress these accordingly. What medico-legal processes have been established to manage situations such as when the patient record on the PCEHR system conflicts with the local record or when an error is stored on the system and there is no local record at all? This question is particularly significant in emergency situations and when patient care depends upon the Consolidated View of a record in the system. Information indexed through the PCEHR system may not ever provide a reliable information source for patient care. **The APF suggests that a mechanism to warn clinicians about potential human error embedded into the PCEHR system must be clearly outlined in the ConOps and needs to occur prior to July 2012.**

8. *List of implementations for initial PCEHR build*

The document makes no coherent statement as to what Australians can expect from the initial build of the PCEHR system. Neither does it guarantee to incorporate all of the ideas the draft contains.

However section 9 does refer to "evidence-based implementations" as an important step in an ongoing evaluation process. Logically, proposed system enhancements will be informed by these evaluations. Health authorities ought not to change the PCEHR system as desired without reference to due process or open and transparent debate. NGO consumer groups must be involved in developing the metrics to inform Key Performance Indicators (KPI) that will be applied to the evaluations. This is especially important to those evaluations assessing the qualitative and quantitative realisation of benefits around better healthcare and improved satisfaction of individuals receiving healthcare.

The APF asked NEHTA about NGO consumer group involvement in devising the KPI metrics applied to ongoing system evaluations at the recent Melbourne meeting (12). The formal response we received was as follows:

> *"The Benefits Partner will be involved in the Change and Adoption consultation activities and will be consulting with end users to assess the benefits and evaluation criteria".*

The response does not answer the question adequately. NGO consumer group involvement in devising the KPI metrics should be added to the tender document that potential Benefits Partners will address.

The ConOps should:

1. **Itemise the benefit individuals can expect to receive from the PCEHR as of July 2012 and**
2. **Embed NGO consumer group consultation processes in the Benefits Partner tender document discussing proposed enhancements to the system.**

9. *"PCEHR" or "the PCEHR system"*

Terms "PCEHR" and "the PCEHR system" seem to be used interchangeably throughout the ConOps. Is there a distinction between the terms – i.e. does PCEHR refer to a singular record not attached to the mooted system or is this simple a consistency error? **Terms need to be harmonized throughout the ConOps or, if we are referring to two unique terms, each must be operationalized accordingly**.

10. *Health insurance*

According to briefings received at the Four Corners Roundtable held in Sydney recently, health insurers will be able to ask patients whether or not they have enrolled in the PCEHR system and vary premiums accordingly (5). Is this the case? If so, we feel such arrangement need to be manifest in the draft ConOps. **The APF believes the draft must clearly inform the community of this matter so that individuals can decide whether this decision contravenes the spirit of government moves to ensure health care insurers will not use any PCEHR system information for the management of claims or to determine eligibility.**

11. *Pseudonyms and Medicare benefits*

Hansard shows the government believes pseudonymous care will not impose a requirement that healthcare providers use an IHI when providing healthcare services, nor will identifiers be required for claiming healthcare benefits (4). Anecdotally, we understand that some patients have been denied a Medicare benefit because they used a pseudonym to obtain health care. Pseudonymous care is the only option open to many people wanting to protect identities for the purpose of their health and wellbeing (e.g. battered wives). Many of these people need the rebate in order to afford clinical care in the first instance. Pseudonymous care is totally different to anonymous care, as reiterated at the Melbourne meeting (12).Evidently a patient can apply to the Individual Health Identifier (IHI) Service Operator for a pseudonym and is then provided with a new identifier linking to the actual IHI. How will this process relate to claims for healthcare benefits? No information about the process of obtaining a pseudonym or healthcare benefits for pseudonymous care is currently available in the ConOps document. **We believe it is very important for the draft ConOps to be revised in order to show how the management of pseudonymous care will function with regard to the IHI, the PCEHR and claims for healthcare benefits.**

12. *Genetic data and storage*

The draft makes no reference as to whether genetic data is managed in the same way as other key health information about individuals. We believe newborn babies will automatically be opted into the PCEHR without parental consent (5). The information stored about newborns in the PCEHR is likely to comprise genetic information from the "heel prick" test. There are radically different, existing rules

throughout Australian States and Territories as to the storage of (and access to) "heel prick" data: the draft appears to assume that all such individual rules will be overridden by the first build of the PCEHR system. However we have learned that processes to harmonise the existing privacy rules throughout Australia will not occur before July 2012 (12). **We submit that the draft ConOps should explain to the community the way genetic data will be managed in the initial PCEHR system build.**

Also, genetic profiling is increasingly influencing Australian health care outcomes, as supported by a recent Public Interest Determination (6). The issue of whether genetic data should be stored in an individual's health record or indexed via national repositories to personalise medicine is already being discussed in the peer reviewed literature. **The issues of overridden consent in some instances and genetic data storage overall are factors that must be discussed in the ConOps so that all Australians may reflect on potential risks in the context of information stored in the PCEHR system.**

13. *Length of data storage*

Several speakers at the Four Corners Roundtable in Sydney stated that information will be stored in the PCEHR system for 110 years (5). What will occur to the stored data after this period? **The APF is surprised the ConOps neither mentions the arrangement nor discusses data disposal measures.**

14. *Access rules*

The document also does not explicitly outline everyone who will have access to the stored data, under what rules. This is particularly confusing with regard to emergency access. Information we received during several stakeholder meetings have explained there will be no way to override exclude lists or the lack of a PCEHR enrolment on the one hand, yet the Draft ConOps takes a contradictory position (5). We understand that legislative concerns with regard to emergency access provisions are still being discussed, but this cannot be comprehended by anyone reading the draft. **The APF believes that the community requires a clear explanation of emergency rules in the context of clinician access to the PCEHR system before the initial build is decided.**

The Con Ops suggests authorised representatives of an HPI-O, who may view a record, will not be identified on the system. The draft system will also permit patient information to be downloaded and printed by HPI-O staff. The document also states that health organisations will be responsible to pass protective obligations through all inter-connecting system parts along with the data. Yet evidence suggests no such responsibility may apply in real life situations, as the following example indicates. Serious information breaches were reported to the Department of Health and Ageing in the context of Medicare Australia's administration of the PBS link in pharmacies last year. The pharmacies evidently took no action. The Department argued the breaches were not their concern and took no action either (11). **The APF maintain that technical audit arrangements outlined in the draft document make no reference to human factors and are unacceptable at this stage.**

15. *The IHI*

The Individual Health Identifier (IHI) is the bridge that links information to the PCEHR system and the national repositories. According to Hansard records, the IHI was passed to replace the allocation of patient identifiers by each service provider (7). We now know this is not the case and that parallel identifiers will be allocated to patients along with the IHI as means of ensuring patient identification (8). Accordingly, the government has authorised a system for mandatorily and uniquely numbering all citizens from birth to grave for one purpose, whereas the architects of the PCEHR propose to use the IHI for a contradictory purpose. The contrary purpose will magnify existing confusion in clinical settings and may actually increase rates of adverse health error. **We submit that the matter of compulsory numbering for all Australians must be returned to Parliament for review in light of this function creep to ensure the health safety of all Australians.**

16. *NHHRC report*

The PCEHR system, as currently designed, distorts findings from the National Health and Hospitals Reform Commission Report, June 2009, as to recommendations about the development of personally controlled health care records (9). The PCEHR Con Ops distorts the report findings beyond recognition. **We urge health authorities to revisit the NHHRC report with a view to implementing the Report's PCEHR system recommendations therein.**

17. Consumer booklet

The consumer booklet should be at the heart of the process of engaging the broader public with the PCEHR system; but this is not the case. The booklet should explain as clearly as possible, with text and simple diagrams, to consumers how PCEHR system information will be diced, controlled, moved around and used, at a big picture level. By contrast with the existing glossy consumer booklet, health authorities have an obligation to create such a document in order to enable a much broader understanding of the big picture of the proposed PCEHR system and its assumptions and risks. The structure of the national PCEHR system's governing model for access and use needs to be addressed in the booklet (and the ConOps), as do issues of whether all protective obligations pass through all inter-connecting system parts along with the data. The identity of the single role that is responsible for compliance and breaches should be identified too. **The APF maintains that the consumer booklet should be revised so it is made clear enough for everyone to grasp the essential parameters, rules and roles being proposed in the ConOps.**

REFERENCES

1. Fernando, J., & Dawson, L. (2009). 'The health information system security threat lifecycle: An informatics theory', Int. J. Med. Inform., pp. 815-826
2. Greenhalgh T, Stramer K, Bratan T, Byrne E, Russell J, Potts HWW. Adoption and non-adoption of a shared electronic summary record in England: a mixed-method case study. BMJ. 2010;340.
3. E-Health: Healthcare Identifiers Service http://www.health.gov.au/internet/main/publishing.nsf/ Content/pacd-ehealth-consultation
4. Senate Official Hansard http://www.aph.gov.au/hansard/senate/ dailys/ds150310.pdf
5. Four Corners Roundtable http://newsletter.nehta.gov.au/industry-brief/industry-brief-archive/archive/view/listid-4-industry-ezine/mailid-66-industry-brief-special-bulletin-march-2011
6. PID 11 and 11A._ Regarding the collection and use of contact details of genetic relatives to enable disclosure of genetic information without consent, dated 5 August 2010.)
7. The second reading of the Healthcare Identifiers Bill 2010 and the Healthcare Identifiers [Consequential Amendments] Bill 2010, Thursday June 24.
8. (NEHTA Security and Access Framework, http://www.nehta.gov.au/component/ docman/doc_download/877-security-and-access-framework)
9. A healthier future for all Australians - Final Report June 2009 http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report).
10. Consultation Process re PCEHR, Further Letters to NEHTA Clinical Lead re PCEHR Process Matters, and to NEHTA CIO re PCEHR Design Issues. APF. (15 Nov 2010) http://www.privacy.org.au/Papers/NEHTA-PCEHR-Process-101115.pdf)
11. Brettingham-Moore, C. "Pharmacy-held data security questioned." Medical Observer, June 4 2010.
12. Consumer and Clinician Roundtable, NEHTA, Melbourne, May 25 2011.
13. Draft Concept of Operations relating to the introduction of a personally controlled electronic health record (PCEHR) system. Consumer, Healthcare, Provider, ICT Industry, and Policy Consultation Report January to April 2011, NEHTA.