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Privacy  
Foundation**

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## **APF feedback about the Personally Controlled Electronic Health Record (PCEHR) system:**

### **Legislation Issues Paper.**

July 12 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. Our response to your request for community feedback on the “Personally Controlled Electronic Health Record (PCEHR) system: Legislation Issues Paper” is detailed below.

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.

This submission is drafted in two sections. Section one summarizes our key concerns with Paper in the context of several previous submissions (one attached for information). The Legislation Issues Paper explains that feedback about the PCEHR system itself is out of scope (p.3) yet the publication nonetheless expends two sections on the system as context. The links between system and legislation are irrefutable and so section one is drafted accordingly. The second section directly responds to the 34 questions and 41 proposals in the Paper and is also formatted accordingly.

### **Section One: the Legislative Approach**

The PCEHR System Legislative Issues Paper overlooks important broad NGO community concerns that have been clearly expressed both to the National E-Health Transition Authority (NEHTA) and Department of Health and Ageing (DoHA). The recent APF submission on the Concept of Operations for the system and relevant e-health policy statements setting out the broad concerns are publicly available on our website (<http://www.privacy.org.au>) and have been attached to this submission for information. These concerns centre on 3 major themes: scientific rigour, quality of care and legislative issues.

## 1. Scientific rigour

The Paper makes a plethora of unduplicatable and unscientific assertions throughout. For instance the term “will” instead of “may” permeates rhetoric to support claims about the unproven social value of the proposed system. Despite ongoing allusions to standards there is no reference to a specific standard or standards. The PCEHR system is reported as relying on a foundation of distributed systems while the Figure on page 9 (see notes, “Participants and Information flows in a PCEHR system”) supports the concept of centralised national repository of personal Individual Health Identifier (IHI) information under a single management. The Paper draws generalisable conclusions without ever consulting or researching a representative sample of the Australian community. **The APF believe that without any real-life, duplicatable evidence the notion of social value pervading the Paper presupposes a potentially dangerous scientific validity.**

## 2. Quality of Care

The APF is critical of assumptions of social value that are supposed by the Paper’s authors. Although the Paper outlines number of questions and proposals for feedback at the domain level, these are founded on ideas that do not reflect many real life experiences stakeholders present to the Foundation. The “invitation only” series of consultations about the PCEHR system indicates a lack of proactive engagement with the broad community and weakens the reliability of assertions as to their concerns (5). **The assumptions suggest that health authorities have paid insufficient attention to the community feedback provided thus far during consultations.**

The Legislation Issues Paper states the initial PCEHR recruitment procedures a will focus on key groups in the community that health authorities have tagged as “those likely to receive the most immediate benefit, including those suffering from complex and chronic conditions ...” (p10). Individuals suffering from complex and chronic conditions suffer a combination of the same range of illnesses suffered by the community more generally as well as other illnesses (such as Diabetes) and complications thereof. On reflection, authorities seem to assume chronic or complex illnesses are homogeneous when in fact we are speaking of heterogeneous and a complex range of conditions. **While administrative applications of the PCEHR, such as contact details and lists of tests or allergies, are likely to prove useful in this context, we cannot see how the system provides further clinical benefit to patients with chronic or complex health conditions.**

“Motherhood” statements about patient-centred care in the Legislation Issues Paper require an evidence-based foundation. The Paper implies individuals must work through a bureaucratic trail of as yet unspecified third parties to review details from the electronic audit of their PCEHR or, worse, to amend medical information errors. The patient care consequences of the manual systems remain untested. However, the government seeks wide system uptake by the community. Such uptake will depend upon the quality of data stored and a coherent, speedy process to rectify errors. **The APF maintains that rather than reliance on a mixture of communication technologies, the legislation needs to incorporate a direct and efficient means of complaints. The legislation also needs to enable the individual’s direct access to information stored about oneself (i.e. without the intervention of PCEHR systems operators).**

The Paper promises the end of data fragmentation (p.5). The APF is confused by this assertion because our reading of the Paper suggests otherwise. Adding a parallel health information system that duplicates current practice information systems seems to serve no purpose. Furthermore, commercial entities are

already selling patient-held cards for consumers which will store “milestone” health information (3). **During a consultation, the APF is concerned clinicians may feel forced to refer to care information stored in the formal PCEHR system, the range of commercial services offering ways for the community to retain custodianship of their health information and their own practice records simply to comply with their medico-legal and Hippocratic perceptions of high quality patient care; this will add to the complex and confusing business of health care service delivery and may foster new forms of patient care error.**

Emerging evidence-based research findings show electronic health records can be as likely as handwritten ones to contain errors (4). The community requires clear guidance as to exactly which records a clinician should use to ensure his or her access to the most reliable and up-to-date information for patient diagnosis and treatment. **The APF underlines the logical inconsistency of implementing parallel systems for the purpose of ending data fragmentation and associated medical error.**

The Paper defers legal and workflow liability for the PCEHR system to the individual clinician or health organisation, yet medicos have made it very clear that they will not use the system as outlined (see attached ConOps sub for detail). Individual control of the health record is promised to the community in the full knowledge of this major limitation. The doctors are unlikely to rely on PCEHR health summaries or information provided by various unknown clinicians and possibly held by patients for care. **The APF is concerned to see the matter of clinician intent resolved before the new PCEHR system is marketed to the community.**

For the PCEHR system to function, clinicians must be registered on the system as well as the patient. After July 2012, individuals and their clinicians, depending on their respective views, may well need to sort through antagonistic PCEHR system positions on a case-by-case basis. **The APF is concerned about the ongoing quality of patient-clinician trust relationships when the legislation seems to embed an adversarial role for each group respectively.**

The market for commercial services selling ways for the community to retain custodianship of their health information suggests legal frameworks for the PCEHR system are not keeping pace with stakeholder views (4). The commercial sector is already exploiting individual fears about controlling their health and personal information stored or indexed in the PCEHR system. Evidently, many in the community do not feel adequately protected by the current patchwork of Australian health privacy protective legislations across the country or by the proposed national harmonisation of these. **The APF is alarmed to notice that a new and robust “fear creation” market is emerging in Australia as a consequence of the introduction of the PCEHR system.**

Finally, Privacy Commissioner Timothy Pilgrim is recently quoted in the press as saying that the groups with which government authorities have consulted do not necessarily reflect the views of the broader community, who may interact less frequently with the health system (5). Commissioner Pilgrim’s comments support notions of a market niche emerging as the consequence of a mismatch of beliefs between government health authorities and the broader community about custodianship of health information. **The APF believes the PCEHR Concept of Operations and proposed legislation should address Commissioner Pilgrim’s concerns in an open, publicly available and transparent way before enabling legislation is introduced to Parliament.**

### 3. Legislative Issues

The PCEHR Legislative Issues Paper does not thoroughly consider medico-legal accountability as well as other legislative issues. The Paper continues to overlook Individual Health Identifier (IHI) function creep, which despite protestations to the contrary, cannot safely determine patient identity (11). **The Australian e-health experiment perplexes the APF and we are sceptical of claims that the PCEHR system will necessarily improve patient care outcomes or reduce identity-linked adverse health error.**

NGO consumer groups have pointed to the need for government to review an Insurers legal right to know about an individual's PCEHR and set premiums accordingly for some time. We believe this decision contravenes the spirit of earlier PCEHR system publicity indicating that health care insurers will not use any system information for the management of an individual's claims or to determine eligibility. **The APF feels an Insurer's legal right to know and set premiums according to an individual's PCEHR enrolment choice should be made explicit in enabling legislation to ensure public awareness of the decision prior to July 2012.**

As the Paper states, 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. The document provides no information about pseudonyms and Medicare or other health rebates. 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 (6). **The APF urges health authorities to ensure the legislation explicitly comments on the management of pseudonymous care with regard to the PCEHR system and Medicare and other health benefits.**

The Issues Paper suggests legal changes required to enable the PCEHR will be harmonized in unspecified tranches leaving the community, including clinicians, to wonder how their genetic information will be managed. State and Territorial jurisdictions manage genetic data harvested from the "heel prick" test of new-borns differently. **The Paper does not refer to the management and storage of an individual's genetic information at all, while in real life the community will need to sort out these thorny matters from the very first day of PCEHR system implementation. The APF asks that this matter be addressed in enabling legislation.**

The legislation is likely to authorise health organisations to download, print and store an individual's information on practice systems without consent in accordance with current local healthcare practice norms. The Paper assumes current Australian legislation offers adequate protection of community privacy. No evidence supporting this assumption is provided in the Paper. Abundant examples of the reverse permeate the published, peer-reviewed international literature as do findings from the recent Australian Law Reform Commission's review of privacy (1, 7). Commercial interests are already using community perceptions of potential threat to their information as a way to sell "fear-based" services (see Patient Care Section above for further information)(3). **The PCEHR system promises substantial improvement as the result of health reform dependent upon computerised security systems that assume legal safeguards are sufficient, yet authorises risky paper-based workarounds for health services.**

Moreover, health authorities consistently speak about the way the PCEHR will improve healthcare on the one hand while on the other hand, many of our expressions of concern about the System are rebuffed with the response “but this is no different from current systems”. The authorities’ responses beg questions about why we should fund a new system if Australians will continue to rely on the old. **The national e-health system should and can be better than, not the same as, health information systems that presently exist in the community. The APF maintains that, the use of paper-base practice tools informed by the PCEHR system is inconsistent with notions of health improvement and should be rectified in enabling legislation.**

Legal sanctions for deliberate misuse of a PCEHR, another key APF concern, are outlined in the Paper but public domain evidence suggests these sanctions have not previously been applied. Even when an organisation has been shown to contravene the law, government authorities do not recommend penalties due to ostensible human error concerns (1). We ask how the concept of “deliberate” misuse is tested against “human error” when health professionals often function in privacy invasive premises that are controlled by the organisation rather than the clinician. One only need refer to the instance of failed Pharmacy data audits last year to question the veracity of the sanctions outlined in the legislation (2). **The APF suggests the track record of various government bodies does not inspire community confidence in the efficacy of legal sanctions outlined in the Paper.**

Anecdotally, we are receiving communications from several individuals who are patients at Lead Sites for the PCEHR system. Evidently legacy health information is in the process of digitisation in preparation for the introduction of the system. These patients have been advised through 3<sup>rd</sup> party legal organisations that the health sites in question comply with Australian legal requirements. The individuals’ actual concerns about the way their legacy and current health information has been managed are not addressed at all. Neither do the legal responses actually identify the specific laws with which they comply. The community require access to resources explaining what they might realistically expect from the PCEHR system **The APF urges health authorities to establish and fund a service to directly address these community concerns about legacy data in the public domain.**

**The PCEHR system represents revolutionary health care reform that will dramatically influence the lives of every single Australian and the APF is therefore surprised by the lack of substance contained in the Legislation Issues Paper.**

## **Section Two: the APF response to Questions and Proposals.**

This section outlines the APF response to the 34 questions and 41 proposals contained in the PCEHR Systems Legislation Issues Paper. We will attempt to indicate all those to which we have previously responded to avoid duplication.

*Q1. Are there other potential participants in the PCEHR system and what is their role?*

**As one commentator recently pointed out “creating a system to be used by consumers and clinicians ... will satisfy neither (8). The APF requests the team drafting the Legal Issues Paper and associated PCEHR system projects to rectify this so that the Australian community can enjoy the ostensible benefits of such.**

*Proposal 1: Legislation would specify that an individual would be entitled to be registered for a PCEHR if:*

- *he or she has a verified IHI; or*
  - *in the case of individuals under 12 months who do not have a verified IHI, he or she has an unverified IHI;*
- and*
- *the identifying information has been provided to enable registration.*

*Proposal 2: Legislation would enable the information flows necessary to verify the identity of individuals, and to create legally recognised rights and responsibilities for individuals.*

**As NEHTA's own risk analysis shows the IHI cannot reliably verify individual identity, so that Proposal 1 and 2 are moot (11). The APF is concerned the Legislative Issues Paper specifies reliance on the problematic and unproven IHI number rather than a 2 or 3 factor process of patient identification for health care.**

*Q2. Should portals for consumer registration be provided by organisations other than health related organisations, including government organisations?*

**Stakeholder responses to this question will not provide evidence of community support for the integration of government services, such as Centrelink or Medicare, into the PCEHR system. The APF cannot respond to this question in the absence of a suitable governance framework and other relevant information.**

*Proposal 3: Legislation would provide a broad framework permitting an individual to participate in the PCEHR system through an authorised representative.*

*Proposal 4: Administrative and/or policy arrangements would provide the detail for how a person can be recognised by the PCEHR system as an authorised representative.*

*Proposal 5: Legislation would not prescribe eligibility criteria for authorised representatives, but would recognise authorised representatives established under existing Commonwealth, state and territory laws.*

**The APF welcomes codification of authorised access to an individual's PCEHR.**

*Q3. What possible barriers are there to the participation of individuals through their authorised representatives?*

**The health status of an individual generally changes over time and this may present barriers to the participation of individuals through their authorised representatives as these may also change, i.e. adult children caring for elderly parents or other family members. .**

*Proposal 6: Legislation will not prescribe the age at which a person under 18 years of age is presumed to have capacity to manage their own PCEHR.*

*Proposal 7: Consistent with the approach taken by Medicare Australia, an administrative/policy framework will provide for participation in the PCEHR system by minors. The general participation arrangements will apply as follows:*

- *up to 14 years of age – a parent or legal guardian will be responsible for the child's PCEHR, including whether to register the child for a PCEHR and managing the access controls of the child's PCEHR;*
- *14 to 18 years of age – a young person will be presumed to have capacity to make decisions in respect of their PCEHR. If the child elects to manage their own PCEHR they can decide whether or not to participate*

*in the PCEHR system and manage the access controls of their PCEHR including choosing whether to allow their parent or legal guardian access. If a young person chooses not to manage their own PCEHR, the parent or legal guardian would continue to manage the young person's PCEHR;*

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

*Requests by minors under 14 years of age to manage their own PCEHR will be considered on a case by case basis by the PCEHR system operator.*

**The APF is generally satisfied with the Proposals, but if a minor is responsible for their own PCEHR then it is logical to assume that they seek confidentiality in the first instance. No-one but the individual concerned and their authorized or nominated representatives and those with legal authority have the right to inform the parents or any other 3<sup>rd</sup> party of PCEHR contents.**

*Q4. What other circumstances might need to be accommodated in the administrative arrangements for minors?*

**This question is beyond the purview of the APF.**

***Proposal 8:** The PCEHR system will support the creation and use of a PCEHR using a pseudonymous identity and healthcare identifier.*

**The APF beseeches health authorities to ensure that non- participation in the PCEHR system will have no impact on Medicare, Insurance and health benefits more generally (see above), as stated on p.6 of the Paper.**

*Q5. What are the possible risks related to the creation and use of a pseudonymous PCEHR?*

**None beyond current practice that the APF can envision.**

*Proposal 9: Legislation would specify that in order to be eligible to register for the PCEHR system a healthcare provider organisation must:*

- have a HPI-O;*
- conform to specified technological requirements; and*
- agree to prescribed terms and conditions.*

*Proposal 10: Legislation would provide a framework for standards with which healthcare provider organisations must comply.*

*Proposal 11: Legislation would provide authority for the making of terms and conditions which will apply to a healthcare provider organisation regarding the authorisation and identification of eligible users of the PCEHR system within the organisation.*

*The legislation will describe that, to be eligible as an authorised user:*

- healthcare providers must have an HPI-I and be identifiable in the healthcare provider organisation's local system; and*
- other individuals within a healthcare provider organisation, such as contracted service providers and administrative staff, must be identifiable in the healthcare provider organisation's local system and have a legitimate need to access the PCEHR system.*

**As is discussed in Section 1, these Proposals cannot elicit a response, firstly because no actual standard is in the public domain, secondly because many clinicians cannot yet enrol for an health identifier and finally, because there is evidence to indicate that DoHA will not hold organisations into account for audit failure.**

*Q6. Are there other terms and conditions that should apply to healthcare provider organisations in regulating the eligibility of authorised users?*

**See above**

*Proposal 12: Legislation would provide a framework for rules and standards with which a nominated healthcare provider must comply in authoring and managing a shared health summary.*

*Proposal 13: The legislation may set out a framework for the rules and standards that relate to the authorship of other PCEHR documents.*

**Regardless of framework, the APF does not believe many clinicians will base patient care on a shared health summary that is authored by other, unknown clinicians. The patient will continue to provide key information to a clinician and at best, may only confirm information stored in the summary.**

*Q7. What are the essential rules and standards with which a nominated healthcare provider should comply in relation to authoring and managing a shared health summary?*

**In this context, it is essential for nominated healthcare providers to links to raw data test results rather than rely on professional opinions, which are subject to human error.**

*Proposal 14: The legislation would establish the PCEHR system operator, prescribe the operator's functions and responsibilities and establish an administrative framework for setting the service levels and operational rules that the PCEHR system operator would need to meet.*

*Proposal 15: The HI Act would be amended to explicitly support the use of healthcare identifiers by the PCEHR system operator.*

**These Proposals seem to hinder direct access to their PCEHR system by individuals, while empowering the private sector system operator with the access. Given evidence suggesting potential data quality threats embedded in the PCEHR system, the APF is confused by the purpose underpinning the Proposals. We ask whether these proposals are included in the Legislative Issues Paper for the purpose of providing a "straw-poll" mandate to support the registration of private sector PCEHR system-operators into the national health system.**

*Q8. What are the essential obligations that should apply to the PCEHR system operator?*

**The PCEHR system operator should be obliged to provide publicly available real time reports over the Internet and in the popular press that evaluate their functions as outlined in the Legislative Issues Paper. The Directors of organisations registered as system operators should always be subject to Australian legal frameworks so that corporate responsibility cannot be deferred by claiming residency outside the country.**



*Proposal 16: The legislation would define repository operators to include registry operators and provide a framework for the regulation of PCEHR-conformant repositories, including:*

- *a framework for allocating identifiers to PCEHR-conformant repositories;*
- *requiring that all health information used for PCEHR system purposes must be held in Australia; and*
- *requiring that repository operators are a legal entity within Australia.*

*Proposal 17: The legislation would establish the role of the National Repositories Service, identify its operator and provide any unique criteria which will apply to the National Repositories Service.*

*Proposal 18: Relevant legislation would be amended to enable specific data sources held by Medicare Australia to be compliant repositories for the PCEHR system.*

**The APF asks whether Proposal 16 is intended to mitigate ability of cloud solution or private sector providers to deliver adequate privacy protections. See our response to Q8 for our response.**

*Q9. What are the essential obligations that should be met by repository operators?*

*Q10. What additional criteria might be applicable to the national repositories?*

**The APF needs to understand what the proposed functions of the national repositories actually are before providing a meaningful response to the questions. Do the repositories store data as the ConOps and Issues Paper suggest or do they act as a conduit through which health information flows in a federated fashion, as recently indicated by NEHTA representatives at a meeting in Melbourne?**

*Proposal 19: The legislation will authorise the use of data held by Medicare Australia, DVA and the Department of Defence as trusted data sources for identity verification purposes.*

*Proposal 20: The legislation will allow for future trusted data sources to be identified through regulations.*

**The APF firmly believes the legislation should NOT allow future, seemingly trusted data sources to be identified through regulation.**

*Q11. Are there any other trusted data sources that should be included in the legislation from the outset of the PCEHR system?*

**There are none of which we are aware.**

*Proposal 21: The legislation will provide for the participation of portal providers.*

*Proposal 22: The legislation will provide a framework for the regulation of PCEHR-conformant portals, including:*

- *a framework for allocating identifiers to PCEHR-conformant portals;*
- *requiring that all servers used for PCEHR system purposes and all demographic information used for PCEHR system purposes must be held in Australia; and*
- *requiring that portal providers are a legal entity within Australia.*

**See APF comment re Proposals 16-18**

*Q12. Are there any other essential requirements for portal providers?*

**As we read the Paper, health services may provide portals in a commercial sense. If we are correct then it is essential that this capacity is made apparent to the community in the PCEHR legislation.**

<p><b>Portal providers and the Directors of these companies must be subject to Australian law.</b></p> <p><b>The APF understands some consumers will use multiple portals and/or change portal providers from time to time. Portal providers may also withdraw from the market. The legislative framework for the regulation of PCEHR-conformant portals must allow for the possibility of change and consumer choice.</b></p> <p><b>We also ask how the legislation will function in the likely event of some consumers wanting to manage their PCEHR by hosting their own portals- i.e. the individual and the portal provider are a single consumer or community group.</b></p> <p><b>Finally, the APF suggests provision for cloud and similar services be made explicit in the legislation.</b></p>
<p><i>Proposal 23: The assignment of intellectual property rights for the PCEHR system would be based in either legislation or contract. The changes required will be further developed as feedback is received as part of the consultation process.</i></p> <p><b>We have no meaningful comment to make regarding Proposal 23.</b></p>
<p><i>Q13. Are you aware of specific examples of information for which intellectual property rights might present a significant barrier to the use of the information in the PCEHR system?</i></p> <p><b>We have no meaningful comment to make regarding Q13.</b></p>
<p><i>Proposal 24: The legislation would require retention of documents which have been indexed/accessed by the PCEHR system for 15 years since last action on record (or in the case of a minor, until they are 30 years of age).</i></p> <p><i>Q14. Can you identify any other options for records retention and can you identify any other issues regarding records management that have not been considered in this paper?</i></p> <p><b>Please refer to the APF comments for Q12 and Section 1, genetic information.</b></p>
<p><i>Proposal 25: Legislation would set out the individual's role in setting access controls, authorising others to access their PCEHR, choosing which information is published to and accessible through their PCEHR, viewing an activity history for their PCEHR and making enquiries and complaints.</i></p> <p><i>Q15. Are there additional access functions for individuals that need to be included in legislation?</i></p> <p><b>Direct access functions for individuals working with data about themselves needs to be included in the legislation.</b></p>
<p><i>Proposal 26: The broad framework which permits an individual to participate in the PCEHR system through an authorised representative (see proposal 3) will provide the necessary legislative support for access by authorised representatives.</i></p> <p><i>Q16. Should any specific restrictions apply to the extent to which an authorised representative can act on behalf of the individual within the PCEHR system?</i></p> <p><b>Informed consent processes should apply to the extent to which an authorised representative can act on behalf of the individual within the PCEHR system.</b></p>
<p><i>Proposal 27: The legislation would allow an individual to nominate one or more persons to be their nominated representative for the purpose of viewing the individual's PCEHR.</i></p> <p><i>Q17. Are there any other essential or additional requirements or obligations of a nominated representative that should be supported in the PCEHR legislative framework?</i></p> <p><b>Evidence of an individual's informed consent for nominations should be supported in the PCEHR legislative framework.</b></p>
<p><i>Proposal 28: Legislation would not prescribe eligibility criteria for nominated representatives, thereby allowing</i></p>

*for representation by minors.*

*Q18. Are there any reasons why an individual should not be able to choose a minor as their nominated representative?*

**The APF sees no reason why individuals should not be able to choose a minor as their nominated representative.**

*Q19. Would it be desirable to include any other eligibility criteria for a nominated representative?*

**It is desirable for the legislation to specify clear procedures outlining the informed consent process that will be required to nominate a representative. In some cases this may be verbal and/or during an episode of care. The informed consent needs to be noted in the individual's PCEHR as well as in local practice records.**

*Proposal 29: Legislation is required to define authorised users who may access a PCEHR when they have been granted permission to do so by the healthcare provider organisation they work for and in line with the access control settings established by the individual.*

*Q20. Are there additional issues in relation to authorised users that should be addressed in the legislation or regulations?*

**The APF has no in principle comments to make regarding Proposal 29 or Question 20.**

*Proposal 30: Emergency PCEHR access is already provided under existing privacy and health legislation.*

*Q21. Should there be additional legislative provisions for emergency access to PCEHR information?*

**The APF has no in principle comments to make regarding Proposal 30 or Question 21. However we are concerned about the potential for human error to occur when clinicians depend upon the contents of a summary record for patient care in an emergency situation given the untested manual processes discussed in Section 1.2 of this submission. We also ask whether medico-legal issues will become relevant if, as occurred in the UK, clinicians largely overlook information stored in an individual's summary care records in emergency settings to avoid medical error (9).**

*Proposal 31: In relation to the system operator and portal operators, the legislation should ensure that a body may not perform that role unless it is subject to the Privacy Act.*

*Proposal 32: In relation to repository operators, the legislation should ensure that a body may not perform that role unless it is subject to privacy obligations under Australian law.*

*Q22. Will this provide the necessary level of protection for personal information uploaded to the PCEHR system?*

**We welcome Proposal 32. However evidence-based analyses of the Australian the Privacy Act indicate it does not function efficiently or effectively to protect the privacy of the community either generally or in the specific context of health information (2). Please refer to Section 1.3 of this submission for feedback as to Q22.**

*Q23. What privacy legislation should apply to repository operators?*

*Proposal 33: Healthcare providers will be subject to the privacy coverage provided by existing law.*

Repository operators need to comply with Proposals 31 and 32. See the APF response above in the context of the Australian Privacy Act and associated regulation.

*Q24. Are there any reasons why clinical information downloaded from the PCEHR system should be required to be handled differently to other information held by a healthcare provider in their local records?*

*Q25. If so, how could the practical difficulties be overcome?*

**There is evidence indicating that current healthcare practices often threatens the privacy of clinical information (1,2,8). If information taken from a PCEHR is held by a provider as well as the system then the magnitude of private health data stored and held by a provider is likely to be richer than previously and may act as a “honey pot” to hackers. The storage exposes an individual to increased risk of breaches to data stored in the PCEHR, especially (and in light of recent Sony events) if the hacker in question believes provider e-health systems are easier to hack than government systems.**

**Instead, medical records might point to relevant PCEHR records or note the computer location where they are stored for “just-in-time” care. The PCEHR system seems to be a parallel, often manual, system adding to data fragmentation and the complexity of clinical work, fostering human error and so risks to the privacy of patient information. Also, the storage of addition data downloaded from a PCEHR to local systems is unwarranted, works against the “need to know” privacy principle and exposes clinicians to an increased range of medico-legal concerns. The practical difficulties indicated in Q25 will be resolved if data stored in the PCEHR system CANNOT be downloaded to provider systems.**

*Proposal 34: The legislation would not displace the exceptions to the prohibition on use and disclosure of health information in the Privacy Act. The Commonwealth will work with states and territories to identify any existing reporting or secrecy provisions that may impact on the operation of the PCEHR system.*

*Q26. Are you able to provide examples of existing reporting or secrecy provisions that might impact on the PCEHR system operations?*

**Mandatory reporting of public health concerns, professional misbehaviour or child abuse might impact on PCEHR system operations.**

*Proposal 35: The legislation will provide a framework to support ongoing security of the PCEHR system, but will not set technical requirements, to allow for quick and flexible responses to technological change.*

*Q27. Are there technical aspects of the PCEHR system design that are so critical to security and sufficiently stable over time as to warrant inclusion in the legislation or regulations?*

**Please refer to the APF policy documents attached to this submission for our response to Proposal 35 and Q27.**

*Proposal 36: Criminal offences would be included in PCEHR legislation covering officeholders or other legal entities involved in the management or control of the healthcare provider, to address:*

- failure of a registered healthcare provider to notify the PCEHR system operator within a specified period when it ceases to meet the requirements for registration to participate in the PCEHR system;*
- requests for and receipt of a record from the PCEHR system by a healthcare provider, when the provider or her/his requesting employer or contractor is not authorised to do so; and failure of a registered healthcare provider to meet audit trail or other record-keeping obligations imposed by the legislation.*

**The legislation should precisely define the difference between human error and other forms of error, such as workplace layout, infrastructure and other physical or managerial elements in the context of criminal offence. Such offences should ensure HPI-Os and the work environment they provide for clinicians are legally accountable for such rather than assume the clinician or other health professionals are always responsible for data breaches.**

*Q28. Is the size of the penalty (50 penalty units or \$5,500) used in the HI Service appropriate for the PCEHR*

system?

**The size of the penalty must relate to the misdemeanour or crime and so needs to vary accordingly.**

*Q29. Is it appropriate to impose a penalty on the individual who requests a record from the PCEHR system when not entitled to do so?*

**It is only appropriate to impose a penalty on the individual if access was obtained. The individual who requests a record from the PCEHR system when not entitled to do so should be formally warned by the HPI-O and the PCEHR system operator and a note kept of the request and subsequent warnings.**

*Proposal 37: Criminal offences would be included in PCEHR legislation which relates to the participation in the PCEHR system by a repository or portal operator, where that body has failed to meet or maintain the requirements for participation in the system.*

*Q30. What specific breaches of requirements should result in an offence and penalty for repository or portal operators?*

**Please refer to our comments in Section 1.3 and sections above.**

*Proposal 38: The legislation may not include an obligation of confidentiality on the PCEHR system operator or its employees or contractors. Instead, inappropriate handling of personal information would be dealt with under existing privacy, disciplinary or criminal law.*

*Q31. If the system operator is an agency and its employees are subject to the Code, would these disciplinary measures be sufficient?*

**No, refer to our previous response in Section 1.3 and relevant responses above for further information.**

*Q32. If the PCEHR system operator is a private sector organisation would additional mechanisms be required?*

**Yes, an explicit link needs to be made between the Australian identity and legal responsibilities of such operators and the terms and conditions of employment of individuals working with Australian data. See our response to Q 12 and cloud computing for additional information.**

*Proposal 39: The Commonwealth will assess the coverage of existing Commonwealth offences to determine whether specific PCEHR offences are needed to better enable the Commonwealth to have jurisdiction in PCEHR-related identity crime matters.*

*Proposal 40: The Commonwealth will seek to amend its existing computer offence provisions to remove existing constitutional limitations. This will enable the offences to apply to all PCEHR-related cyber crime matters.*

*Q33. What are your views about the preferred governance structures for the PCEHR system and national e-health elements more broadly?*

**The APF has responded on Proposal 39, Proposal 40 and Q33 in submissions for more than a decade. Please refer to our policy documents (attached) our submission on the PCEHR ConOps (attached) or our web page at <http://www.privacy.org.au/> for a more detailed response.**

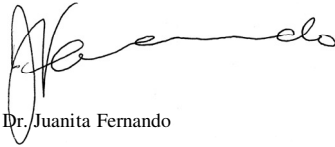
*Proposal 41: The Commonwealth, in collaboration with the states and territories, will develop proposals for a single entry point for PCEHR privacy complaints which are then referred to the appropriate regulator(s).*

*Q34. What would be your preferred single entry point for PCEHR privacy complaints?*

**The office of an independent government-supported Health Privacy Commissioner in every State or Territory that is obliged to provide publicly available work/case reports over the Internet and in the popular press on a quarterly basis.**

Our clear impression is that health authorities are still “rearranging deckchairs on the Titanic” rather than grappling with the real life privacy and security issues generated from our submissions regarding the PCEHR system ConOps and supporting legislation.

Yours sincerely



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<http://www.privacy.org.au/About/Contacts.html>

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