

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

7 February 2012

Dear Committee Secretary

Submission to the Inquiry into the Personally Controlled Electronic Health Records Bill 2012 and one related bill

Thank you for the opportunity to make a submission on the Senate Standing Committees on Community Affairs Inquiry (**Inquiry**) into the *Personally Controlled Electronic Health Records Bill 2012* (Cth) (**Bill**) and one related bill.

Our comments are restricted to one aspect of the Bill, an omission which we believe drastically and unnecessarily reduces the value of the personally controlled electronic health records (**PCEHRs**) that will be established under the Bill.

1. Summary of submission

(a) The submission

In our view, the Bill should permit research using identifiable information that relies on linking information in PCEHRs with other datasets on the following conditions:

- (i) the research complies with guidelines issued by the Australian Information Commissioner along the lines of the existing *Guidelines approved under section 95A of the Privacy Act (Australian Information Commissioner Guidelines)*, which guidelines set out principles and procedures for the ethical use of health information for research and the compilation or analysis of statistics, relevant to public health or public safety, and in the conduct of health service management activities, and
- (ii) the linkage is performed by an organisation that is accredited to conduct best privacy practice linkage such as the Centre for Health Record Linkage (**CHeReL**) at the Cancer Institute NSW, where the reduction in privacy protections due to linkage is negligible.

(b) The rationale for the submission

The Bill differs from privacy law generally in prohibiting use and disclosure of information included in PCEHRs for the secondary purpose of research: see paragraphs 2 and 3.

Information included in PCEHRs is an extremely valuable dataset for research: see paragraph 4(a).

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The value of the PCEHR dataset is enormously augmented by the ability to link that dataset to other datasets: see paragraph 4(b).

It is not practically possible to have a consent-based system for accessing identifiable information in PCHERs that will provide a non-biased (ie, useful for research) sample: see paragraph 4(c).

The CHeReL – and organisations like it – are able to link information in different datasets with negligible infringements on privacy: paragraph 4(d).

It will be very difficult to make an amendment to this effect once the Bill is passed because it will be seen as an infringement on the privacy in PCEHRs: paragraph 4(e).

(c) Conclusion

By using best privacy practice linkage techniques with identifiable PCEHR information, it is possible to substantially increase the value for research of the PCEHR dataset by linking it to other datasets with negligible reduction in privacy protection.

2. The Bill does not permit research using identifiable information while the Privacy Act does

(a) The position under the Bill

Under s 59 of the Bill, it is an offence for a person to collect from the PCEHR system health information included in a consumer's PCEHR unless it is authorised in Part 4, Division 2 of the Bill if the person knows or is reckless as to that fact. That means that, unless the Bill specifically permits it, it is not permitted.

The Bill does not specifically permit collection of (identifiable) health information for the purpose of research without the consumer's consent, so collection for that purpose is prohibited.

The Bill currently does not mention research. The Companion Guide to the Bill, *Personally Controlled Electronic Health Record System: Exposure Draft Legislation* (2011) implicitly recognises this fact on p 28:

Research

The Draft Bill allows a consumer to consent to the collection, use and disclosure of information included in their PCEHR (see section 59). This takes into account occasions where a consumer has consented to have their information used and disclosed for research purposes. In this case the information is identifiable. Consistent with the current position under the Commonwealth Privacy Act, consent is not required if de-identified information is released for research purposes.

That is, research using information included in PCEHRs is permitted:

- (i) using health (ie, identifiable) information, where the consumer has consented to that use, or
- (ii) using non-identifiable information, without the need for consumer consent.

(b) The position under the Privacy Act

While the Companion Guide recognises that the position in the Bill as regards research using deidentified information is consistent with the position under the *Privacy Act 1988* (Cth) (**Privacy Act**), it glosses over the fact that the Privacy Act also permits use and disclosure of personal (ie, identifiable) information for the purpose of research and the compilation or

analysis of statistics without the need for the consent of the person, a position that differs significantly from the position under the Bill.

The relevant provision, NPP 2.1(d) of the Privacy Act, provides:

2.1 An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless:

...

(d) if the information is health information and the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety:

(i) it is impracticable for the organisation to seek the individual's consent before the use or disclosure; and

(ii) the use or disclosure is conducted in accordance with guidelines approved by the Commissioner under section 95A for the purposes of this subparagraph; and

(iii) in the case of disclosure—the organisation reasonably believes that the recipient of the health information will not disclose the health information, or personal information derived from the health information; ...

3. The rationale for permitting collection, use and disclosure for the purpose of research

The standard test for collection, use and disclosure of identifiable information for a purpose other than the primary purpose of collection (**secondary purpose**) is if the public interest in the secondary purpose outweighs the public interest in maintaining the protection of privacy in the relevant identifiable information.

This test and its rationale on this issue are explained in *W v Edgell* [1990] 1 All ER 835 by the English Court of Appeal per Bingham LJ:

The decided cases very clearly establish (1) that the law recognises as important public interests in maintaining professional duties of confidence but (2) that the law treats such duties not as absolute but as liable to be overridden where there is held to be a stronger public interest in disclosure.

This rationale is reproduced at the very start of the Australian Information Commissioner Guidelines:

These guidelines provide a mechanism for weighing the public interest in research relevant to public health or public safety against the public interest in the protection of privacy. The public interest in the research activity must substantially outweigh the public interest in maintaining the level of privacy protection afforded by the NPPs (other than NPP 10.3(d) and NPP 2.1(d)).

4. The case for permitting collection, use and disclosure of identifiable information in PCHERs for the purpose of research

We are not sure why the PCEHR Bill has departed from the standard circumstances in which identifiable information in health records is permitted to be used and disclosed for the secondary purpose of research. Our guess that it is to honour the greater sensitivities over privacy that many people feel in relation to PCEHRs.

While we recognise and respect the greater privacy interest in PCEHRs, we feel that there is a strong case that, when best privacy practice linkage using identifiable information is performed, the public interest in use and disclosure of information in PCEHRs for the secondary purpose of research substantially outweighs the public interest in protection of privacy in PCEHRs.

(a) Information in PCEHRs has high value for research

PCEHRs contain a large amount of crucial health information about a large number of people in coded ways that permits relatively quick and easy aggregation and analysis of that information. The value of this information to researchers is immense and self-evident.

For much research using just PCEHR information, it will not necessary to identify the individuals involved and deidentified information will be as useful as identifiable information.

Being able to identify individuals is, however, crucial when you want to link information in the PCEHR dataset with information in other datasets, so that you can match the record in the PCEHR system that relates to Mary Kwong with the record that relates to her in the Admitted Patients Data Collection or the Australian Bureau of Statistics Perinatal Deaths dataset. Once the linkage is performed, the information can be deidentified so that researchers can only access deidentified information.

(b) The value of information in PCEHRs for research is enormously augmented by linking it with other datasets

The ability to link different datasets enormously augments the value of information in any given dataset. That is the reason why so much health research uses this technique.

(c) Although consent is ethically the strongest basis for handling personal information, consent is not a feasible basis for use and disclosure in large number research

Ethically, consent is the strongest basis for handling another person's information.

Unless consumers are asked when registering for a PCEHR to consent to any and all research using their identifiable information, it will almost never be possible on a practical level to seek consent to access a large number of PCEHRs for research.

Even if it were possible on a practical level to seek the consent of all people registering for a PCEHR, the fact that a proportion will refuse consent (or simply not bother to consider the issue and not opt in to doing so) means that the resulting collection of those who have consented will be self-selecting and therefore biased, substantially compromising the representativeness of the resulting sample, and making it unreliable for most research purposes.

So, if it is desired to access identifiable PCEHR information for use in large number research, it is necessary to have a non-consent based system.

(d) The privacy protections available for linking identifiable records are virtually as strong as the protections for research using deidentified information

The Centre for Health Record Linkage (**CHeReL**) housed in the Cancer Institute of NSW – and no doubt other similar facilities in Australia - uses a technique whereby it receives basic demographic information relating to each health record in a particular health dataset and the record number for that record. The actual health information attached to the record is shorn from the information the CHeReL uses. When linking records from different datasets, the CHeReL uses probabilistic matching techniques with the demographic data attached to the records in seeking to link all records in all surveyed datasets relating to a particular individual but the individual's identity is deleted and they are assigned a Project Person Number instead.

The information given to the researcher will show that Project Person Number 13258 (who, unbeknownst to the researcher, is actually Mary Kwong) has information relating to her in a PCEHR and that information relating to her in the Australian Bureau of Statistics Perinatal Deaths dataset.

The upshot is that:

- (i) the researcher receives the relevant information linking all relevant datasets without receiving any identifiable data
- (ii) the only person to see the identifiable data is in the CHeReL, and
- (iii) the information seen by the person in the CHeReL is only demographic data because all the health data has been shorn from the records that the CHeReL is linking.

(e) Making this kind of amendment after the Bill passes may be very difficult

It may be very difficult to make an amendment of this kind once the Bill has passed because it may be seen as a widespread infringement to the privacy in PCEHRs. That is why it is crucial to ensure from the outset that the legislation permits use of identifiable information for research in the stated circumstances.

Yours faithfully

Geoff Bloom etc