



SUBMISSION TO DEPARTMENT OF HEALTH AND AGEING ON PERSONALLY CONTROLLED ELECTRONIC HEALTH RECORDS BILL 2011 AND A RELATED BILL
12 January 2012

INTRODUCTION

Aged and Community Services Australia (ACSA) and the Aged Care Association of Australia (ACAA) have sought independent legal advice on the Personally Controlled Electronic Health Records Bill 2011 and a related bill and we provide the comments below on the basis of that advice.

Firstly, we understand that the Personally Controlled Electronic Health Records System (the PCEHR System) is:

- a) designed to be a more modern, flexible and accessible system of centralised electronic health records; and
- b) intended to reduce health information fragmentation and deliver better health outcomes.

However, with final legislation to be introduced later this year and operative from July 2012, the timeline appears ambitious and the process of uptake and implementation is likely to be lengthy. There are many outstanding details to be considered:

OVERVIEW

The Bill confirms many of the features of the PCEHR System as it relates to aged care providers:

1. As with the *Privacy Act 1988* and similar legislation, most aged care providers of various types should be within the definition of a “healthcare provider organisation” within the meaning of the Bill;
2. This means they would be eligible to register to participate in the PCEHR System. Registration is to be a voluntary, opt-in procedure for both providers and consumers of health services. We understand that registered participants will be required to have unique identifiers pursuant to the *Healthcare Identifiers Act 2010*;
3. Once registered, certain employees (which include contractors providing services to a provider) will be able to operate the PCEHR System. Other persons not employed or contracted by the provider (for example, an external medical practitioner providing services at an aged care facility) will be required to have their own unique identifier and their own registration to use the PCEHR System;

4. Subject to a range of exceptions, the consumer will be required to provide consent to the collection, use, access and uploading of health information onto the PCEHR System. The consumer can set different access controls to allow different providers to have access to different information. A “nominated healthcare provider” can author and upload a “shared health summary” of a person’s medical information; and
5. Civil penalties will apply for unauthorised collection, use or disclosure of health information. The penalty provisions operate in such a way as to place the onus on the person using or disclosing health information to ensure it is an authorised use or disclosure.

KEY FEATURES OF THE EXPOSURE DRAFT

Lack of detail

Of concern to both organisations is the lack of detail in the Bill itself. The Regulations and the PCEHR Rules have not yet been drafted and may vary over time, yet they are to contain significant particulars of the PCEHR System and will be incorporated as parts of the Act.

The Rules and Regulations will include such matters as:

- requirements that healthcare and information technology providers must meet to allow registration;
- storage of data and records, administration, day-to-day operations and physical and information security.
- requirements when a person’s registration under the scheme is cancelled;
- types of records that must be prepared by an individual healthcare provider (a medical practitioner) to be allowed to be uploaded into the PCEHR System;
- considerations to be taken into account when determining to refuse registration on grounds that the security or integrity of the PCEHR System will be compromised;
- classes of persons who can be “nominated healthcare providers”;
- default access controls to the PCEHR System;
- verification of identity and capacity of a consumer at the time of registration; and
- specific information to be included in the Register when a participant is registered or registration is cancelled.

Until the Rules are drafted, aged care providers cannot know conclusively whether they will even be able to fulfil the requirements to participate in the PCEHR System or what they might have to change to do so. They also cannot ascertain the types of information they can author and upload and the employees who are entitled to do so, nor the types of records they can enter or the circumstances under which those people are to be managed and authorised.

Accordingly, it is difficult to ascertain whether perceived barriers to participation will be removed. It is also difficult to assess how the system will integrate with existing systems, including systems established for accreditation and certification of aged care services under the *Aged Care Act 1997*.

Parallel record-keeping

The Bill confirms the intention of the PCEHR System not to replace existing record-keeping systems. As a voluntary opt-in scheme, healthcare providers and recipients who participate will face an additional layer of record keeping regulation. However, we understand that State laws will be overridden to the extent that they cannot operate concurrently.

Aged care providers will need to ensure they have procedures in place to deal with the new requirements and to identify which apply to their consumers and other participants of the PCEHR System. This issue might be complicated for aged care providers given arrangements with visiting health care professionals and the existence of multi-disciplinary teams who may have different levels of involvement with the PCEHR System. Additionally, there are no specific procedures for verifying whether a person is registered, which will be a practical issue for providers who are not participants in the PCEHR System.

The Bill aims for consistency between existing record-keeping restrictions and requirements and the PCEHR. However, there are significant complexities in the relationships between the new system and existing record-keeping. For example, penalties apply to the unauthorised use or disclosure of information obtained through a person's PCEHR. However, those penalties would not apply if information is legitimately accessed from a PCEHR, downloaded into a clinical file and accessed through that file by a person *not* registered with the PCEHR System.

Authorised representatives, consent and capacity

Under the new system, minors and adults who lack capacity can have a PCEHR file managed by an "authorised representative". PCEHR System Operator must be "satisfied" that the consumer is "not capable of making decisions for himself or herself". The PCEHR System Operator must then be satisfied that the representative is authorised to "act on behalf of the consumer" pursuant to a law or court order.

The Bill confirms that words of "general authorisation" are sufficient for the relevant satisfaction but provides no specific guidance as to the process or threshold of the relevant satisfaction. There are also no provisions for the revocation of authorised representative status, when satisfaction might lapse, whether authorised representatives are obliged to notify the PCEHR System Operator of a change in circumstances or whether an authorised representative is entitled to rely on an existing authorisation.

The companion documents to the Bill suggest that the provisions are intended to cover any relevant formal Commonwealth or State power of attorney or VCAT/court order, but it is unclear if that is a correct interpretation of the operation of the Bill.

The situation with a consumer who lacks capacity but has no official attorney, guardianship or administration arrangements in place is not clear.

Consent of the consumer is central to the PCEHR System. The Bill does not provide guidance as to the level of informed consent required, the details of how consent is to be obtained or what occurs if it is withdrawn or lapses due to incapacity. In particular, where a person has registered for the PCEHR System and lost capacity, it is not clear what the status of their records will be.

FURTHER LEGAL ISSUES

There are numerous other legal issues evident from a review of the Bill which raise issues for aged care providers:

1. The definitions of "healthcare" and "healthcare provider organisation" mean the position of some aged care providers is uncertain under the Bill;
2. The definitions of "employee" and the categories of employees authorised to use the PCEHR System on behalf of a healthcare provider organisation are ambiguous and may capture contractors (which may result in liabilities being transferred to operators despite assumed

contractual protections). Providers will be required to be vigilant to ensure relevant persons are properly authorised to use the PCEHR System;

3. The definition of “entity” appears to be broadly and ambiguously drafted but fails to identify common operating structures, such as entities created by statute and common corporate structures such as companies and incorporated associations;
4. The presumption of default access controls being set for a consumer appears inconsistent with a consumer being required to actively agree to participate but then having no input into the applicable controls;
5. Access does not appear to be linked to an insurance scheme or be conditional upon users having a minimum level of insurance cover, which may impact on consumers and providers;
6. The Bill is silent as to the interaction between the PCEHR System and the duties of care of participants or other persons relying on the PCEHR System;
7. The Bill puts the onus on the person uploading information to ensure ownership of copyright over the material or on the relevant authority to copy it onto the PCEHR System. What additional burdens this will place on providers to ensure systems of copyright recognition/consent are in place is not explained. Equally, what practical issues will arise in multi-disciplinary teams and with community aged care providers and visiting professionals is unclear. What does a provider utilising the PCEHR System do if they have pertinent documents or information and cannot verify the intellectual property status of the material?;
8. The civil penalty provisions provide for defences of reasonable and honest mistakes of fact but contain no “reasonable excuse” defences. Some sections have the potential to expose providers as a result of inadvertent breaches of civil penalty provisions;
9. The interaction between the compliance provisions of the Bill and existing aged care accreditation, sanctions and funding regimes is not clear;
10. A “nominated healthcare provider” has special status in the Bill. A provider must be an individual who agrees to be the nominated healthcare provider and has a healthcare identifier (and are generally nurses or medical practitioners). The procedure for agreement is not specified. The situation with an employee of an aged care facility (for example, a registered nurse) who is nominated by a consumer is unclear. For example, will they require a separate identifier (in which case they can access the PCEHR System in dual capacities)? What happens where the individual agrees but their employer objects?;
11. Similar issues arise with “nominated representatives” (who are any persons who agree to be nominated representatives). They are authorised to receive information from a participant about a registered consumer;
12. There is no guarantee of representation on the Advisory Committee to the PCEHR System Operator by a person with specific knowledge of the aged care sector;
13. There is no requirement to provide information about the risks or limits of the PCEHR System to consumers at the time of registration;
14. The Bill requires that a person not be discriminated against in relation to the provision of healthcare simply because they are not registered. It is not clear whether this encompasses indirect discrimination, which may be a significant risk where the PCEHR System is relied upon by a provider in their delivery of healthcare;
15. The provisions for accessing the PCEHR System in an emergency situation are ambiguously drafted (including as to when there is an absence of consent);

16. In circumstances of contravention or potential contravention of the PCEHR System, the PCEHR System Operator is under no obligation to notify affected providers, thereby limiting the ability of providers to identify and deal with risks. Nor is the PCEHR System Provider required to notify affected consumers of a breach, which will seemingly avoid accountability and in turn erode confidence in the System. There is no guidance as to whether a determination of the Independent Advisory Council will stand if the prescribed procedural requirements have not been met, such as avoiding conflicts of interest;
17. The asserted limit on records being held or taken outside of Australia may not be consistent with the technology platforms utilised as part of the PCEHR System, or the expectation of consumers; and
18. If a decision is made by the System Operator, the decision stands even if the Operator fails to notify an affected person that they may seek a review of the decision. All affected persons should know of the outcome of a decision and the right to appeal the decision before it can be said to be final.

BROADER PRACTICAL ISSUES

Broader practical issues still exist in relation to the PCEHR System such as the following questions:

- 1 What are the costs of implementation and who bears them?
- 2 What ownership and responsibility arrangements relate to infrastructure and/or software?
- 3 What value is a system that has no guarantee of completeness?
- 4 What value is a system of medical record-keeping to which lay persons can access and enter information? Will there be sufficient audit trails and procedures to identify contributors to records and their qualifications?
- 5 What value is a system where medical practitioners are restricted as to the information they can access by consumers?
- 6 What will the likely uptake be amongst consumers and participants? What are the incentives to providers to adopt the PCEHR System?

Both ACSA and ACAA have been contacted by McKinsey and Co. in their capacity as *National Change & Adoption Partner (NCAP)* for the *Personally Controlled Electronic Health Record (PCEHR)* program and we will therefore also be raising the above issues with them.

In any event, please contact the ACSA and ACAA national offices should further information be required about any particular aspects of this submission.