



18 January 2012

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

College House
1 Palmerston Crescent
South Melbourne
Victoria 3205

Tel 03 8699 0414
Fax 03 8699 0400
www.racgp.org.au

ACN 000 223 807
ABN 34 000 223 807

Dear Dr Holland

Re: Submission to the Community Affairs Legislation Committee on the Personally Controlled Electronic Health Records Bill 2011 and the Personally Controlled Electronic Health Records (Consequential Amendments) Bill 2011

The Royal Australian College of General Practitioners (RACGP) thanks the Senate for the opportunity to provide comment on the Personally Controlled Electronic Health Records Bill 2011 and the associated Consequential Amendments.

The RACGP is the specialty medical College for general practice in Australia, responsible for defining the nature of the discipline, setting the standards and curriculum for education and training, maintaining the standards for quality clinical practice, and supporting general practitioners in their pursuit of excellence in patient care and community service.

As stated in its original comments to the Department of Health and Aging in October 2011, the RACGP believes that clinical leadership and strong clinical engagement are required for the successful uptake of e-health initiatives by Australian general practice. General Practitioners will need to be confident that the Personally Controlled Electronic Health Record (PCEHR) system, and the legislation that supports its function will be robust, secure, and function as designed.

The RACGP believes that there are a number issues yet to be addressed in regards to the legislation including the consequential amendments. These relate to the issues identified as:

1. The provision of a clear governance structure to oversee:
 - a. The System Operator of the PCEHR
 - b. Information Commissioner
 - c. Repository System
 - d. Secondary use of PCEHR data
2. The level of administration essentials that are required by the Systems Operator to register and comply with operating criteria

3. Professional and financial risk of breaching the system.
4. Governance in relation to the Health Identifiers Act amendments.

1. Governance structure

The RACGP is of the opinion that confidence in the PCEHR system is paramount to its success. Without a clear governance framework, the users of the system cannot trust that it will provide the functions it is designed to deliver. A clear demonstration of the privacy and security protections delivered by the system will further instil confidence in all who participate. The RACGP believes that more clarification regarding the following four components as part of the governance structure are included in the legislation:

- a. The System Operator of the PCEHR

The PCEHR system is managed by the System Operator and the specific entity of the Service Operator is not clearly defined. Further, there are references to operational matters that again are not defined and without which the provisions in the legislation cannot be judged.

- b. Information Commissioner

The role of the Information Commissioner implies a significant role, yet the scope and responsibilities are not clearly defined in the legislation.

- c. Repository System

The national repository system, portal system, and third party service providers will be operated by a mix of private and public sector organisations. An entity which operates as such will be required to apply to the PCEHR System Operator to register. States and Territories will need to comply with state and territory privacy law or if not possible, must opt-in to the Commonwealth Privacy Act 1998. This may cause confusion and conflict with privacy laws that are not harmonised nationally. Hence the true custodian of the data held within these repositories is unclear and which Privacy Laws apply. The RACGP is concerned about the preservation and availability of data when a repository operator unregisters or ceases to exist as an entity.

- d. Secondary use of PCEHR data

The RACGP provides the Secretariat for the General Practice Data Governance Council. This council aims to support an appropriate information sharing environment for secondary use of general practice data in order to improve patient and population health outcomes, enhance the quality and efficiency of health care delivery, support research and education, and strengthen the viability of general practice.

The revised Concept of Operations suggested that the PCEHR data may be used for secondary purposes. The legislation does not regulate the use of de-identified PCEHR information since it deals with this issue only under *Clause 66 Collection*

use and disclosure with consumer's consent. However, at the time of consent a PCEHR is created, the potential uses for research are not specifically known, and hence the consumer cannot give fully informed consent for this. In addition, the legislation makes no reference to decision-making in this area in regard to access to PCEHR data for research purposes and other secondary uses. The RACGP believes this to be an omission in the legislation and leaves the use of the PCEHR for research or other purposes unclear.

2. Burden of Administration

The RACGP understands that the PCEHR system relies on individual healthcare providers and their organisations to self-report any changing eligibility criteria/conditions that would alter their permissions to work within the PCEHR system. Essentially, this system relies on providers being cognisant of any changes of eligibility among their employees or the organisation and reporting to the system operator in a timely manner. This will add another administrative burden on general practice due to the requirement for providers and their organisations to take on a reporting role in addition to their usual duties.

The design of appropriately tested and proven IT systems must reflect the additional administrative workload and provide intuitive solutions to ensure that healthcare providers and the organisations that they work within are protected.

3. Professional and financial risk of system breaches

The RACGP believes the additional financial and professional risks to General Practitioners of being investigated or reported over an unintended breach may be a disincentive to participate.

The RACGP seeks clarification as to whether or not general practitioners and general practices will be:

- Financially and professionally impacted by investigations regarding alleged PCEHR system breaches
- Able to continue to access the PCEHR system if under investigation for a system breach
- Able to seek reimbursement for damages if an alleged breach and investigation are unfounded
- Able to appeal decisions.

4. Governance in relation to the Health Identifiers Act amendments

The RACGP believes that the consequential amendments to the Health Identifiers Act do not provide sufficient governance regarding the changes imposed by the amendments. For instance,

- Item 15 to section 18 giving the “HI service operator the discretion not to provide a consumer, or a person responsible for that consumer, access to the healthcare identified and audit log for the consumer”: This discretion is left to the HI service operator and whilst intended only to be exercised in exceptional circumstances, the HI Act does not state under what circumstances these are. The intent is provided in the explanatory memorandum to apply to children. However the omission in the legislation of exact criteria means this could be applied in other circumstances and there is no provision for penalties for inappropriate exercising of this discretion by the HI service operator.
- Item 21 which inserts new Division 2A into Part 3 of the HI Act, refers to disclosure of information to a participant in the PCEHR system [22D (1)(d)] and the explanatory memorandum refers to strict technical and procedural rules yet this requirement is not reflected in the amendments or the existing legislation.

Concluding comment:

The RACGP is committed to the uptake of e-health initiatives within the health sector. The College continues to strongly support the PCEHR and the foundations of electronic communications. However the PCEHR must meet the needs of clinicians and patients.

The four areas identified by the College reflect our concerns that they constitute a disincentive for the general practice profession to engage in the PCEHR system. Therefore, we would encourage the inquiry to address these concerns.

I trust that the information contained within this submission will help to inform the inquiry by the Senate Community Affairs Legislation Committee. If you have any questions or comments regarding this matter, please contact Ms Judy Evans, Manager e-Health on (03) 8699 0493 or at judy.evans@racgp.org.au.

Yours faithfully,

Professor Claire Jackson
President
RACGP