



AUSTRALIAN MEDICAL  
ASSOCIATION  
ABN 37 008 426 793

T | 61 2 6270 5400  
F | 61 2 6270 5499  
E | info@ama.com.au  
W | www.ama.com.au

42 Macquarie St Barton ACT 2600  
PO Box 6090 Kingston ACT 2604

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

Dear Secretary

The AMA is pleased to make a submission to the Senate Community Affairs Legislation Committee inquiry on the Personally Controlled Electronic Health Records Bill 2011.

### **Questions about the design, functionality, and capability of the PCEHR**

#### *Opt-in design undermines the goals of the system*

The AMA is a proponent of an opt-out PCEHR. The opt-in design of the system will undermine the object articulated in clause 3, 'reduce the occurrence of adverse medical events and the duplication of treatment'.

Experiences of opt-in systems from Australia and from overseas indicate that adoption amongst consumers will progress slowly. For example:

- In the Northern Territory Shared Electronic Health Record service, from launch on 1 July 2005 to 30 June 2008, "over 25,000 consumers had registered to participate"<sup>1</sup>, or around 11% of the population.<sup>2</sup>
- In the Czech Republic, the IZIP national electronic health record system enrolled "10% of the population and over one third of all healthcare organisations" from 2005 to 2009.<sup>3</sup>

Another convenient comparison is the implementation of the *Healthcare Identifiers Act 2010* from 1 July 2010. In its 2010/2011 Annual Report<sup>4</sup>, the HI service operator reported the assignment of healthcare identifiers in the first year of operation as follows:

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<sup>1</sup> EHealth NT 2009. Shared Electronic Health Record Timelines and Achievements. Online: [http://www.ehealthnt.nt.gov.au/Shared\\_Electronic\\_Health\\_Record/Timelines\\_and\\_Achievements/index.aspx](http://www.ehealthnt.nt.gov.au/Shared_Electronic_Health_Record/Timelines_and_Achievements/index.aspx), accessed 22/12/11.

<sup>2</sup> ABS 2011. 1362.7 - Regional Statistics, Northern Territory, Mar 2011. Online: <http://www.abs.gov.au/ausstats/abs@.nsf/Products/1362.7~Mar+2011~Main+Features~Population?OpenDocument>, accessed 22/12/11.

<sup>3</sup> European Commission 2009. eHealth in Action: Good Practice in European Countries. Online: <http://www.epractice.eu/files/media/media2609.pdf>, accessed 22/12/11.

- 24,051,919 healthcare identifiers assigned to individuals;
- 528,300 healthcare identifiers collected or assigned to individual healthcare providers; and
- 170 healthcare identifiers assigned to healthcare provider organisations.

While identifiers of individual consumers and providers of healthcare are for the most part automatically assigned, organisations are required to apply to the HI service operator. Given that there were 1326 hospitals in Australia in 2009/2010<sup>5</sup> and 19,464 private medical practices in 2001/2002<sup>6</sup>, the uptake of 170 HPI-Os is not encouraging of the willingness of these organisations to ‘opt-in’ to the HI system in the absence of an immediate and compelling reason to do so. Consumers may behave similarly with regard to the PCEHR.

If that is the case, in the early days we are concerned that if medical practitioners search for a PCEHR they will often not find one for their patient. This may deter future attempts by medical practitioners and consequently lead to a very low uptake of the proposed PCEHR by medical professionals. We predict it will be many years before the PCEHR becomes ubiquitous in health care.

When introducing this legislation to Parliament, Minister Roxon said that “studies in hospital environments have indicated that between nine per cent and 17 per cent of tests are unnecessary duplicates” and that “up to 18 per cent of medical errors are attributed to inadequate patient information”. The Government has not discussed the rate of uptake by consumers of the PCEHR that would be necessary to achieve an improvement in these metrics.

What rate of uptake does the Government forecast? If we can expect that around 10% of the population were to opt-in during the first years of operation of the PCEHR, would that be enough to achieve the objectives in the Bill? To our knowledge, the Government has not presented any supportive data to justify that the opt-in design of the system will deliver an appropriate level of participation.

A much simpler and more effective design would have been achieved by making the record opt-out. The vast majority of patients want their doctors to have access to their critical medical information so they can receive the best possible care. Consumers with serious concerns about privacy, or an objection to their medical and health information being shared could actively make the choice not to participate in an opt-out system.

At the same time, those patients most in need of an electronic health record with complex or chronic health conditions – usually the elderly – would reap the benefits of improved

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<sup>4</sup> Medicare Australia 2011. Healthcare Identifiers Service Annual Report 2010-11. Online: <http://www.medicareaustralia.gov.au/provider/health-identifier/files/8101-08-11-his-annual-report-2010-11.pdf>, accessed 22/12/11.

<sup>5</sup> AIHW 2011. Australia's hospitals 2009-10 at a glance. Health services series no. 39. Cat. no. HSE 106. Canberra: AIHW. Online: <http://www.aihw.gov.au/publication-detail/?id=10737418683>, accessed 21/12/2011.

<sup>6</sup> ABS 2003. 8685.0 - Private Medical Practices, Australia, 2001-02. Online: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/8685.0Main+Features12001-02?OpenDocument>, accessed 21/12/11.

sharing of information between treating medical practitioners without having to actively participate to the extent that the current proposals will require them to do.

*Access controls can undermine the functionality and capability of the system*

The AMA is pleased that default access controls will apply to the PCEHR if consumers do not set advanced access controls.

However, under sub-clause 61(b)(ii) of the Bill these default controls may be set in the PCEHR rules *or* by the System Operator if they are not set in the rules. Given the practical significance of the default access controls, they must be subject to stakeholder consultation. It is not appropriate for the System Operator to be able to set these defaults independently. The legislation should be amended to require the default controls to be specified in the PCEHR rules, to afford Parliamentary scrutiny.

Initially, the most important types of patient information that should be available to treating medical practitioners by default are:

1. pathology results;
2. diagnostic imaging results;
3. hospital discharge summaries; and
4. medications dispensed.

Other important clinical information that should be available by default includes but is not limited to allergies, alerts, adverse reactions, current ECG, blood type, vaccinations, infectious disease status, surgical operations, prostheses, clinical assessment, diagnoses, treatment pathways and referrals, advance directives and demographic data including details of a person to contact in an emergency.

Again, there is no public data to show how many people are expected to set advanced access controls themselves. Additionally, given the opt-in design of the PCEHR we anticipate that those consumers who do register for the PCEHR will be engaged individuals, selected at a time of enthusiasm. These consumers will be likely to set, and possibly forget, advanced access controls to their patient information, without due regard for the long term consequences. Our concern is that the capacity for patients to allocate advanced access controls will mean that even if a PCEHR could be found for a patient, medical practitioners may not have access to important clinical information in the PCEHR.

*Opt-in design combined with access controls creates unnecessary complexity and additional work*

It is reasonable to expect medical practitioners to appropriately equip their practices and train their staff in the use of the tools and services they need to provide medical care to their patients. However, the complex nature of the PCEHR means that extra work will be required of medical practitioners and their staff that is directly related to maintaining the PCEHR system itself, outside of the existing clinical workflow.

The purported effectiveness of the PCEHR system in collating key clinical information for patients is likely to be offset by the additional administrative responsibility of using the PCEHR.

To date no data has been made available measuring the impact of using the PCEHR on clinical workflows. No information has been released from the lead implementation 'wave' sites to show how the system is working in practice. This information is critical to assisting medical practices and other healthcare organisations to integrate the use of the PCEHR into their every day practice.

Our concern is that the PCEHR may add to the "information chaos" apparent in today's medical practices. Described by Beasley et al, this phenomenon is one in which problematic information arrives from many sources and "can impair physician performance, increase workload, and reduce the safety and quality of care delivered."<sup>7</sup> If doctors have to interrupt their clinical workflow to check if a patient has a PCEHR, and then could find that the information they need is not accessible, this will make it more difficult to deliver quality patient care, not less.

While acknowledging the role that is played by other health providers, and the 'team care' approach to modern patient care, the AMA has no doubt that the principal users of the PCEHR will be the medical profession. It follows, therefore, that any record system that fails to provide medical practitioners with fast and easy access to concise, complete and reliable data is unlikely to be widely adopted by a profession that is constantly under pressure to provide safe, effective, high quality medical care in the face of practical time constraints.

### **The level of functionality of the PCEHR at 1 July 2012**

This legislation and the PCEHR itself will be an empty promise if the medical practice software packages that many medical practitioners rely on do not support the PCEHR. Without this essential infrastructure in place, it will be very difficult for medical practitioners to deliver the benefits to their patients that motivate this legislation.

There is no indication of what the technical functionality of the PCEHR will be at the start date of 1 July 2012. This is contingent on the finalisation of technical standards and the capacity of the IT industry to introduce interoperable features for the PCEHR into existing clinical software.

Noting the release of the NEHTA Specifications Standards Plan on 16 November 2011, the medical software industry has a considerable task to deliver the technical infrastructure supporting the PCEHR. The advice provided by Giesecke & Devrient, one of the ICT industry advisors to NEHTA, is that "our experiences with interoperability issues in other agencies suggest this task is often understated and under estimated."<sup>8</sup>

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<sup>7</sup> Beasley JW et al. Information Chaos in Primary Care: Implications for Physician Performance and Patient Safety. *Journal of the American Board of Family Medicine* 2011; 24 (6): 745.

<sup>8</sup> Giesecke & Devrient 2011. Submission on: Exposure Draft Personally Controlled Electronic Health Records Bill. Online: <http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/PCEHRLegSubmissionsReceived> accessed 20/12/11.

Delivery of the technical infrastructure supporting the Healthcare Identifier service has not resulted in extensive use of the service during the first year of operation. According to the Annual Report, IHIs were disclosed through web services 782 772 times.<sup>9</sup> Minister Roxon referred to a figure of 1.1 million downloaded identifiers in her introduction of the PCEHR legislation to Parliament. This does not compare well with the total number of emergency department visits in 2009/2010 (approximately 7.4 million), the total number of outpatient episodes of care delivered by public hospitals (approximately 42 million)<sup>10</sup> or the total number of GP consultations (approximately 119 million).<sup>11</sup>

It is increasingly apparent to the AMA that delays in the availability of appropriate, tested, proven and affordable practice software will be a significant barrier to the medical profession using the PCEHR in their clinical practice. Again, this concern is borne out in the slow uptake by healthcare provider organisations of the HI system and the availability of clinical practice software to support healthcare identifiers at the time the HI system was launched.

### **Privacy issues/ Privacy Breaches/ Penalties for breaches**

The integrity of the confidentiality of the patient medical record is absolutely essential to developing, enhancing, and underpinning the therapeutic relationship between medical practitioners and their patients. This confidentiality secures the necessary trust and openness that characterises the ongoing communication between doctors and their patients to optimise patient care. Confidentiality is regarded as one of the most important aspects of good medical practice.

The medical profession's commitment to confidentiality is apparent in professional standards and codes such as *Good Medical Practice: a Code of Conduct for Doctors in Australia*, produced by the Medical Board of Australia, *Standards for general practices 4<sup>th</sup> edition*, produced by the Royal Australian College of General Practitioners, and our *AMA Code of Ethics*. In addition, medical practitioners are subject to the *Privacy Act 1988* and the National Privacy Principles with respect of medical records. Guided by documents such as these, the medical profession is adept at managing the privacy of patients in regular clinical practice.

#### *Clause 59 Unauthorised collection, use and disclosure of health information included in a consumer's PCEHR*

It is important that patients and doctors are confident that the existence of the PCEHR will not compromise the confidentiality of the doctor/patient relationship. While we are not experts in privacy protection laws, the AMA has no concerns with the provisions in the Bill to ensure patient information is protected.

However, we are concerned that the provisions under clause 59 and clause 60 for preventing and penalising unauthorised interactions with the PCEHR are not clear. Reference is made to the collection, use, disclosure and secondary disclosure of health

<sup>9</sup> Medicare Australia 2011.

<sup>10</sup> AIHW 2011.

<sup>11</sup> Department of Health and Ageing 2011. Medicare Statistics - September Quarter 2011, Table B1A – Number of Services. Online: <http://www.health.gov.au/internet/main/publishing.nsf/Content/medstat-sep11-tables-ba>, accessed 10/01/12.

information. In clause 5, the definition of the use of health information in the PCEHR includes accessing, viewing, modifying and deleting the information.

What actions are these clauses supposed to proscribe?

The explanatory memorandum indicates that hacking into the PCEHR system will be penalised as per the Criminal Code in respect of computer systems so we understand that this type of unauthorised interaction is not the intended target. Therefore we assume that these penalties are intended to capture situations where someone working in a healthcare provider organisation uses their legitimate credentials with the PCEHR system to access information about a consumer without authorisation.

We are uncertain of the practical difference between ‘collection’ and ‘use’. For example, a medical practitioner may download a clinical document from the PCEHR because it has informed a clinical decision; we assume that this constitutes ‘collection’ of the information. But in doing so they have also accessed and viewed the information. If the medical practitioner was not authorised to download the information, do these provisions mean that they would be penalised twice, once each for sub-clause 59(1) and sub-clause 59(2)?

It is unclear what sorts of activity would be unauthorised. Referring to the explanatory memorandum, we can see that “participants who inadvertently or mistakenly access a PCEHR do not contravene the provision” of sub-clause 59(1).<sup>12</sup> Noting that this perpetuates our confusion about the difference between ‘access’, ‘use’ and ‘collection’, we wonder if this includes situations where medical practitioners are mistaken about their authority to access a record, or mistakenly access a record for which they do not have authority, or both. Given that there will be access controls on each PCEHR, defining who has access to which information, how would the system allow unauthorised collection/use in the first place? We highlight this to illustrate the complexity of the system, and the barriers doctors face as they prepare to share patient information electronically.

It is also unclear to us whether these same penalty provisions might be used to penalise an individual person and a body corporate for the same offence. If a person who has accessed the PCEHR system through the ‘employee’ or ‘contractor’ provisions of clause 99 performed an unauthorised action, does that person attract the penalty or penalties, or the healthcare provider organisation, or both?

*Clause 74 Registered healthcare provider organisations must ensure certain information is given to System Operator*

Health practitioners access patient information every day, every time they treat a patient. Similarly, administrative staff members, contractors, students and other individuals have access to patient information delegated to them as part of the normal clinical workflow.

The *Privacy Act 1988* and the National Privacy Principles, along with professional standards, already direct controls over access to patient information for individuals performing different roles within healthcare provider organisations. At present, this does not extend to documenting who has accessed patient information, what they have accessed, and when they have done that.

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<sup>12</sup> PCEHR Bill Explanatory Memorandum p38.

The requirement to give this information to the PCEHR System Operator, or face substantial penalties, will impose a new and burdensome responsibility on already busy practices. For example, in a practice of five GPs, access to the PCEHR could occur 175 times each day for the medical practitioners alone. The healthcare provider organisation would have to ensure that they have a way to record, store and communicate information about each of these occasions to the System Operator.

In the explanatory memorandum associated with this legislation it is stated, “the obligation to provide the information has been placed on healthcare provider organisations. This is because they will be best placed to ensure that their IT systems are configured to provide the necessary information to the System Operator”.<sup>13</sup>

There is no assurance that IT systems able to be configured in this way will be tested, proven and widely available when the PCEHR is launched. We do not yet know what the market price of these systems will be. Indeed, some medical practices do not use specialised medical practice software at all. In these situations, where the requisite IT systems are not available, the provisions of this clause would require an unacceptable overhead of manual records keeping that many practices would simply avoid by not using the PCEHR.

Even if IT systems with this capability are available, in use and correctly configured, healthcare provider organisations could attract substantial penalties for what amounts to a technical fault or configuration mistake. This would be a penalty for breaching the administrative functions of the PCEHR, not for actual breaches of privacy.

The AMA recommends that:

1. these penalty provisions should not commence until the IT systems required to automatically record, store and communicate every access that occurs to the System Operator are available and at a reasonable market price; and
2. penalties should be reduced to reflect the likely technical nature of breaches.

*Clause 76 Requirement to notify if cease to be eligible to be registered*

Given that Part 3 of the Bill refers to registration of consumers, healthcare provider organisations, repository operators, portal operators and contracted service providers, but not to individual healthcare providers, this clause should be amended by adding “organisation” after “registered healthcare provider” to read: “A registered healthcare provider *organisation*, a registered repository operator, a registered portal operator or a registered contracted service provider must give written notice to the System Operator within 14 days of ceasing to be eligible to be so registered.”

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<sup>13</sup> Ex memo, p47.

### **Any other issues the Committee considers appropriate**

#### *Payment for being the nominated provider*

The PCEHR Concept of Operations states, “one of the key clinical documents shared via the PCEHR System is an individual’s Shared Health Summary.”<sup>14</sup> The explanatory memorandum associated with this legislation states that “nominated healthcare providers play an important role in providing key health information for a consumer’s PCEHR by creating and maintaining a consumer’s shared health summary.”<sup>15</sup>

It is essential that provision is included for the nominated provider to be remunerated for their important work creating shared health summaries.

There are substantial disincentives to medical practitioners using the PCEHR, including the risks, costs and challenges that we have described in this submission. On top of this, medical practitioners are expected to do more work to create and maintain a shared health summary for their patients – for free. In their submission on the exposure draft of this legislation, the Medical Software Industry Association addressed the need for remuneration:

It is hoped that the Government will follow this recommendation by the Deloitte National E-Health Strategy and National Health and Hospital Reform Commission so that there are the requisite drivers, including financial incentives for use of the PCEHR, in place to make the PCEHR useful and successful upon its introduction in July 2012.<sup>16</sup>

The MSIA is referring here to general use of the PCEHR. However, the “additional effort” that they have referred to is particularly true of shared health summaries created by nominated providers.

#### *Medico-legal concerns*

The AMA holds many reservations about the medico-legal implications for medical practitioners in using the PCEHR. Consultations with medical indemnity insurers have illustrated to us that these implications will be numerous and diverse, and that this is directly related to the complex nature of the PCEHR system. The nature of these concerns will be contingent on the final manifestation of the PCEHR system, the legislation, the rules and subsequently on case law as it is established.

#### *The AMA will continue to work with the Government on the PCEHR*

We will continue to work with the Government to make the PCEHR as successful as it can be in the confines of its construct. By incorporating our suggestions and addressing our concerns we hope that the Government could still deliver a system that offers the benefits for patients and healthcare providers that are the objectives of this legislation,

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<sup>14</sup> NEHTA 2011. Concept of Operations: Relating to the introduction of a Personally Controlled Electronic Health Record System, p50.

<sup>15</sup> Ex memo, p5.

<sup>16</sup> MSIA 2011. Submission on: Exposure Draft Personally Controlled Electronic Health Records Bill (‘Draft Bill’). Online: <http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/PCEHRLegSubmissionsReceived> accessed 20/12/11.



without imposing the substantial burdens on medical practitioners and their practices that we have identified.

Despite our concerns, we are working to ensure that medical practitioners are well supported to use the PCEHR in whatever final form it is delivered. Particularly, we will be looking to provide advice to medical practitioners on how good medical practices apply to this new entity, for example what the expectations and obligations are of medical practitioners when advising patients about the PCEHR system.

If you require any further information about our submission, please contact Belinda Highmore, Senior Manager, Medical Practice and eHealth on 02 6270 5439 or by email to [bhighmore@ama.com.au](mailto:bhighmore@ama.com.au).

Yours sincerely

Dr Steve Hambleton  
President

13 January 2012