The Pharmacy Guild of Australia

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12 January 2011

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

By email: community.affairs.sen@aph.gov.au

Dear Dr Holland,

Inquiry into the Personally Controlled Electronic Health Records Bill 2011

The Pharmacy Guild of Australia (The Guild) welcomes the opportunity to provide a submission to the Senate Community Affairs Committee's *Inquiry into the Personally Controlled Electronic Health Records Bill 2011* (the Inquiry).

Please note that the Guild is comfortable with this submission and its contents being made publicly available.

The Pharmacy Guild of Australia (the Guild) is an employers' organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

The Guild looks forward to the provision of the Inquiry report and would welcome the opportunity to clarify and expand upon our submission, should it be required, in a hearing of the Committee.

Yours sincerely,

Patrick Reid
National Director
Business Development, eHealth and ICT

The Pharmacy Guild of Australia

Submission to the Senate Community Affairs Committee Inquiry into the Personally Controlled Electronic Health Records Bill 2011

Executive Summary

The Pharmacy Guild of Australia (the Guild) was established in 1928, and is registered under the federal Fair Work Act 2009 as an employers' organisation. The Guild's members are the owners of approximately 4,500 of the 5,100 community pharmacies in Australia.

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This paper reviews the contents of the Personally Controlled Electronic Health Records (PCEHR) exposure draft legislation as well as the Guild's August 2011 submission (the August 2011 submission) on the PCEHR Legislation Issues Paper. The following observations are made with particular reference to areas not fully dealt with in the Guild's August 2011 submission.

Key concerns relating to the Draft Legislation for the Guild are outlined in this document, but the Guild felt it would also be pertinent to raise some issues that sit outside the legislation itself, but will be key to the success of the PCEHR and e-health in general for Australia.

Electronic prescriptions

Community Pharmacy has been proactive in e-health for many years and was the first health profession to have their clinical records fully computerised. The Guild has fostered the development of a national Electronic Transfer of Prescription system (ETP) through the companies eRx (erx.com.au) and Fred Health (fred.com.au).

Aspects of the eRx system are:

- Prescriptions are encrypted and sent to a secure gateway, for retrieval at a patient's pharmacy of choice.
- eRx is a platform designed to easily incorporate e-health standards as they are finalised and implemented.
- eRx Script Exchange is an industry initiative integrating 19 leading medical and pharmacy software vendors.
- 4,249 community pharmacies and 12,941 Doctors are signed onto the eRx system.
- By late 2011, 3.2 million prescriptions items, potential eHealth records, were dispensed through the system per week.

There are two concerns that the Guild has with respect to electronic prescriptions:

1. The Guild is concerned that money that has been set aside within the 5th Community Pharmacy Agreement[1] ($75.5 million) for the uptake of electronic prescriptions is currently lying mostly unused because of an arbitrary description developed by the Department of Health and Ageing that only recognises doctor electronically generated prescriptions, ignoring the 60% of prescriptions that comprise the majority of prescriptions utilised by consumers – repeat prescriptions. This has led to only 2% of prescriptions being eligible under the DOHA definition and thus starving the ETP

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/CFF66BFC540B84BBCA2578AA007DDC84/$File/5CPA%20Agreement%2005%20August%202010.pdf

systems of income required to continue development and compliance with the emerging technical specifications such as interoperability, contrary to the tenor of the Agreement to utilise the $75.5 million for infrastructure development and delivery.

2. Currently there is no ability for a pharmacy to add a patient's medication history to the PCEHR and there is no strategy or process in place at this time to enable this to occur. ETP is a reality in both pharmacies and surgeries now and as it stands approximately 3.2 million records could be added to the PCEHR weekly through this system.

The Guild believes that both NEHTA and DOHA should, as a matter of urgency, remedy:

- the flow of 5th Agreement funds by enabling the loading of non-electronic repeat PBS prescriptions to be remunerated per the original intent of the Agreement, and;
- Provide a stratagem to enable the integration of patient medication data from community pharmacy as a priority using the MedView Project (medview.com.au) as the basis for this remedy.

Work flow for pharmacists

The Guild has concerns that aspects of change and adoption for the PCEHR may prove logistically and operationally difficult for community pharmacy to implement. Given that community pharmacists are the most accessible health professionals in Australia it will be important that the introduction of any e-health initiative does not impose undue or untenable cost or time burdens upon the community pharmacy sector. Security and privacy are of utmost concern; however these will need to be dealt with pragmatically where onerous or complex requirements impede the ability of a community pharmacy to provide adequate and timely care to a patient.

Medication history

The Guild is concerned that data feeds of patient medication history will initially only be sourced from data sets held by the Commonwealth, such as through Medicare. It is felt that the uptake and adoption by health practitioners will be stymied as they will not see the PCEHR as a true current record of a patient's medication record and may lead to clinicians not trusting the system accuracy or completeness. This issue is exacerbated by the lack of a strategy or process to enable these records to be included.

Community pharmacy has attempted to address this shortfall through the Wave 2 funded Medview Project which demonstrates the ability of consumers and health professionals to access consented patients' medication history via a PCEHR conformant medicines repository using electronic transfer of prescriptions. However, NEHTA has stated that this project is limited to the second wave and will not be considered as national infrastructure.

National Infrastructure

The Guild has concerns that the national infrastructure required to underpin the uptake and adoption of the PCEHR will not be ready within suitable timeframes to enable adequate use of the system. Systems such as the Nation-wide Authentication System for electronic Health records (NASH) and the Health Identifiers (HI) service may not be adequately staged to enable the timely rollout of the PCEHR.

Doctor Centric model and Opt-in model

The Guild is concerned that the Opt-in model chosen will stymie uptake by consumers in numbers that will provide critical mass to the system, given that the range of available features and benefits for both consumers and health practitioners are limited in the initial phases. The uptake will also be limited due to the reliance on general practitioners and a limited sub set of

third parties who will be able to register consumers into the PCEHR. Although the Guild believes community pharmacy has the skills and patient access to enrol and guide consumers through the PCEHR, it believes that an opt-out model is the most sensible and pragmatic method for uptake of the PCEHR.

Part	Section / Clause	Item	Comment/s
1	Division 5	Definition of 'healthcare'	The definition is considered sufficient when reviewed in context and compared to the *Privacy Act 1988*
1	Division 5	Definition of 'healthcare provider organisation'	This definition is considered sufficient when reviewed in context to Community Pharmacy operations
1	Division 5	Definition of 'nominated healthcare provider'	The definition indicates that a Pharmacist cannot prepare a shared health summary record for a patient; although Pharmacists and other allied health professionals may be subsequently added by regulation. The Guild believes as a frontline contact for patients that a Pharmacist is well placed to provide such services to the community. The Community Pharmacy network in Australia is extensive with over 5000 locations and Pharmacists have proven through previous e-health pilots and programs that they have the skills to perform such activities to the benefit of the patient and Government.
1	Division 6	Definition of 'authorised representative'	The Guild interprets this definitions to mean that someone who is a parent or guardian of a child, or who has responsibility for a child under various decisions made under the Family Law Act 1975 (or in extreme conditions, a person is nominated) is a child's authorised representative. However, someone under 18 will be able to effectively remove the authorisation where the System Operator is satisfied the child wants to make PCHER decisions and is capable of making decisions for themselves. For consumers 18 or older, before appointing someone as an authorised representative the System Operator must be satisfied the person is not capable of making a decision for themselves and the person is authorised to act on behalf of the consumer under a law of a Commonwealth, State or Territory or a decision of an Australian Court. The Guild believe it is peculiar that the System Operator must be satisfied a person is not capable of making a decision for themselves before allowing someone with (for instance) an enduring power of attorney to be able to be appointed as an authorised representative. It is particularly difficult to see what evidence over

			and above the existence of a court order or power of attorney the System Operator may need to appoint a relevant person as an authorised person as well as what experience the System Operator has in making these sorts of decisions. There is also a concern that some time could be taken to make the decision, causing inconvenience to the patient. It needs to be articulated how the System Operator will decide how a person is not capable of making relevant PCEHR decisions for themselves in this context. It is also uncertain how a service provider, like a Pharmacist, is to know whether a minor has control of their PCEHR, when a parent does not have authority to deal with their child's PCEHR (because of family court decisions) or when someone is either an authorised or nominated representative. Clarification on this matter needs to be provided. The Guild August 2011 submission also sought clarification on patients that are not computer literate and expect their children (for example) to fulfil the role of authorised representative as opposed to a nominated representative. This question has not been answered.
2	Clause 10	Identity of the System Operator	The Guild is greatly concerned that the appropriate governance framework is yet to be determined and that the Secretary of the Department of Health and Ageing will fulfil the role. Governance of such an important system **should not** be vested in a single person who may or may not choose to follow the advice from the Jurisdictional Advisory Committee and the Independent Advisory Council. It is also notable that the AHMC has no specific oversight role.
2	Clause 11	Functions of the System Operator	Some of the more important functions of the operator are to establish and maintain an index service. Whilst this is generally satisfactory, the current lack of structure, function and governance of the System Operator and supporting roles is of great concern and the Guild believes that these must be addressed and finalised before the system is operational. To proceed without these key components will greatly increase the risk for patients and participating health professionals. The Guild ***will not*** support the roll out through Community Pharmacy until these issues are addressed.
3	Clause 37	When a healthcare provider organisation	It is unclear as to what the authentication service is to certify. Clarity and further detail is required on this

		is eligible for registration	clause in order to make an accurate assessment.
3	Clause 39	Condition of registration	The legislation indicates that the health care provider organisation will be required to effectively license system users to utilise records that are uploaded by the organisation so that there is no infringement of the organisation's copyright. It is implied that once placed in an accessible repository that the repository operator would be treated for the purposes of the PCEHR as owning the information subject to any access controls imposed by the patient. However, the companion document suggested that the healthcare provider organisations are responsible for determining the status of a record's intellectual property before it is uploaded. In the context of Community Pharmacy, this would mean that a Pharmacist would need to ascertain whether a particular medical practitioner is one of a small number purporting to assert IP rights over medical records, including prescriptions. This is further complicated in the Community Pharmacy context whereby almost all information pertaining to a PBS prescription is provided to the Government. The Guild is also concerned with the intellectual property of a Pharmacist and/or Community Pharmacy where an Event Summary is created for in-pharmacy services and made available in the patient's PCEHR. The exposure draft legislation also suggests that consumer information can only be uploaded into the PCEHR if the patient consents. Although it further provides for 'general consent' it is silent as to how this consent is to be conveyed, what the life time of the consent is (single purpose or multipurpose) and for what activities the consent may be for.
3	Division 3	Registering repository operators, portal operators and contracted service providers	The Guild recognises that Community Pharmacies may be expected to register as a repository operator in order to provide data to the index service. However we believe that such a system will be unwieldy and difficult to maintain in the long term without substantial assistance from the software vendors and pharmacy IT support organisations.
4 (and 8)	Division 4 (of Part 8)	Treatment of certain entities	The Guild believes that even though the PCEHR imposes civil and not criminal liability, the same concept should apply in this context to partnerships, unincorporated associations and trusts.
6	Division 6	Civil penalty supporting provisions	The Guild is satisfied that PCEHR prosecutions should be dealt with as a civil matter.

8	Clause 96	Review of operation of Act	The Guild agrees that the legislation should be reviewed no more than 2 years after its commencement.
8	Clause 97	Minister may make PCEHR Rules	It is noted that the making of rules is at ministerial discretion and that they need not necessarily be made. However, the companion paper proceeds to say that the 'known matters' likely to be addressed include the security and technical requirements of participants. This is a very broad statement that will have a significant impact on software vendors. It is also noted that the Minister does not need to take technical advice when making an instrument such as the PCEHR rules. The Guild believes that provision and acceptance of technical advice is of paramount importance for a system that is essentially technical in nature. It is unlikely that the Independent Advisory Council would have the scope of expertise to assist in the making of such rules. The Guild believes that the Minister would be better served by a specific committee of information technology and health informatics professionals to guide the development of these rules. Furthermore, the Minister should 'have regard' to the advice of this committee before making PCEHR rules. Moreover, a full regulatory impact statement should be provided given the clear cost to Community Pharmacy that will flow in ensuring that technology and work practices are compliant with the PCHER. Finally, the Guild ***cannot*** fully support the continued development and implementation of the PCEHR until such time as it is satisfied that the PCEHR Rules are satisfactory and do not contravene patient safety, software vendor viability and Community Pharmacy and Pharmacists reputation.
Other matters		Guild August 2011 submission	Substantial matters raised in the August 2011 submission that have not been dealt with in the Bill include: (a) the risks to healthcare outcomes arising from allowing consumers to use pseudonyms and to impose access conditions on health information. The Bill still permits these things. As they appear a critical part of the 'sell' of the overall scheme, as well as something that privacy law expects to be in legislation such as the PCEHR legislation, it is unlikely that these provisions will be removed. There is scope for some provision to seek an indemnity for a health provider who, acting in good faith on the information available to the provider nevertheless causes loss to the patient

		because some information was contained under a pseudonym unknown to the provider, didn't have access to information because of an access limitation etc; (b) national consistency as to how long records are to be retained; and (c) absence of an express confidentiality provision.

Addendum

1. Extract from the THE FIFTH COMMUNITY PHARMACY AGREEMENT

(**http://bit.ly/ydP17L**)

Electronic Prescription Fee

12.8. The Commonwealth will, from 1 July 2010, pay a fee of $0.15 per transaction to Approved Suppliers dispensing Electronic Prescriptions in the manner set out in clause 12.10.

12.9. The forecast funding for this initiative over the Term of this Agreement is $75.5 million.

12.10. An Electronic Prescription Fee is only payable if the electronic prescription:

a. is a PBS or RPBS prescription (including prescriptions for items priced below the maximum general patient contribution as defined in the Act) dispensed by an Approved Supplier that is generated electronically in accordance with the process described in the definition of 'Electronic Prescription' in clause 2.1 and the NEHTA specification for ETP,- or

b. a repeat authorisation and/or a deferred supply authorisation :

i. downloaded from a PES; and

ii. related to an original Electronic Prescription satisfying paragraph 12.10.a;

and

c. the Electronic Prescription is processed through a PES; and

d. if the Electronic Prescription relates to an item priced below the maximum General patient contribution as defined in the Act, the following information in the Electronic Prescription has been validated and, if necessary, corrected by the approved supplier:

i. the patient's name;

ii. the patient's Medicare number;

iii. information about the prescription (including the date of prescribing and supply, the PBS code number, the drug

name and form, the quantity dispensed and the number of repeats);

iv. the prescriber approval number; and

v. the Approved Supplier number.

12.11. The Electronic Prescription Fee will be paid to Approved Suppliers by Medicare Australia in response to claims made through PBS Online in relation to eligible Electronic Prescriptions.

12.12. Software vendors will have no more than 24 months from the time of publication of:

a. relevant standards by Standards Australia; and

b. if the NEHTA specification for ETP is revised, the revised version of the NEHTA specification for ETP,

to comply with the Australian Standards specified in the relevant version of the NEHTA specification for ETP.

12.13. All PES prescribing and dispensing providers will be required to satisfy the standards described in the definition of PES in clause 2.1 and the standards described in clause 12.10 to enable Approved Suppliers to be eligible for the Electronic Prescription Fee.

12.14. The ACC will regularly monitor compliance with clauses 12.8 to 12.13 during the Term of the Agreement, including taking into account the following matters (without limitation):

a. the proportion of prescriptions being generated as Electronic Prescriptions by prescribers;

b. the progress in developing and implementing a Commonwealth approved individual electronic health record;

c. the development of the NEHTA specification for ETP; and

d. the level of expenditure by the Commonwealth on the Electronic

Prescription Fee and how this compares to the forecast total expenditure in clause 12.9, any potential over- or underexpenditure, and the reasons for this.

12.15. As a result of monitoring under clause 12.14, the ACC may make recommendations to the Minister regarding possible changes to the clauses of this Agreement relating to the Electronic Prescription Fee.