Australian Dental Association Inc.

PCEHR Legislation Submission

Department of Health and Ageing

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Authorised by
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1. About the Australian Dental Association

The Australian Dental Association Inc. (ADA) is the peak national professional body representing over 13,000 registered dentists and dental students engaged in all areas of dental practice. ADA members work in both the public and private sectors. The ADA represents the vast majority of dental practitioners.

The primary objectives of the ADA are to:

• Encourage the improvement of the oral and general health of the public and to advance and promote the ethics, art and science of dentistry; and

• To support members of the Association in enhancing their ability to provide safe, high quality professional oral healthcare.

There are ADA Branches in all States and Territories other than in the ACT, with individual dentists belonging to both their home Branch and the national body. Further information on the activities of the ADA and its Branches can be found at www.ada.org.au.

2. Introduction

The ADA welcomes the opportunity to provide comment on PCEHR Bill 2011 and the PCEHR (Consequential Amendments) Bill 2011. The Bills aim to create the legislative framework to support the establishment and implementation of a national personally controlled electronic health record (PCEHR) System. The ADA recognises that the PCEHR System is a key element of the e-Health reform agenda being introduced by the Government.

The ADA acknowledges that some of its previous recommendations have been adopted by these Bills, namely:

- The Bill must have a provision that would allow individual health practitioners and their associated assistants/administrative officers to enter data or access records relating to their patients;
- An exception be included to enable courts/tribunals to request the PCEHR System Operator to produce contents of a consumer's PCEHR in proceedings relating to health practitioners' liability; and
- Permitting providers and organisations to exercise control over their identifiers under the circumstances outlined:
    - With the consent of the healthcare provider or organisation; and
    - For a legitimate business purpose.

However the ADA further urges government to consider the recommendations in this submission to ensure the PCEHR System better delivers the outcomes sought for patients, not only in a dental practice environment, but also in all healthcare provision environments generally.

The comments below have been made in relation to particular Parts of the PCEHR Bill 2011 (herein referred to as "the Bill") - as discussed by the Explanatory Memorandum. The Explanatory Memorandum was provided to outline the

proposed legislative provisions in plain English, to explain the reasons behind those provisions and to describe how they are intended to operate.

The ADA has correspondingly framed its responses around the commentary made in that document and will provide its responses in the order that they are addressed in the Explanatory Memorandum. The ADA's comments are based on consultations it has had with its members and from its Branches. We trust the ADA's comments provide a constructive contribution to the further refinement and implementation of the legislative framework for the PCEHR system and so lead to improved health outcomes for patients.

3. Executive Summary

Recommendation 1: That a minimum three healthcare provider member positions be required to represent healthcare providers on the Independent Advisory Council so as to ensure the adequate representation of the broad range of healthcare practitioner types and healthcare environments.

Recommendation 2: That 100 points of identification should be required before a consumer is registered in the PCEHR system; namely the same identification requirements and verification methods when applying for a Medicare Card, Driver's Licence or Passport.

Recommendation 3: That the PCEHR system not allow for the use of pseudonyms.

If however the Bill continues to allow consumers to use pseudonyms under the PCEHR System, the Department of Health and Ageing (DoHA) should ensure that health practitioners are adequately educated and supported to respond to any impact on privacy Policies and Procedures and that pseudonyms can only be used as a secondary form of identification at the practice or service level as per the current system.

Recommendation 4: Where arrangements proposed in the Bill pertaining to minors alter regulations under the *Privacy Act (1988)* and require changes to existing Policies and Procedures in the healthcare and practice setting, healthcare practitioners should be given fair notice and assistance.

Recommendation 5: Adopt an "Opt out" approach whereby all Australians are registered on the PCEHR System with the same access/control privileges as currently outlined unless they actively choose to opt out. Government must ensure adequate funding to assist health practitioners to familiarise themselves with the processes and operations of the PCEHR system.

Recommendation 6: Where consumers are participating in the PCEHR system and they allow a health practitioner to access their PCEHR, the consumer should not be able to determine the level of access. The health practitioner should be able to access all information in that record.

Recommendation 7: The Bill should enable the health practitioner access to the Shared Health Summary (SHS) as a minimum if the provider is given permission by the consumer to access their PCEHR.

Recommendation 8: The Bill should have a provision indemnifying health practitioners from any liability arising from their reliance on consumer's PCEHR.

Recommendation 9: Guidelines should to be developed by DoHA to show health practitioners how to contribute to the PCEHR.

Recommendation 10: The penalty unit amounts in the Bill are too high and should be reconsidered. The fact that there is a penalty unit regime further highlights the need for Government to ensure they provide adequate education, system training and support to all relevant participants.

Recommendation 11: To ensure practitioners' effective participation in the PCEHR system, NEHTA should provide a sufficient level of transparency about the use of data by government.

Recommendation 12: The Bill should place a presumption that the Information Commissioner accepts voluntary undertakings. Where the Information Commissioner does not accept a voluntary undertaking the Bill should require the Information Commissioner to give reasons and the person allowed to seek a review of, or challenge that decision.

Recommendation 13: Where required, the PCEHR Rules/Regulations should outline that 100 points of identification are needed for an individual to create a PCEHR.

4. Governance arrangements

a. Part 2, Division 3: Independent advisory council

While the ADA welcomes the Bill expanding the Independent Advisory Council (IAC)'s membership to a minimum of seven members, it notes that the Bill states three of these members must represent consumers' interests and must have significant knowledge of consumers' receipt of healthcare (paragraph 27(2)(a)).

The ADA refers to its original Recommendation made to the draft exposure legislation that a minimum three members representing healthcare providers (other than a medical practitioner) be appointed to the IAC. The ADA insists these three healthcare provider member positions be drawn from professional bodies representing health professions.

This broader range of healthcare provider membership on the IAC would enable these groups to have confidence in the PCEHR System and to ensure that system users respect its rules and guidelines. Each health discipline has its own culture and conventions for creating and using health records, and bringing each of them into a shared environment requires careful attention to practitioner engagement. If the work flow and day to day perspectives of health practitioners are not considered, then the proposed reform will fail.

While more of an implementation issue, DoHA should also consider providing funding support for these professional associations to be actively involved in educational programs assisting their members to make the required adjustments to established work processes and habits.

Recommendation 1: That a minimum three healthcare provider member positions be required to represent healthcare providers on the Independent Advisory Council so as to adequately represent the broad range of healthcare practitioner types and healthcare environments.

5. Registration

a. Part 3, Division 1: Registering consumers

More robust identification requirements to register consumers

This Division, amongst other things, requires the PCEHR System Operator to register a consumer's request for the PCEHR, which application requires the following minimum information:

- Full name;
- Date of birth;
- Healthcare identifier or Medicare number or DVA file number; and
- Sex.

While many dental patients are well known to their dentist many others may be new to a practice. Therefore the ADA is concerned about the lack of personal identification required to release information from personal medical records and the establishment of a PCEHR to a member of the public. The information above could be easily used by a member of the public to establish an unauthorised PCEHR for another person by simply having access to their purse or wallet.

The Bill appears to allow regulations to be developed to outline more robust identification requirements (namely clause 40 paragraph (b)(v)). These should be utilised to meet the recommendation made below:

Recommendation 2: That 100 points of identification should be required before a consumer is registered in the PCEHR system, the same identification requirements and verification methods when applying for a Medicare Card, Driver's License or Passport.

Pseudonyms

The ADA expresses great concern about the potential for pseudonyms to be abused as a means to fraudulently misuse the already constrained resources of the healthcare system; not to mention the potential extra burden pseudonyms would have on the data storage capacity of the PCEHR System.

If an individual wishes to participate in the System then there should be no place for pseudonyms. Utilisation of pseudonyms is both wasteful and dangerous - there would be no guarantee that relevant medical information would be provided to medical and other health practitioners if the consumer chooses not to link their two accounts. The risk of adverse outcomes is increased.

The ADA believes that the existing privacy protection regime and patient/healthcare practitioner obligations are adequate to address consumer's confidentiality concerns.

Recommendation 3: That the PCEHR system not allow for the use of pseudonyms.

If however the Bill continues to allow consumers to use pseudonyms under the PCEHR System, DoHA should ensure that health practitioners are adequately educated and supported to respond to any impact on privacy Policies and Procedures and that pseudonyms can only be used as a secondary form of identification at the practice or service level as per the current system.

Minors

The ADA acknowledges that the Bill's arrangements for minors have been based on existing arrangements established by the Medicare program in order to closely reflect the accepted approach of acknowledging the growth in maturity and capacity that occurs during the teenage years and the differing family circumstances that can occur.

However the ADA expresses its concerns about minors' ability to manage their own health records, and notes the attendant risks towards not providing adequate and relevant information to enable the health practitioners to provide effective care. Allowing minors even graduated control over their PCEHR may create a precedent which could have unintended consequences.

Recommendation 4: Where arrangements proposed in the Bill pertaining to minors alter regulations under the *Privacy Act (1988)* and require changes to existing Policies and Procedures in the healthcare and practice

setting, healthcare practitioners should be given fair notice and assistance.

"Opt out" recommended

The ADA supports the Australian Medical Association and the Consumer Health Forum's recommendation that the PCEHR System be adopted on the basis that all patients are included into the system and that those who choose to "opt out" can do so. This is to avoid the risk that the Australian community does not participate in the PCEHR System thus rendering the entire policy a failure at great expense to the taxpayer.

Recommendation 5: Adopt an "Opt out" approach whereby all Australians are registered on the PCEHR System with the same access/control privileges as currently outlined unless they choose to opt out. Government must ensure adequate funding to assist health practitioners to familiarise themselves with the processes and operations of the PCEHR system.

Do not allow access controls to PCEHRs

Under the Government's proposed approach PCEHR consumers retain access control rights to their PCEHR.

The ADA recommends that any consumer under the PCEHR System should not have the ability to withhold selected information as this will compromise the integrity of the record and not lead to the envisaged improvement in patient care. If consumers are worried about sensitive information then they should not "opt in" and existing processes continue to be used.

While under this recommendation consumers can choose which practitioners to access their information, however once they allow such access the ADA believes the Bill should enable the complete record to be accessed by that practitioner.

It is absolutely essential the practitioners who have access to PCEHRs have confidence that the record is complete and can be used to influence clinical decisions. If practitioners lose confidence in the PCEHR System (due to consumers making decisions as to what health information to disclose – creating the risk that medically relevant information is omitted from health practitioner's clinical assessments), they will stop using it and it will fail.

Again the ADA would refer to the UK's difficulties of implementing an e-Health record system to provide a strong caution on how this issue is managed.

The ADA supports only the nominated provider being able to update the SHS.

Recommendation 6: Where consumers are participating in the PCEHR system and they allow a health practitioner to access their PCEHR, the consumer should not be able to determine the level of access. The health practitioner should be able to access all information in that record.

b. Part 3, Division 2: Registering healthcare provider organisations

Conditions of registration (non-discrimination) - Adverse event risks

While the ADA supports the Bill's position that healthcare is provided regardless of a patient having a PCEHR, the ADA is deeply concerned that allowing the consumer to control the amount of information available to the health practitioner creates significant issues as to the degree of reliability, safety and quality of the care that is to be delivered.

As outlined above any masking of information about a patient's health conditions and treatment could lead to 'medical' error and interfere with the objective to ensure the right treatment is given to the right patient at the right time. Practitioners will not be able to rely on the health summaries providing the essential information required to ensure patient safety and this would defeat the purpose of having the PCEHR.

Furthermore each of the various types of health practitioners contributing information into the PCEHR do not even know with any degree of certainty what exactly it is that other health disciplines will need to know in the interests of effective diagnosis and care.

The SHS is the central clinical document within the PCEHR that outlines an individual's medical history and details of medications. The SHS should be the minimum baseline information that can be accessed by a health practitioner (provided they have the relevant consent from the consumer) – noting that there will need to be agreement with the health care sector on the relevant information that is to be included in that section.

Recommendation 7: The Bill should enable the health practitioner access to the SHS as a minimum if the provider is given permission by the consumer to access their PCEHR.

Limiting liability where health practitioners rely on PCEHR information

The patient's PCEHR may omit medical information that is relevant to dental treatment. Likewise, the information available may contain inaccuracies. An adverse outcome may occur as a consequence of the reliance of the dental practitioner on the PCEHR.

Recommendation 8: The Bill should have a provision indemnifying health practitioners from any liability arising from their reliance on a consumer's PCEHR.

Implementing shared health summaries

The Bill outlines that only the consumers' nominated healthcare providers will be permitted to upload their shared health summary.

While this is an implementation issue, the ADA requests DoHA consider the fact that the dental profession needs to liaise with dental software vendors on the way they are approaching the incorporation of shared health summaries in their upgrades of dental software. End-user perspectives need to be taken into account. This is an aspect of data governance not yet being addressed.

While only significant events will be included in the PCEHR and the nominated provider will update the SHS, dentists may be the first practitioners to, for example, suspect an allergy which can be added by them to the Events Summary.

It is essential they are informed how to make such valuable contributions to the PCEHR.

Recommendation 9: **Guidelines should to be developed by DoHA to show health practitioners how to contribute to the PCEHR.**

6. Collection, use and disclosure of health information included in a registered consumer's PCEHR (Part 4)

While the ADA supports the Bill's privacy arrangements that have been drafted with the intention to displace existing privacy and health information law to the minimum extent possible, it outlines the following concerns:

a. Part 4, Division 1: Unauthorised collection, use and disclosure of health information included in a registered consumer's PCEHR

While supporting the rationale of deterring behaviour that breaches the unauthorised use/access provisions, the ADA submits the penalty units in the Bill are excessive.

The ADA does not anticipate that its members would knowingly participate in unauthorised disclosure of information relating to consumers' PCEHRs. It suggests that adequate system training and support must be provided by DoHA.

Recommendation 10: **The penalty unit amounts in the Bill are too high and should be reconsidered. The fact that there is a penalty unit regime further highlights the need for Government to ensure they provide adequate education, system training and support to all relevant participants.**

b. Part 4, Division 2: Authorised collection, use and disclosure

Research and secondary uses

The Bill allows a consumer to consent to the collection, use and disclosure of information included in their PCEHR such as for research purposes. Consistent with the current position under the Commonwealth *Privacy Act*, consent is not required if de-identified information is released for research purposes.

Recommendation 11: **To ensure practitioners' effective participation in the PCEHR system, NEHTA should provide a sufficient level of transparency about the use of data by government.**

7. Voluntary enforceable undertakings

a. Part 7: Voluntary enforceable undertakings

Recommendation 12: **The Bill should place a presumption that the Information Commissioner accepts voluntary undertakings. Where the Information Commissioner does not accept a voluntary undertaking the Bill should require the Information Commissioner to give reasons and the person allowed to seek a review of, or challenge that decision.**

8. Other matters

a. Part 8, Division 7: PCEHR Rules, regulations and other Instruments

PCEHR Rules / Regulations

The ADA refers to one of the matters that are likely to be addressed in the PCEHR Rules; namely:

"To detail requirements regarding the identity of a consumer to which the System Operator should have regard in registering a consumer".

Recommendation 13: **Where required, the PCEHR Rules/Regulations should outline that 100 points of identification are needed for an individual to create a PCEHR.**

9. Conclusion

The ADA supports the introduction of an e-health system for the Australian public including the PCEHR because it has potential benefits to assist in the provision and administration of healthcare services in the 21st century.

While some of the ADA's recommendations were adopted following feedback into the exposure draft legislation, the ADA remains concerned that this Bill contains gaps which, if not attended, would weaken the PCEHR System's ability to operate and be used effectively by health practitioners and consumers alike.

The ADA's concerns with the Bill revolve around the ability for the system to operate in a manner which effectively recognises the unique environments in which the range of different healthcare practices operate. It is with this in mind that the ADA has made recommendations to require adequate representation of healthcare providers in the Independent Advisory Council; adopt an "opt out" system where all Australians are automatically on the PCEHR System (retaining their access/content controls) unless they choose to opt out; ensure the PCEHR is to contain as much medically and clinically relevant information as possible; and to confirm that health practitioners can access enough information to make informed decisions in the interests of their patients while preserving consumer choice and privacy as much as is realistically possible.

In adopting the recommendations set out in the Executive Summary, the Bill that establishes the PCEHR System will be better able to operate in accordance with its objectives, and assist in the delivery of health outcomes for all Australians and provide efficiencies for all healthcare providers.

Should further explanation or detail be required please contact the ADA office at 02 9906 4412 or email to ceo@ada.org.au.

Dr F Shane Fryer
Federal President
Thursday 12 January 2012.