



Response to Request for Comment

on the Personally Controlled Electronic Health Record (PCEHR) Proposals for Regulations and Rules

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Executive Summary

The Australasian College of Health Informatics (ACHI) welcomes this opportunity to comment on the "Personally Controlled Electronic Health Record (PCEHR) Proposals for Regulations and Rules" released by the Department of Health and Ageing in March 2012.

The College is the professional body for Health Informatics in Australia and New Zealand. The credentialed Fellows and Members of the College are national and international experts, thought leaders and trusted advisers in Health Informatics. ACHI sets standards for education and professional practice in Health Informatics, supports initiatives, facilitates collaboration and mentors the community. The Fellows and Members of the College are widely involved in e-Health research, standards development, system design and implementation work in Australia, the region and globally.

ACHI supports the Australian government's national health reform agenda and welcomes an agenda that aims to create an improved healthcare system that is safe, of high quality and which is transparent, accountable, affordable and sustainable.

The College agrees that e-Health is an important enabler to the way healthcare is delivered and is supportive of a robust regulations and rules framework that ensures that the legislation supporting the Personally Controlled Electronic Health Record¹ is implemented in an operationally effective manner. Therefore, the College welcomes the Department's release of the "Personally Controlled Electronic Health Record (PCEHR) System: Legislation issues paper"² for public comment. The Fellows and Members of the College have reviewed the draft and have identified some issues of concern, which it believes require due consideration.

In summary, there are a number of areas where the College believes clarification and improvements are required and has formulated **13 recommendations** for the Department's consideration, namely that:

Recommendation 1: *further time be allowed for consultation on the PCEHR Regulations and Rules in advance of the passage of the draft legislation currently before Parliament.*

Recommendation 2: *the PCEHR Regulations and Rules provide policy guidance to the system operator by setting the terms and conditions for technical access to the PCEHR system.*

Recommendation 3: *the PCEHR Regulations and Rules should consider mechanisms to provide medico-legal protection for users acting in good faith to accepted clinical standards.*

Recommendation 4: *the relationship between the Jurisdictional Advisory Committee (JAC) and the Independent Advisory Council (IAC), and their respective roles, be further clarified in consultation with stakeholders, including ACHI.*

Recommendation 5: *the PCEHR Regulations and Rules provide further detail with respect to privacy and security and the management and control of audit trails.*

Recommendation 6: *the concept of "a minimum data set for PCEHRs" be removed from the document.*

¹ The "Personally Controlled Electronic Health Records Bill 2011" and "Personally Controlled Electronic Health Records (Consequential Amendments) Bill 2011"

² "Personally Controlled Electronic Health Record (PCEHR) Proposals for Regulations and Rules", Australian Department of Health and Ageing, March 2012, Publications Approval Number: D0679

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Recommendation 7: *in addition to consultation with the JAC, the Minister be required to consult with the IAC prior to making Rules under the PCEHR legislation.*

Recommendation 8: *DoHA consider initiating action to establish the Independent Advisory Council in advance of the legislation coming into effect as soon as practicable.*

Recommendation 9: *the Rules described in relation to access controls within healthcare provider organisations be substantially revised to take account of existing practice and legislation.*

Recommendation 10: *the system operator and DoHA assure themselves, through testing, that the identification of consumers wishing to access the PCEHR is fully fit for purpose and meets consumer expectations.*

Recommendation 11: *the Rules provide further clarity on the concept of document authors/authorisers and their obligations with respect to uploading to the PCEHR.*

Recommendation 12: *the Rules dealing with risk mitigation for gaining participation take account of the scale and complexity of the provider organisation.*

Recommendation 13: *the Rules dealing with risk mitigation emphasise the critical nature of encrypting all PCEHR data.*

The Australasian College of Health Informatics looks forward to further working with DoHA on the draft legislation, to support the creation and usage of PCEHR e-health systems that will enable the common goal of better healthcare for all Australians.

General Comments

- a. The proposed PCEHR Regulations and Rules should effectively support those groups of consumers for which the use of the PCEHR is targeted in the first instance. The initial communities of interest that have been identified include Aboriginal and Torres Strait Islanders, chronic disease, aged care and mothers and babies.
- b. The PCEHR Regulations and Rules should meet the requirements of these communities, including recognising their need for support from providers and nominated representatives who they trust and operating in a manner cognisant of their general health literacy and awareness of e-health.
- c. From the perspective of providers, interaction with the PCEHR system must be workable and pragmatic and operate with a minimum of intrusion on current practice, for a system that is already operating under considerable demand pressure in all settings.
- d. The short time allowed for consideration of these rules and regulations has limited the capacity for broad consultation of what are complex and important matters for the healthcare system.
- e. It is also disappointing that the paper does not include the actual drafts of the proposed Regulations and Rules rather than simply providing commentary on the drafting intentions.

Recommendation 1: *That further time be allowed for consultation on the PCEHR Regulations and Rules in advance of the passage of the draft legislation currently before Parliament.*

Section 1.2 Introduction: What is not in scope

- f. The exclusion of any rules or regulations relating to the technical design or administrative operations of the system, which are proposed to be established through contractual arrangements with the system operator, is considered a significant omission for two reasons:
 - There will be no independent review of the terms and conditions to participate, which will be at the sole discretion of the system operator (DoHA)
 - The terms and conditions that currently drafted are held on an access-controlled website (www.vendors.nehta.gov.au). The site is not readily available to consumers, particularly those who may be considering the security of their information and whether to use advanced access controls. We note that at the time of writing the terms and conditions have been withdrawn for further consultation.
- g. As technologies will change and evolve over time, it is not considered necessary that all of the detail of these requirements be included in the regulations but at a minimum, they should include the principles describing the basis on which the terms and conditions are to be established by the system operator.

Recommendation 2: *That the PCEHR Regulations and Rules provide policy guidance to the system operator by setting the terms and conditions for technical access to the PCEHR system.*

- h. A key element that appears to be missing from the regulations is some form of indemnity / medico-legal protection for users acting in good faith. How is it proposed to cover that issue?

Recommendation 3: *That the PCEHR Regulations and Rules should consider mechanisms to provide medico-legal protection for users acting in good faith to acceptable clinical standards.*

Section 3 Overview of the PCEHR Bill

Section 3.1 Governance

- i. The Jurisdictional Advisory Committee (JAC) has been established to represent the organisations substantially funding the PCEHR (either directly or indirectly). What is their relationship to existing national governance bodies established under the Australian Health Ministers Advisory Council, such as the National Health Information and Performance Principal Committee, noting that their purpose under the legislation is “to advise the System Operator on matters relating to the interests of the Commonwealth, states and territories”?
- j. The purpose of the Independent Advisory Council (IAC) is “to advise the System Operator on matters relating to the PCEHR system, participation in the PCEHR system and consumer security, privacy and clinical matters relating to the operations of the system”. It is unclear how the JAC views on these matters are taken into account or can be resolved if there are differing views. The relationship to the role of the Australian Office of the Information Commissioner on these matters also needs to be clarified.

Recommendation 4: *That the relationship between the Jurisdictional Advisory Committee (JAC) and the Independent Advisory Council (IAC), and their respective roles, be further clarified in consultation with stakeholders, including ACHI.*

Section 3.2 Participation

- k. Very limited information is provided on the proposed rules governing the operations of repository operators, portal providers and contracted service providers. As these type of organisations are new concepts in the context of the PCEHR it is essential for the protection of both the organisations and consumers that the regulations and rules governing their operations are appropriate to the need and are transparent.
- l. The details provided are vague or ambiguous. For example, what constitutes a record held by a repository operator “for PCEHR purposes”? Does this imply that a radiology service that uses a reporting service overseas at night is prohibited from doing so (or cannot participate in the system) because that record might be available to be indexed by the PCEHR?

Section 3.3 Privacy and Section 3.4 Security

- m. It is disappointing to note that the proposal paper conflates privacy with security. These are vastly different concepts.
- n. It is a common practice in all modern computer systems to maintain audit trails but the presentation of the information contained in those audit trails can be quite confusing and inappropriate for general use. It is unclear what a consumer will actually see when they access their “audit trail”. Will they have access to the name of the organisation, the name of the individual healthcare provider or authorised user involved and their role?
- o. How will they be given access to this information if it is available and what comprises the “more detailed record of flows of information” available from the System Operator on request? What are the obligations of the System Operator (and the Healthcare Provider Organisation) to protect the privacy of the individuals who accessed the record?

Recommendation 5: *That the PCEHR Regulations and Rules provide further detail with respect to privacy and security and the management and control of audit trails.*

Section 3.5 Access and retention of certain records

- p. The concept of a "minimum data set" for the PCEHR" appears inappropriate as it is not a primary data source and as a consequence of being consumer controlled may contain as much or as little information as the individual deems appropriate. The concept is not defined and therefore its significance cannot be determined.

Recommendation 6: *That the concept of "a minimum data set for PCEHRs" be removed from the document.*

Section 3.6 Status of PCEHR Rules

- q. The Minister is required to consult with the JAC before making rules but not with the IAC. This appears inconsistent with the role of the IAC as the expert advisory group with respect to matters relating to the PCEHR system, participation in the PCEHR system and consumer security, privacy and clinical matters relating to the operations of the system. It would also be expected that where advice was rejected, information would be provided as to the reasons for rejection.

Recommendation 7: *That in addition to consultation with the JAC, the Minister be required to consult with the IAC prior to making rules under the PCEHR legislation.*

Section 4.4.4 Nomination of members

- r. The Australasian College of Health Informatics would be pleased to provide a nomination to the Independent Advisory Council if requested.

Section 5 PCEHR Rules

- s. As noted above, it is considered essential that as well as the JAC, the Minister consults with the IAC, particularly noting the need for "fast and flexible responses to evolving technologies and security risks".

Section 5.1 Preliminary

- t. As the rules commence on the day the Bills commence (planned for 1 July 2012) it is not possible to bring the governance mechanisms fully into effect in advance of that date. What consideration has been given to initiating the establishment of the IAC informally as soon as possible to facilitate the process and be in a position to respond quickly to any changes should such a need arise in the early stages of operation of the PCEHR?

Recommendation 8: *That DoHA consider initiating action to establish the Independent Advisory Council in advance of the legislation coming into effect as soon as practicable.*

Section 5.2 Access Control Mechanisms

- u. The fourth dot point on p.16 states consumers can "limit the kind of health information that can be collected". This wording is misleading. The operation of the PCEHR does not change the clinical processes for the capture of information at the point of care. Should clinical documents

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are added to the PCEHR, they are added in their entirety and cannot have parts of their content "masked" from the viewer (but can be completely removed from all but the author's view). This dot point should be rephrased to better reflect the actual extent of personal control over information in the record.

- v. The complexity of the access rules continues to be a concern and appears to have been "over-engineered", with insufficient consideration of the target audience. For example, the reason that many consumers will have a nominated representative (other than for children) is that they may not be particularly comfortable with dealing with the technology. It is proposed that they can then elect, however, to be notified by SMS or email (but presumably not by letter) when events occur in relation to their record, including access by the trusted person they nominated.
- w. Section 5.3 (e) imposes a set of requirements on the use of HPI-Os and HPI-Is which has as its starting assumption that the primary purpose of these identifiers is to support the PCEHR and that the System Operator can therefore dictate their use by Healthcare Provider Organisations, including where necessary stepping in and directing the establishment of their network hierarchy. This assumption fails to recognise that identifiers may be used for a wide range of purposes within organisations, including managing internal access policies and to support secure messaging between provider organisations. The HI Act thus enables considerable flexibility in how network and seed organisations may be set up, in recognition of the complexity and dynamic nature of these relationships. It is inappropriate for the System Operator to determine the internal access policies of organisations already operating in accordance with national and state legislation.

Recommendation 9: *That the rules described in relation to access controls within healthcare provider organisations be substantially revised to take account of existing practice and legislation.*

Section 5.3 Identity verification

- x. The provisions for establishing the identity of the person creating a PCEHR relies exclusively on the consumer confirming to the System Operator that they have a verified Individual Healthcare Identifier. Given the criticality of that identifier, how is it to be validated and protected against misuse? In what circumstances is it expected that the System Operator would initiate action "to satisfy itself that the identity of a consumer has been appropriately verified"?
- y.

Recommendation 10: *That the system operator and DoHA assure themselves, through testing, that the identification of consumers wishing to access the PCEHR is fully fit for purpose and meets consumer expectations.*

Section 5.4 Restrictions on records that may be uploaded by healthcare providers to the PCEHR system

- z. A record is required to be "authored by a healthcare provider who has been assigned a healthcare identifier under paragraph 9 (1) (a) of the HI Act". This is an overly simplistic view. In preparing a hospital discharge summary there may be many contributing "authors" of the document (all of whom have a healthcare identifier) and one "authoriser" who takes responsibility for the content but may not necessarily be the provider who sends the discharge summary to the patient's GP or the PCEHR.

Recommendation 11: *That the Rules provide further clarity on the concept of document authors/authorisers and their obligations with respect to uploading to the PCEHR.*

Section 5.5 Participation requirements

- The proposed arrangements for risk mitigation appear particularly burdensome on smaller healthcare provider organisations and may result in a reluctance to participate if seen to impose a high administrative cost. It is not that the mitigation measures described are necessarily unreasonable (particularly for larger institutions) but any consideration of risk has to take into account a range of factors including the environment in which the risk is assessed. The “one size fits all” approach is inappropriate in an industry that has such a diverse range of provider organisations in focus, scale and complexity. It may be preferable to consider requiring that provider organisations are able to evidence compliance with NEHTA’s recently published National EHealth Security and Access Framework (NESAF). This would potentially provide greater flexibility of application in the way information is being handled across the system at both the local and national level to which the NESAF also applies.

Recommendation 12: *That the Rules dealing with risk mitigation for gaining participation take account of the scale and complexity of the provider organisation.*

- aa. A key risk mitigation that would not be burdensome on smaller healthcare providers is that all PCEHR information is encrypted. This means that unintentional error cannot be cached and published by search engines on the internet.

Recommendation 13: *That the Rules dealing with risk mitigation emphasise the critical nature of encrypting all PCEHR data.*

Section 5.6 Technical specifications

- bb. As noted above under Scope, the exclusion of any rules or regulations relating to the technical design or administrative operations of the system, which are proposed to be established through contractual arrangements with the system operator, is considered a very serious omission

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