

5 January 2012

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

Dear Dr Holland.

Inquiry into the Personally Controlled Electronic Health Records Bill 2011

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Senate Community Affairs Committee's Inquiry into the Personally Controlled Electronic Health Records Bill 2011 and one related bill (the Inquiry).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF's submission draws on consultation with our membership, which includes organisations advocating for older consumers, disease specific groups and networks, state and territory peak consumer organisations and individual consumers. Our submission addresses legislative proposals to support the PCEHR system, as well as access, privacy, security and governance.

Key concerns for CHF include consumer control, oversight and the importance of functionality in the initial rollout of the PCEHR system. CHF's submission calls for greater accountability and independence in the long-term governance arrangements, provisions to allow consumers to mark a clinical document as 'no access,' and reconsideration of an opt-out model. These issues are outlined in more detail in our submission.

CHF looks forward to reviewing the report from the Inquiry. We would welcome the opportunity to expand on our submission in a public hearing of the Committee.

Please do not hesitate to contact me should you wish to discuss any aspects of this submission further.

Yours sincerely,

Carol Bennett CHIEF EXECUTIVE OFFICER



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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomes the introduction of the *Personally Controlled Electronic Health Records Bill* 2011 (the Bill) and the opportunity to comment on the Senate Community Affairs Committee Inquiry into the *Personally Controlled Electronic Health Records Bill* 2011 (the Inquiry).

Our submission draws on consultation with our membership, which includes organisations advocating for older consumers, disease specific groups and networks, state and territory peak consumer organisations and individual consumers. CHF's submission also draws on consultations undertaken through our *Facilitating Consumer Input on the PCEHR* Project, consumer input on CHF's response to the Concept of Operations, and a dedicated consumer forum on legislative issues relating to the PCEHR held on 26 October 2011.

CHF's response covers legislative proposals to support the PCEHR system, access, privacy, security and governance, including:

- The importance of consumer participation in the governance of the PCEHR system
- The importance of transparency and accountability in the operation of the PCEHR system
- The need to engender robust consumer access controls
- The importance of consumer ownership of the PCEHR system.

Key concerns for CHF include consumer control, oversight and the importance of functionality in the initial rollout of the PCEHR system. CHF's submission calls for greater accountability and independence in the long-term governance arrangements, strong consumer access controls and reconsideration of an opt-out model.

Overall, CHF welcomes the Bill and agrees that the PCEHR has the potential to be a powerful vehicle for empowering consumers to manage their own health.

The System Operator, Advisory Bodies PCHER System Governance

Throughout CHF's consultations on the PCEHR, consumers have emphasised the importance of long-term governance relating to the system and the centrality of these arrangements to consumer confidence. Appropriate governance structures and mechanisms will be essential to the successful delivery of the national PCEHR system, and CHF welcomes the additional detail contained in the Bill for the governance of the PCEHR system. However, consumers consulted by CHF have proposed changes to the framework outlined in the Bill. These are outlined below.

The System Operator

According to Sections 14 and 15 of the Bill, the PCEHR system will be managed by the PCEHR System Operator. The Bill identifies the PCEHR System Operator as the Secretary of the Department of Health and Ageing, or another body established by the regulations.

CHF understands that the Secretary will fill the role of PCEHR System Operator initially, with further discussions to be held with the states and territories around possible future options for the long-term governance of the PCEHR. CHF believes that this legislative framework provides sufficient flexibility to establish a long-term governance model, but stresses the importance of consultation to consumer confidence in the system.

CHF considers that the adoption of long-term governance structures, including the long-term adoption of the arrangements outlined in the Bill, must be subject to an extensive public consultation process.

Ultimately, consumers consulted by CHF on the development of the legislation wanted to see a transition away from the governance structures as proposed in the Bill in favour of an independent System Operator. Consumers called for the establishment of a statutory authority independent of the Department of Health and Ageing, Medicare Australia and the states and territories.

Consumers understood that it would not be possible to establish such an authority for the initial implementation of the PCEHR, but instead suggested that a review of the interim arrangements after two years would provide sufficient time for preliminary work to establish an independent authority, while also providing consumers with an opportunity to provide input into the long-term operation and governance of the PCEHR system. The review would also highlight any necessary changes to other elements of the PCEHR system governance, such as the advisory bodies.

CHF supports the governance arrangements outlined within the Bill on an interim basis only. CHF calls for these arrangements to be reviewed after two years, with a view to appointing an independent PCEHR System Operator into the long term.

Composition and Role of the Advisory Bodies

According to Section 24 of the Bill, the System Operator will receive guidance from two advisory bodies, a Jurisdictional Advisory Committee comprised of representatives of the states and territories, and an Independent Advisory Council. Membership of the Independent Advisory Council will comprise:

¹ CHF (2011) National Consumer Personally Controlled Electronic Records (PCEHR) Workshop Report. CHF: Canberra.

- A Chairperson, to be appointed by the Minister on a part-time basis
- A Deputy Chair, to be appointed by the Minister on a part-time basis
- Between seven and ten other members to be appointed by the Minister on a part-time basis. In appointing members, the Minister must ensure that three of the members have experience of receipt of healthcare as a consumer. The remaining members must have experience in one or more of the following fields:
 - Provision of healthcare as a medical practitioner
 - Provision of healthcare as a healthcare provider (other than a medical practitioner)
 - Law and/or privacy
 - o Health informatics and/or information technology relating to healthcare
 - Healthcare administration
 - Aboriginal and Torres Strait Islander healthcare
 - o Regional and rural healthcare.

CHF's response to the Exposure Draft legislation called for the inclusion of at least one dedicated consumer representative to the Independent Advisory Council. CHF is therefore pleased that the Bill now includes provisions for the appointment of three consumer representatives who cannot also be health professionals. This represents a considerable strengthening of consumer representation from the provisions that were initially proposed.

CHF welcomes the inclusion of provisions for the appointment of three consumer representatives, who cannot also be health professionals, to the Independent Advisory Council.

While consumers consulted by CHF supported the appointment of additional consumer representatives, they also called for more detail on how consumer representatives would be appointed. They also suggested the inclusion of nomination structures to ensure that representatives had the confidence of, and connections with, broader consumer networks. CHF looks forward to receiving additional information about these aspects of the appointments.

Consumers were also concerned that while the PCEHR System Operator is required consider the input of the advisory bodies, it is under no obligation to accept their recommendations. Consumers did not consider it appropriate to require the PCEHR System Operator to accept the advice, but instead called for the recommendations made by the advisory bodies and the PCEHR System Operator's response to the advice to be made public.

CHF calls for any recommendations made by the advisory bodies to be released to the public. If the PCEHR System Operator does not accept the recommendations made by the advisory bodies, it should provide a rationale for this decision.

Registration and Participation in the PCEHR System

According to Sections 39, 40 and 41 of the Bill, registration is voluntary and consumers who choose not to register for a PCEHR will continue to be able to access healthcare services and medical benefits.

When a consumer registers, she or he can set the access controls that determine which healthcare provider organisations can access the PCEHR, and whether any other persons can access the PCEHR.

Following registration, a consumer must continue to meet the registration eligibility criteria. If the PCEHR System Operator considers that a consumer is no longer eligible for registration, the PCEHR System Operator may suspend or cancel the participant's registration (for example, in the case of identity fraud).

CHF has consulted with consumers on these and other issues relating to registration and participation in the PCEHR system. Comments and recommendations are provided below.

Nominated and Authorised Representatives

According to Section 6 of the Bill, consumers who have limited or no capacity will be able to have a PCEHR through the use of an authorised representative. An authorised representative will be able to register a person for a PCEHR and manage the access controls on behalf of the person. This is distinct from a nominated representative as described in Section 7 of the Bill, whose terms of access are determined by the consumer.

Consumers consulted by CHF agreed that the concept of representation is particularly relevant to health service delivery. Consumers are often supported by other people when accessing healthcare services and it is important that the provisions for authorised representatives are flexible enough to support the full range of arrangements that might be needed.

Consumers noted that the legislation is only intended to provide a broad framework to support the participation of individuals through authorised representatives, and that more information about these arrangements will be provided in the administrative policies. Nevertheless, consumers were pleased that the legislation acknowledged authorised representatives, as they will have the ability to decide whether to create a PCEHR for the individual they represent and to complete the registration process for that individual. On this basis, CHF supports the Bill's framework permitting an individual to participate in the PCEHR system through an authorised representative within the legislation.

CHF also notes that the Bill enables consumers to determine the terms of access for nominated representatives. This measure was proposed by CHF in response to the Exposure Draft legislation, creating levels of representation between what was originally proposed for nominated representatives and authorised representatives. As noted in the Bill's Explanatory Memorandum, this means that nominated representatives can now assist in the management of the PCEHR. CHF welcomes these amendments.

CHF supports the Bill's framework permitting an individual to participate in the PCEHR system through an authorised representative within the legislation. CHF also supports the ability of consumers to determine the terms of access of any nominated representative.

Young People and Access to the PCEHR

According to Section 6 of the Bill, parents and guardians of minors will be recognised as authorised representatives. Minors will be able to participate in the management of their PCEHR from the age of 14 and can also apply to take complete control of their own PCEHR from that age if they can demonstrate a need for this. Control of the PCEHR will be withdrawn from parents and guardians when the minor turns 18.

In practice, this will mean that when a minor turns 14 the System Operator will advise them in writing of the ability to take control of their PCEHR and explain how they could pursue this. The PCEHR system will enable the minor to choose to manage their own PCEHR, including the capacity to participate, withdraw, manage their access controls or withdraw a representative. When a consumer turns 18, the System Operator will again advise them in writing explaining how they may take control of their record.

This matter was the subject of debate amongst the consumers consulted by CHF. Some suggested that applications for the removal of parental control from the PCEHRs of young people under 18 should only occur in consultation with parents and guardians. Others noted that this would be inconsistent with the approach taken by Medicare Australia, and felt that young people should be encouraged to start managing their own healthcare and information as early as possible.

After some discussion, it was generally agreed that young people should be allowed to apply to autonomously manage their PCEHR in the appropriate circumstances, noting the importance of protecting vulnerable young people and the complexity of their situations.

Consumers were concerned, however, about proposals contained in the Exposure Draft legislation, which would have seen the PCEHR deactivated when a young person turns 18, pending advice that they wish to continue participating in the system. Consumers instead proposed the reverse, calling for the PCEHR to remain active until the PCEHR System Operator is advised that its owner no longer wishes to participate in the system.

CHF is therefore pleased with the changes to the Bill. According to the Explanatory Memorandum, during the period between the consumer turning 18 and taking action to either manage their PCEHR or cancel their registration, the PCEHR will be functional but dormant. This means that it can still be used and that information can still be uploaded subject to the access control settings in place immediately before the consumer turned 18. At this point, their parents, guardians or other authorised representatives will automatically cease to be authorised representatives and lose all access to the PCEHR.

CHF supports provisions for the PCEHR of a young person to remain active after they turn 18, until the PCEHR System Operator is advised that its owner no longer wishes to participate in the system.

Access Controls for the PCEHR

According to the Explanatory Memorandum, default settings will be available for the consumer to allow any healthcare provider providing care to the consumer to access the PCEHR. Alternatively, the consumer can elect to implement more complex control settings in relation to the type of information that can be accessed by healthcare providers of the consumer's choosing.

In CHF's consultations, consumers strongly supported the use of access controls to moderate access to their PCEHR by participating healthcare organisations. However, the access

controls have been significantly weakened since the release of the final Concept of Operations document in October 2011, hindering the ability of consumers to set controls around provider access and weakening authorisation processes for access to the PCEHR.

The major change in this area has been the removal of the ability to mark a clinical document as 'no access.' According to the Concept of Operations, this was because:

Many submissions stated the opinion that provisions must be made to make all PCEHR information available to healthcare personnel when it is in the patient's best interest.

Considering the centrality of these access controls to consumer trust, it is extremely disappointing that this change was made without reference to the preferences of consumers and without further consultation. CHF urges the Committee to revisit this issue as part of the current Inquiry.

When consulted by CHF, consumer representatives to the National eHealth Transition Authority (NEHTA) expressed concern that the decision to remove this access control went against the advice of the NEHTA Consumer Reference Forum. In addition, consumers are extremely dissatisfied with suggestion that documents could be 'effectively removed,' considering it important to have the information on the record for their own information and for information to be returned to be available to be returned to the record if the consumer wishes to provide health professionals with access to it.

Throughout CHF's consultations on the PCEHR, including our recent consumer forum on the Exposure Draft legislation, there has been unanimous support for the reinstatement of 'No Access' consumer control. Many consumers have described this issue as a 'deal-breaker' in terms of their participation in the PCEHR system. These findings are consistent with those of previous CHF consultations and international literature scoping.²

CHF acknowledges that limiting access is a challenging topic. Concerns have been raised by healthcare providers about the potential consequences of limiting access to clinical information. However, consumers are likely to withdraw participation, refuse to grant access or simply withhold information to work around the absence of this feature.

CHF does not support the removal of provisions enabling consumers to mark a clinical document as 'no access.' CHF is concerned that removal of this provision could undermine consumer confidence in the PCEHR system.

Cancellation, Suspension or Refusal to Register a Consumer to the PCEHR System According to Sections 51, 52 and 53 of the Bill, a range of powers will be given to the PCEHR System Operator, including the ability to:

- not recognise a person as an authorised representative
- refuse to register a consumer
- refuse to register a healthcare provider organisation
- cancel or suspend the registration of a consumer or other participant
- refuse to cancel or suspend the registration of a participant upon request
- vary the registration of a consumer or other participant upon request
- vary the registration of a consumer or other participant.

² CHF (2010) eHealth and Electronic Health Records: Consumer Perspectives and Consumer Engagement. CHF: Canberra.

Consumers consulted by CHF understood the need to give the PCEHR System Operator the power to cancel, suspend and refuse to register certain individuals to the PCEHR, such as those suspected of being based on a false identity, in the interests of broader system security. Participants considered this to be a security measure necessary in the interests of all consumers participating in the PCEHR system.

However, consumers emphasised the importance of advising individuals whose registrations had been cancelled, suspended or refused of the reasons for the PCEHR System Operator's decisions. Those individuals should also be advised of their rights to appeal the decision and notified of the necessary steps to do so. Participants also emphasised the importance of ensuring that the appeals process is accessible.

CHF calls for assurances that individuals whose registrations have been cancelled, suspended or refused will be advised of the reasons for the PCEHR System Operator's decisions. Those individuals should also be advised of their rights to appeal the decision and notified of the appeal process.

Privacy and Security of Health Information in the PCEHR

Sections 72 and 73 of the Bill provide that the authorisations to collect, use and disclose health information will be treated as authorisations under the Commonwealth Privacy Act, and that any breach of the proposed Act will be an interference with privacy. This means that such an act will fall within the jurisdiction of the Information Commissioner to investigate and take appropriate action.

According to the Explanatory Memorandum, the Information Commissioner will be required to report annually on its activities. The Information Commissioner must report to the Minister no more than three months after the end of each financial year. The Minister must then table the report in Parliament within 15 sittings days of receiving it. This provision is consistent with the Information Commissioner's reporting requirements relating to the Health Identifiers Service.

CHF also notes that that there will be civil penalties for any unauthorised collection, use and disclosure of health information contained in a person's PCEHR. The civil penalties will apply to individuals as well as other entities such as corporations.

Authorised Collection, Use and Disclosure of Health Information

When consulted, consumers supported the balance that had been struck within the legislation between protecting the privacy of individual consumers while also enabling de-identified information to be used for population health research. Consumers supported the use of this information without express consent only where it had been completely de-identified.

CHF notes that the authorised uses of consumer information are outlined in the legislation, and that all other uses are not permitted. However, consumers are able to permit other uses of their information, and some participants expressed concerns that consumers could be coerced into permitting access to their record when this will not be in their best interests. Some consumers therefore called for the legislation to be strengthened to specifically exclude the use of the information by third parties including employers and insurers. It was also suggested that additional legislative measures could be necessary to prevent the information in the PCEHR from being used to discriminate against a consumer, potentially following the model of the US *Genetic Information Non-discrimination Act 2008*.

CHF calls for the legislation explicitly prevent the use of PCEHR information by other third parties, such as employers or insurers.

Use of PCEHR Information in Emergency Situations

CHF notes provisions for emergency access under Section 64 of the Bill, which will add the healthcare organisation to the individual's 'include list' and permit access to clinical documents. CHF understands that all episodes of emergency access will be logged and available to view on the audit trail of the PCEHR.

Consumers consulted by CHF accepted that some access controls may be overridden in situations where the individual requires emergency care, but emphasised that this should only occur in situations where the individual is not capable of providing or communicating consent. Consumers also emphasised the need to log emergency access in the audit trail.

CHF supports allowing access controls to be overridden in situations where the individual requires emergency care. However, this should only occur in situations where the individual is not capable of providing or communicating consent. Emergency access of the PCEHR must be logged in the audit trail.

The PCEHR Complaints Mechanism

Throughout our consultations, consumers have emphasised the importance of ensuring that there is a single, clear avenue for making complaints that is accessible to consumers. Consumers have not articulated preferences for what the preferred point of entry should be, except to suggest that the success of the management of PCEHR complaints by Medicare Australia should be reviewed, along with the other governance arrangements, after two years. Consumers should also be provided with educational materials about the right to complain and how to do so, and be assured of prompt responses to complaints.

CHF calls for the success of the management of the PCEHR complaints under Medicare Australia be subject to review, along with the other governance arrangements, after two years.

At CHF's forum on the Exposure Draft legislation, consumers noted the fact that those dissatisfied with the response from the PCEHR System Operator could have their complaint escalated to the Information Commissioner for investigation. However, participants considered it essential that the Information Commissioner be provided with additional resources in order to conduct these investigations.

CHF calls for additional resources to be provided to the Office of the Australian Information Commissioner to ensure it has the capacity to conduct investigations on behalf of consumers.

Notification of All Breaches

CHF understands that consumers will be notified of major breaches relating to their record, but not necessarily more minor ones, as this will be left to the discretion of the PCEHR System Operator.

When consulted on the Exposure Draft legislation, consumers felt strongly that it should not be left to the discretion of the PCEHR System Operator to determine what constitutes a major breach. They called for consumers to be notified of all breaches, whether major or minor.

CHF argues that consumers must be notified of all breaches of the PCEHR system affecting their record.

A Robust Audit Trail

According to the Explanatory Memorandum, the PCEHR system will provide an audit trail showing the organisations that have accessed their records but not the healthcare professionals responsible for the breach. Consumers consulted by CHF considered that this would make it extremely difficult to identify any unauthorised viewings of their PCEHR. CHF therefore considers it essential that consumers will be able to view an activity history for their PCEHR.

CHF calls for the audit trail to provide consumers with information on individual health practitioners who have accessed their record, to assist in identifying misuse and reporting it accordingly.

Functionality and Sustainability of the PCEHR System

Some of the areas of key concern to consumers do not come under the scope of the legislation, including PCEHR capabilities and change and adoption issues. However, CHF considers it essential that the following matters are considered as part of the Inquiry.

Functionality of the PCEHR System

At this stage, the PCEHR will provide few benefits to participants and very few features to assist consumers when it is launched on 1 July 2012. According to the Concept of Operations, from July 2012, the PCEHR system will only be able to offer access to a limited range of clinical documents. These are:

- Shared Health Summaries
- Event Summaries
- Discharge Summaries
- Limited consumer entered information (this will be provided through structured documents that will be verified by nominated providers).

CHF notes that existing electronic records systems in hospitals, general practice and other clinical settings already offer these features, and there is no immediate benefit associated with incorporating this to the PCEHR. This is compounded by the fact that features initially thought to be straightforward inclusions, such as results of diagnostic tests, will not be included as originally planned. CHF is also concerned that to date, no strategy has been released to drive consumer and clinician adoption, for example, through a national campaign or advertising strategy.

All of this suggests that the functionality of the PCEHR will be very limited, and that the system will lack the critical mass required to function effectively. The full value of the PCEHR system will only be achieved if there is widespread adoption across the population, to ensure that there is sufficient data to make the system worthwhile to healthcare providers. Research into the Summary Care Record in the United Kingdom has shown that clinicians are unlikely to look for eHealth records if there is not widespread utilisation of the system because they are unlikely to find them.³ Experiences of eHealth record systems in the United Kingdom and Germany also suggest that is very difficult to reestablish trust in the system if it lacks initial functionality.⁴ CHF is therefore very concerned about the limited capabilities of the PCEHR in the initial rollout.

CHF calls for a revision of the PCEHR Change and Adoption Strategy to include improved functionality of the PCEHR system and initiatives aimed at recruiting consumers and clinicians to participate.

Opt-In Model

Throughout a range of consultations on the PCEHR, a number of submissions from diverse groups expressed concerns that if the PCEHR operated within an opt-in framework, a large portion of the general public will not immediately sign up for a PCEHR. As noted above, this may result in a low level of confidence in the system and lack of critical mass to ensure its success. A number of submissions suggested that an 'opt out' model would be a much more effective way to achieve uptake of the PCEHR.

³ Greenhalgh, T. Stramer, K. Bratan, T. Byrne, E. Russell, J. Potts, H.W.W. (2010) 'Adoption and Non-Adoption of a Shared Electronic Summary Record in England: A Mixed-Method Case Study.' *British Medical Journal*. 340: 3111.

⁴ Tuffs, A. (2010) 'Germany Puts Universal Health e-Card on Hold.' British Medical Journal. 340: c171

After extensive consultation with consumers, consideration of the positions of other key stakeholder groups and review of international experience, CHF has come to the view that the PCEHR system will be more successful if it is to be opt-out, rather than opt-in.

CHF is concerned about the reliance on general practitioners, health professionals and other third parties for registration under the opt-in model. Consumers registering for a PCEHR in a consultation with their doctor, a Medicare office or in a clinical environment may not subsequently review their records and may not engage with consumer controls, such as access settings, consumer-entered data and audit trails. An opt-out model in which consumers are allocated a record and provided with points of access could enhance personal control and increase the likelihood of active consumer participation in the PCEHR.

CHF appreciates the challenges that would be presented by a change to an opt-out model at this stage. However, if the success of the PCEHR system hinges on the adoption of an opt-out model, then CHF considers that it is the approach that Australia must take.

CHF suggests the reconsideration of an 'opt-out' model in light of the overwhelming evidence from other jurisdictions and in the interests of genuine consumer control of their health information.

Conclusion

CHF welcomes the introduction of the *Personally Controlled Electronic Health Records Bill* 2011 and the opportunity to provide input to the Inquiry into the Bill.

Consumers agree that the PCEHR could be a powerful vehicle for empowering consumers to manage their own health. PCEHRs that meet the needs of consumers can build consumer confidence and trust in the health system, and empower consumers to be active partners in their health and make informed decisions about their health care. However, there remain a number of issues that require further exploration or consideration, particularly to ensure that the system is functional and meets the needs of consumers.

Key concerns for CHF include consumer control, oversight and the importance of functionality in the initial rollout of the PCEHR system. CHF's submission calls for greater accountability and independence in the long-term governance arrangements, strong consumer access controls and reconsideration of an opt-out model.

CHF looks forward to participating in further consultations on the development of the PCEHR. We would welcome the opportunity to expand on our submission in a public hearing of the Committee.



The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

- 1. advocating for appropriate and equitable healthcare
- 2. undertaking consumer-based research and developing a strong consumer knowledge base
- 3. identifying key issues in safety and quality of health services for consumers
- 4. raising the health literacy of consumers, health professionals and stakeholders
- 5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach millions of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.