Response to Request for Comment

on the Draft Health Identifier Legislation

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Authored by Fellows and Members of the

Australasian College of Health Informatics

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Executive Summary

The Australasian College of Health Informatics (ACHI) is pleased to provide comment on the "exposure draft Healthcare Identifiers Bill 2010" with its supporting documents. The College combines the region's peak health informatics expertise and experience and welcomes this opportunity to help inform the Health Identifier (HI) national e-Health endeavour from an extensive background of significant knowledge and experience in health information systems and identification implementations.

1. ACHI is concerned the draft HI Bill may be enacted yet COAG has not yet made any decision about a national Electronic Health Records implementation. The draft seems to establish the framework for an e-Health system that may never exist or be funded. It seems to ACHI the information available regarding any possible framework is also very scant and inadequate.
2. There are several major omissions from the draft Bill that are referred to in the documentation supporting the draft Bill, especially the "Building the foundations for an e-health future … update on legislative proposals for health care identifiers:
   - The legislation does not specifically cover consumer ability to access information even though we understand it to be a requirement of the Health Identifier service provider.
   - The Bill appears to lack details of governance arrangements in place to manage the misuse of provider details in the provider directory, eg stalking.
   - There is no information about the NASH process or controls in the draft Bill or in papers supporting the Bill.
   - The Bill appears to lack clarity around the operation and governance of the HI Service.
   - Future development through regulation would be improved by linkages to Standards Australia and the International Standards Organisation.

   In addition, we are concerned that a substantial pilot of the HI system for evaluation has not occurred. Future development through regulation would be improved by linkage to Standards Australia and the International Standards Organisation. We also believe the HI will be affected by the lack of systems to put in place provider details, such as those to enrol some categories of Allied Health Care workers, which may take several years.
3. The punitive measures for the disclosure of patient information risk penalising clinicians in the patient care context, over which most have no control.
4. Any permitted information disclosures should comply with ISO Standard "ISO/TS 25237 Health Informatics: Pseudonomysation" (ISO TS 25237 2008).
5. A process defining the nature of accepted secondary uses of patient data needs to be made consistent with the international standards in this area and be the subject of appropriate public consultation.
6. The draft legislation links personal information to HIS. International and Australian standards on the identification of Subjects of Care and Health Care Client Identification offer a more controlled approach to linkage and implementation that does not appear to have been considered in the Exposure Draft.
7. ACHI suggests that it may be prudent to refer to international and national standards in the draft Bill rather than facilitate personal data linkages based on an outmoded technological stance.
8. The draft legislation leaves many important matters to regulation that has yet to be planned and does not leverage or comply with existing standards.

Response to "Exposure Draft Healthcare Identifiers Bill 2010"

In summary, the College believes that the "exposure draft Healthcare Identifiers Bill 2010" is a timely national e-Health endeavour. The establishment and broad implementation of a Health Identifier requires a comprehensive and mature legislative underpinning, which can be achieved by broad consultation. With this response, the College seeks to support and contribute to this process. In particular, the College believes the identified agreed local and international standards should be leveraged and the issues surrounding implementation that we have identified should be further explored.

The Australasian College of Health Informatics comprises Fellows and Members that have led and contributed to local and international initiatives in the e-Health area for many years. The College would be happy to leverage their expertise and experience to help ensure the national eHealth legislative framework interoperates with international standards, planned and implemented architectures as well as systems that are effective and sustainable. To this effect, ACHI would be pleased to continue and extend its input into future iterations of the legislation.

Section 1: Overview

The Australasian College of Health Informatics (ACHI), the nation's peak health informatics professional body, is pleased to review "The exposure draft Healthcare Identifiers Bill 2010" with a view to enabling efficient and effective national e-Health implementations. The draft indicates the government's willingness to commit resources to implementations that modernise and improve the quality of patient care provision across the country. ACHI welcomes this opportunity to help inform these complex national eHealth endeavours.

Subsection 1a: Planning

The draft Bill enables a compulsory HI number for every Australian. We query the logic of a planning process that enacts the bill before the structure of a national shared e-Health record is finalised and funded. The eventual structure of such a record (be it a distributed, indexed system or centralised managed system) will influence the eventual use and management of the HI program.

The Bill and its supporting documents also appear ambiguous regarding the purpose of the HI: Is it infrastructure that supports all applications in healthcare (including paper-based systems) or is it focussed on enabling specific uses such as an individual electronic health record (IEHR). The College believes that more clarity regarding the purpose of the HI enabled by the proposed legislation would be beneficial to its support by the healthcare community and to its acceptance by the community in general.

Section 2: Major omissions

This section outlines the ACHI response to major questions about the draft Bill and supporting documentation.

Subsection 2a: Consumer access

The draft HI legislation contains no provision for consumers to access or correct information stored about them. This is a major premise of national e-Health initiatives. It is also a part of strategies designed to encourage patient/carer involvement in e-Health as part of the care team.

Subsection 2b: Evaluation of the HI system

At a meeting with government officials from the National E-Health Transition Authority (NEHTA) and the Department of Health and Ageing (DoHA) in November 2009, invitees were advised that the HI system has yet to be piloted in large scale or evaluated in the health care context. A major concern for many consumers centres on the reliability of the HI system with regards to identification linkages. There is no evidence publicly available indicating the planned approach will produce a HI service which is reliable and safe, will work as intended and demonstrated a high degree of assurance that abuse is not possible. ACHI appreciates the difficulty of conducting trials in subject areas that require enabling legislation. The legislators may consider utilising international best practice and draw on published evidence addressing the above concerns.

Subsection 2c: Provider details

The draft Bill and supporting documentation suggests the contact and location information of the 600,000 people who are to be healthcare providers and have provider identifiers will be available to other providers for review and use in a database (AIHW, 2009). Yet in response to a question from the floor in November, it seems many clinicians will be incrementally enrolled into the system over a

period of years. Plans to enable this are yet to be finalised and will presumably be covered by regulation. Until the enrolment occurs consumers will not be able to review a reliable version of this data, if that is what is intended by the exposure draft.

Furthermore, the draft Bill does not refer to misuse of the provider details stored in the database. The risk of unwanted attention from patients to providers is excluded from the Bill although the reverse is true of deliberate use of patient information (see Use and/or Disclosure (Part 3 and 4)). The database must comply with "ISO/TR 12773-1:2009 Business requirements for health summary records -- Part 1: Requirements" before public release.

Subsection 2d: NASH Authentication

The "Building the foundation for an e-health future … update on legislative proposals for healthcare identifiers" explains that security credentials for HI services will use the National Authentication Service for Health (NASH) (Building the foundation for an e-health future … update on legislative proposals for healthcare identifiers, 2009). However the process and controls to secure the PKI service are not discussed, explained nor costed. ACHI does not believe it is possible to achieve the implementation of the proposed NASH with associated smartcards etc within presently announced budgets.

Subsection 2e: Governance

The HI service is evidently intended to be e-Health infrastructure for a decade or more and as such needs clarity around its operations, governance, ongoing funding as well as the other issues discussed below. The draft Bill appears to authorise a system that provides nothing other than a personal health identifier in exchange for a set of demographic data or a card, with no real discussion regarding the sustainability and utility of what is proposed. Our recent response (ACHI Response on "Healthcare identifiers" 2009) outlined a governance framework for the HI service.

Subsection 2f: Development

Future development of the draft Bill as described in "Section 24 Regulations" would be improved by reference to Standards Australia. Regulations should be developed in collaboration and with input from the national and international standards experts. ACHI Fellows and Members have led international initiatives in this area for more than 6 years. Their expert advice and oversight of this process will help ensure national eHealth frameworks interoperate with international software standards.

Section 3: Health Identifier Use and/or Disclosure

This section furnishes ACHI feedback about the scope of breaches to the Use and/or Disclosure (Part 3 and 4) of a patient's Health Identifier (HI) in the draft legislation.

Subsection 3a: Intentional use and/or Disclosure of patient information

Confining the scope of serious breaches in the draft legislation to "intentional" may substantially increase the effects of what are incidental data breaches to patient health information (Building the foundation for an e-health future … update on legislative proposals for healthcare identifiers, 2009). Although we understand that the HI service itself only has limited demographic data, its use may well over time increase the risk of clinical information disclosure. These disclosures tend to be incidental to the provision of patient care rather than a deliberate infraction of an individual's privacy and are not designed to threaten or breach privacy principles. They include those that occur when clinicians share workspace and information communication and technology devices (Fernando & Dawson, 2009). New and emerging evidence suggests batch downloads of health information by

time-poor clinicians, support personnel without formal clinical or health information/informatics qualifications are likely to foster a number of incidental data breaches (Greenhalgh, Potts, etc., 2009). Research shows these occurrences contribute to clinician and consumer scepticism of eHealth and foster avoidance techniques (Fernando & Dawson, 2009)

Subsection 3b: Punitive measures

The HI legislation emphasises punitive measures for information disclosure by clinicians working in the patient care setting and not the organisations that own and furnish infrastructure in the patient care setting, nor the non clinical staff who may have access to that data through information technology support policy requirements. Thus we propose the legislation be amended accordingly.

Section 4: Permitted Information Uses

This section outlines ACHI analysis of permitted information uses beyond those necessary to deliver a health service to individuals.

Subsection 4a: Permitted information disclosures

The draft legislation enables the HI to facilitate secondary uses of health data for purposes beyond those necessary to deliver a health care service to an individual and beyond those currently possible. Any permitted disclosures should comply with the International Standards Organisation standard for Health Informatics Pseudonomysation ("ISO TS 25237 Health Informatics: Pseudonomysation" 2008). International standards need to inform Australian eHealth privacy legislation as the nation looks to interconnect silos of patient information rather than entrench these.

Subsection 4b: Standards-based secondary uses of health data

Research over the last decade or so suggests risk of information disclosure drives patient forays into the “health black market”. Random “spam” checks of most email clients show the “market” exists at present and includes erectile dysfunction services, genetic mapping services, weight loss products and neural enhancement services. This market, both actual and in “real life” is likely to grow as more and more patients believe the HIs may threaten their health privacy. ACHI is happy to meet government officials to determine a process defining the nature of accepted secondary uses of patient data consistent with the international standards in this area. This discussion is presently occurring in the United States, informing decision makers as to the most effective ways to advance eHealth implementations accordingly (Government Health IT, 2009).

Section 5:

This section offers our feedback with regard to the link between personal information and an HI as described in the draft Bill.

Subsection 5a: Standards-based secondary uses of health data

The draft legislation links personal information to HIs. International and Australian standards on the identification of subjects of care and Health Care Client Identification offer a more controlled approach to linkage that does not appear to have been considered here. While we support government emphases on action with regard to e-Health, we wonder whether a more directed, future-proof approach to the draft legislation might enhance the application of an Australian HI.

Subsection 5b: Outmoded technology

There are several systems that do not require personal data linkage to be efficacious. ACHI suggests that it may be prudent to refer to international and national standards in the draft Bill rather than facilitate personal data linkages based on an outmoded technological platform.

Subsection 5c: "Future-proofing" the HI

ACHI is concerned the draft Bill does not embed the concept of "future-proofing" the HIs despite the weight of research evidence suggesting this is a foundation of efficacious national e-Health implementations ("Open EHR vision," 2008). This is reflected in the failure of Australian health care systems to implement the structures provided in existing international and national standards.

The draft legislation leaves many important matters to regulation that has yet to be planned and does not leverage or comply with existing standards. Neither are schedules to enable the regulations evident to date. The paucity of the draft legislation allows for unknown, non-standard regulation to be planned and drafted at some stage in the future. This is of particular concern because government officials have recently suggested the Australian e-Health record may not ever occur or may simply be indexed by government, with commercial interests deciding upon the design of the future electronic health record products.

Conclusion

The ACHI Council would be glad to meet with relevant government bodies or officials to discuss the ways our suggestions might be implemented in future drafts of the legislation.

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