The Medical Software Industry Association

Submission in response

to

Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper

24th June 2015

Introduction

The Medical Software Industry Association (MSIA) has always supported the investment into eHealth and since 2011 has provided a number of submissions to the Department of Health, Department of Human Services and the Royle review panel appointed to produce the *Review of the Personally Controlled Electronic Health Record.*[1] Industry supports the transparency and improved confidence in the operation of the national health system, and welcomes the opportunity to contribute to the discussion paper. Technical and operational issues are out of scope for this discussion paper, many of which have been covered in our previous submissions.

The areas of definition, governance, participation, obligations, privacy and reviews all affect the medical software industry.

For instance, if there is a name change to the name of the national health record, which there has been several times since its inception[2] it will require code changes and changes to operating manuals and other documentation. Brand changes are not cheap for any of the participants, so industry has a recommendation in that regard which may assist all stakeholders and avoid confusion in respect of new names for the same system.

Likewise governance is critical. In fact we have said it is one of the most critical elements to success of the national system. Without trust in the governance, individuals will not use a national system as we have seen overseas and here in Australia.[3] The members of the MSIA are keen to see that governance of the system is a priority.

The right balance of controls over participant's obligations in respect of security and privacy is another area which impacts on industry. For instance many MSIA members have expended significant resources on their connection to the PCEHR, but have then found that few of their clients wish to upload or access the PCEHR due to concerns over what have been considered onerous participation agreements.

Appropriate security and privacy are critical for all participants, and penalties should match the requirements fairly, and provide a disincentive for parties to take short cuts or to the few who may seek to access information illegally. Improvements in the clarity of rules and regulations as well as usability of the system should help to increase confidence and uptake which should benefit all Australians. There is not sufficient detail in respect of the public education process intended in regards to the opt out system, but clearly it will need to be

[1] https://files.edocx.com.au/link/cxmrj5j
https://files.edocx.com.au/link/kxxxm9m
https://files.edocx.com.au/link/fvyhxqy
https://files.edocx.com.au/link/w23er69

[2] SEHR, IEHR, PCEHR and briefly NEHRS

[3] The UK initial shared care record was held not to have the trust of the public resulting in participation less than 5%.

comprehensive across all sectors of Australian public, with the right checks and balances in place in cases of people inadvertently being opted in.

The MSIA has not commented on issues which do not affect MSIA members or their businesses and would be happy to more fully explain any of its responses if required.

1. Name of the PCEHR and Definitions

The name change appears popular and the only recommendation here is that stakeholders be expressly permitted to refer to the system in a generic manner to avoid the wasted resources in re-branding their products and collateral material. For instance the National Health Record, also known as *My Health Record*.

Alignment of all the definitions between the *PCEHR Acts,* the *Health Identifier Act* and the *Privacy Act* makes sense and avoids confusion. Ensuring that the Privacy Commissioner is likewise able to exercise powers over all entities equally would be appropriate and this could be effected by a change in definitions. For instance the exclusion of activities which are not undertaken in the provision of health care makes sense for many stakeholders including medical software industry members.

2. Governance

The proposed restructure appears to address a number of the concerns stated in the discussion paper in respect of representation and confidence.

Likewise the proposal to allow the delegation of duties for the HI Service Operator appears workable. There is a proviso however in that the entity established by Commonwealth law should have strict regulation of its powers of delegation as there have been instances reported of the PCEHR System operator's responsibilities being fully delegated to third party commercial entities which are then in a position to deal with other commercial entities using discretion which may not be appropriate.

The Australian public must have confidence that in the event of technical errors, there is a solid process for remediation. This would cover instances where for instance there was an error in the HI system which resulted in incorrect information being uploaded to an individual's record. The process for dealing with such occurrences however rare must be robust and the MSIA would be pleased to be involved in the development of this important process.

Governance is essential to ensure that there are swift remedial measures in place should the software encounter an error. Unintended or unexpected errors are always a risk and in respect of the interplay between the HI service and the PCEHR, this could render the system clinically unsafe. All systems have unexpected bugs, so the Australian public needs to be assured that there are processes in place to ensure such events are dealt with quickly and appropriately. This is an area where industry expertise could assist in the development of remediation measures.

3. Participation

Opt out is a complex concept for many and trialling different systems in different areas may help ensure that there is a better understanding by Australians of what the impact will be on their personal health information. From an industry viewpoint, it is critical because in the event of people having information uploaded through our member's clinical systems when the individuals were not cognisant of what was happening could present as possible breaches by both MSIA members and their clients.

Improvements in the clarity of rules and regulations as well as usability of these help to increase confidence and uptake should benefit all Australians. Having different participation systems will require a very strong public awareness campaign to avoid the confusion of individuals which will need to be dealt with providers and members of our industry.

It does appear anachronistic for the System Operator to revert to writing and posting a letter to parties who have opted out of having an electronic health record, and it is hoped that the Department may consider some consultation on a more modern approach.

Secondary use of information can be invaluable for national health planning, and provided that any proposed de-identification tool is fail-safe and subject of the proposed consultation. It is essential that that consultation will require technical input from the MSIA and individual medical software providers.

4. Obligations

To make the system more user friendly, the obligations upon participants should be equitable and uniform, so that for instance all participants are treated equally under Part 5 of the *PCEHR Act 2012.* Harmonisation of all legislation relating to the PCEHR, HI Service and privacy and security is desirable so that for example, the new Australian Privacy Principles which came into force on 14 March 2014, apply rather than the stand-alone provisions in Part 5 of the PCEHR Rules. This would help to remove confusion.

Breach notification is considered good remediation by the Privacy Commissioner, but is not mandatory across all participants in the system. In the event that it becomes mandatory for health care providers, there should be consultation with the MSIA in respect of reporting systems to ease what could be an onerous, if justifiable burden on providers.

There will be system changes required to facilitate the various approaches to doctors uploads to the PCEHR. For instance, there will need to be an efficient way for doctors to notify Medicare that the individual does not wish to have information uploaded, but that payment is still due. Industry welcomes consultation in this regard.

Testing environments are valuable and the MSIA looks forward to providing input to the specifications prior to development.

5. Privacy

Threats to privacy would appear to be a sensible expansion of the System Operator's powers of suspension. The impact could be high so it would be vital that this power was not delegated to a third party commercial entity which could have a conflict of interest.

The proposed principles-based approach for the access, collection and use of data would presumably tie in with the Australian Privacy principles to avoid participants having to work under various privacy principles which could lead to confusion and reluctance to participate.

In the event that third party information is to be permitted to be uploaded, it is presumed that the Privacy Commissioner has provided guidance on this as it could lead to individual harm. The owners and customers of clinical systems used to upload such information need to have a strong assurance in this regard.

The expansion of uses for the healthcare identifier has risks, or could be seen as the thin edge of the wedge.[4] It is however a community-wide issue rather than one for the MSIA to comment on further.

The greater the scrutiny over the privacy and security of the HI Service the better for all Australians. The proposed amendment to positively assert the powers of the Office of the Information Commissioner to operate in this area is welcome.

6. Penalties

Consistency with the Privacy Act would avoid complexity and confusion in respect of penalties. It is difficult to justify lower penalties for breaches of health information under legislation aimed at encouraging participation.

7. Review

[4] This has been called an Australia Card by stealth

The proposed review after 2 years makes sense and should be after independent consultation with all the representative types listed as possible members of ACEH.

8. AHPRA

The proposal to include AHPRA in the Information Commissioner's jurisdiction is appropriate particularly given the proposals to make the exchange of information two-way between the HI Service Operator and AHPRA.

On behalf of the MSIA

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