



Australian Government
Department of Health

DEPUTY SECRETARY

Ms Tanja Cvijanovic
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Dear Ms Cvijanovic

Regulation Impact Statement – Final Assessment Second Pass – Proposed Changes for the My Health Record System (ID 21564)

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared for the proposed changes to the My Health Record system (ID 21564).

The regulatory burden to business, community organisations and/or individuals has been identified with burden and offsets quantified using the Regulatory Burden Measurement framework. These have been agreed with your office.

The preferred option for the RIS is to adopt Opt Out arrangements nationally. The business case determined that this option had the best cost-benefit and the measure has a deregulatory impact.

I am satisfied that the second pass final assessment of the RIS addresses the concerns raised in your letter of 11 January 2017. Specifically, responses individually addressing the 10 comments provided in OBPR's first pass review letter are outlined below:

General

- 1. The RIS makes a number of references to the Review of the Personally Controlled Electronic Health Record (PCEHR) and a second-pass business case on My Health Record. Inclusion of more detail of and context for these reports would help with the analysis, given they form a significant part of the evidence to support the final decision. The RIS could also outline results from the trials to strengthen the analysis, particularly those which inform the RJS, such as data that supports the assumption that two per cent of patients will opt out.*

Response: Additional information has been included in the RIS background section which more clearly and concisely articulates the context of the 2013 PCEHR Review. The objective of the Review was to look into concerns about the progress and implementation of electronic health in Australia. One of the main recommendations of the Review was that opt out participation by individuals be implemented nationally.

In response to the Review Recommendations, Opt out participation trials were undertaken in the Northern Queensland Primary Health Network (PHN) and the Nepean Blue Mountains PHN of New South Wales during 2016. The opt out trials were evaluated against the current opt in system operating in the rest of Australia and two trials of innovative approaches to increase participation and use of the My Health Record system utilising opt in arrangements. The independent evaluator found that opt out participation leads to increased use.

2. *The RIS could better articulate what level of take-up is considered to be 'success' of the scheme. This could be drawn from existing information used to inform the original policy, or the subsequent business case and review. This might help demonstrate why the preferred option is the only feasible option (also see paragraph 7 below).*

Response: The critical success factor for the My Health Record system is to reach a level of use that delivers the significant benefits that can be realised through the improved availability of health information to healthcare providers and the health system. Based on experience in the Northern Territory this is expected to be met once participation passes 50% of the population.

3. *There is no mention of risk in the RIS; particularly with regard to what happens in the event of underuse by providers. For example, if even under an opt-out scenario healthcare providers do not consistently use the system, what would be the outcome? While in-depth analysis of the risks is not required, it would benefit from identifying and describing these, in addition to measures in place to mitigate them.*

Response: Additional text has been inserted under the heading of 'implementation' to highlight the specific risks associated with the preferred option, as well as the proposed risk mitigation strategies. Addressing the risk of healthcare providers failing to adopt the system is a central component of the proposal. The adoption of Opt Out arrangements will be supported by significant communications and healthcare provider readiness activities, including education and training materials to build awareness of the benefits of the My Health Record to all Australians and healthcare providers.

The risks of implementing Opt Out arrangements nationally have been detailed in a comprehensive Business Case and Implementation Plan. A number of internal and external reviews and quality assurance activities are included in the implementation of the Opt Out arrangements nationally to manage risks and maximise the likelihood that strategic objectives will be achieved and target benefits realised.

Problem

4. *The problem identification would benefit from a greater discussion, and where possible, quantification of the costs to providers of using the My Health Record system. This may include one-off JCT costs, maintenance costs, or cost of entering or uploading information for patients.*

Response: Additional text has been inserted beneath the problem definition section to address this concern. The 2013 PCEHR review identified that the key barrier to healthcare provider adoption of the My Health Record system was the low level of participation by individuals. In the absence of a high level of consumer participation the initial effort and cost of getting connected and being trained acts as a deterrent to getting started. Barriers to participation include the cost of installing software and the registration and identity management processes which are administratively burdensome for both individuals and healthcare providers.

Options

5. *Generally a RIS should include an assessment of at least three options. Specifically, given the emphasis the RIS has placed on lack of awareness in the problem identification, the RIS could include an assessment of an option for an education and marketing campaign.*

Response: Additional text has been included under the 'policy option' section of the RIS to better explain the rationale and circumstances for choosing fewer than three options. Analysis of the My Health Record trials evaluation report and a detailed cost/benefit analysis prepared as part of the second pass business case determined that there is only one feasible policy option available to address the problem identified in the RIS - which is to move to Opt Out arrangements nationally. The business case/cost benefit analysis showed that Accelerated Opt In- which was largely an education and marketing campaign - delivered significantly reduced benefits with little cost reduction. The current state approach of Continued and Improved Operations is also presented.

Impact analysis

6. *The RIS would benefit from greater consistency in assumptions and analysis across the options. This includes, but is not limited to, treatment of both barriers to and drivers of uptake of the system. For example, the RIS indicates that lack of awareness might explain low take-up, so it appears inconsistent that an option specifically addressing lack of awareness is not considered, or an education campaign might also be part of the preferred option.*

Response: Further information has been added under impact analysis for each option to address this concern, including clarifications regarding the costs and benefits across the options, as well as the assumptions and justifications underlying them. Communication activities are included in the preferred option to address lack of awareness.

7. *The RIS could advise what the incentive is for doctors to participate once most of their patients have a My Health Record (i.e., after the opt out reform is implemented)? This is important, as significant benefits will not be achieved without a large proportion of doctors participating.*

Response: Additional information has been included under the preferred option to qualify the benefits of this option, in particular for healthcare provider entities. Healthcare providers will have additional information available to them to support clinical decision making and will save time in searching for information held by others. Effective use of the My Health Record system will enhance the quality, safety and efficiency of health services by enabling healthcare providers to make better informed decisions about an individual's health based on more complete information available in their My Health Record.

8. *It is not clear why the “improvements in the registration arrangements for the healthcare provider organisations and the maintenance of identity credentials” is part of the preferred option. Should this be part of the status quo? If these changes form part of the status quo option, it would be best practice to not have it comprise part of the preferred option. Otherwise, the RIS should explain why this would only be undertaken under the proposed reform.*

Response: A new paragraph has been placed under the 'preferred option' heading to provide greater clarity regarding the maintenance of identity credentials by providers. In addition to significantly increasing the number of people with a My Health Record, the preferred option also includes major improvements in the registration arrangements for healthcare provider organisations and the maintenance of identity credentials. The

proposed improvements are an interim measure pending development of a wider solution addressing identity authentication across the health sector which is likely to be some time away. Due to the increased level of participation by healthcare organisations it is considered necessary to introduce the interim measures as part of the Opt Out arrangements.

9. *The RIS provides an estimate in the net health benefits of the preferred option as \$1,054.3 million over four years, driven largely by increased participation in the scheme. The analysis would benefit from a more detailed description of these benefits, including quantification and evidence underpinning assumptions.*

Response: A summary titled 'Health Benefits' has been added in the RIS to qualify the benefits of the preferred option, along with new figures to quantify the health benefits. Implementing Opt Out arrangements for the My Health Record system will increase uptake and meaningful use by healthcare providers and bring forward the realisation of benefits of the system for individuals, healthcare providers and the health system overall.

This option will rapidly increase uptake and use of the My Health Record system by healthcare providers thereby delivering net benefits within and beyond the forward estimates period. The health and economic benefits of the My Health Record system are significant, but conditional upon mass-participation including individuals and healthcare providers.

In addition, increasing the uptake and meaningful use of the My Health Record system would lead to:

- Improved health outcomes, avoided hospital admissions and saved lives through fewer adverse drug events (more Australians die each year because of medication errors than from road accidents), better coordination of care for people seeing multiple healthcare providers, and better informed treatment decisions (\$2.10 billion estimated over ten years);
- A much more efficient health system. For example, healthcare providers will spend less time searching for information about their patients (\$2.81 billion estimated over ten years);
- Avoided duplication of diagnostic tests - pathology and diagnostic imaging (\$2.08 billion estimated over ten years);
- Putting the person at the centre of their healthcare, so they play a greater role and take greater responsibility for their own health (\$1.41 billion estimated over ten years);
- Enabling innovation and developments in healthcare through secondary uses of health information, enabling unprecedented levels of insight into population health outcomes, which better-inform policy decisions, make resourcing more sustainable, and inspire new clinical developments (\$6.19 billion estimated over ten years).

Consultation

10. *The RIS needs to explain in more detail the concerns that were raised in consultation and how they are addressed in the preferred option. It would also benefit from a more detailed description of the privacy concerns that were raised.*

Response: New text has been included under the heading of 'consultation' to highlight specific privacy concerns in the preferred option, and the proposed protections to address this matter. Individual support for opt out was conditional on the system offering a high level of privacy and security protection, an easy to use and accessible opt out process, and steps to ensure individuals would be well informed about how their information would be used and how they could control access to it. While there was relatively

minimal opposition to opt out, privacy and security were the main reasons for the opposition.

The concerns regarding privacy are being addressed, some have already been addressed through legislative changes made in 2016 to strengthen privacy protections. The remainder of the concerns will be addressed in the preferred option through the communications activities which will increase awareness and understanding of individuals' privacy rights, the protections afforded by the system, and their right to choose whether to have or how to use a My Health Record; and the design of the implementation of opt out arrangements which will ensure that individuals are given a reasonable period in which to make a considered decision on whether to participate.

The preferred option will also address the engagement of communities from culturally and linguistically diverse backgrounds, those with a disability impacting their ability to understand complex information, and other vulnerable groups, to ensure they are also given a reasonable opportunity to consider whether to participate and to have a suitable channel by which they can exercise their right to opt out.

Accordingly, I am satisfied that the RIS now meets best practice consistent with the *Australian Government Guide to Regulation*.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely



Bettina Konti
Acting Deputy Secretary
Strategic Health Systems and Information Management Group

24 February 2017