Australian Government
Department of Health

DEPUTY SECRETARY

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Regulation Impact Statement – Final Assessment

I am writing to submit the standard form Regulation Impact Statement (RIS) for proposed changes to the personally controlled electronic health record (PCEHR) system. The regulatory burden to business, community organisations and/or individuals has been quantified using the Regulatory Burden Measurement framework, and has been agreed with your office.

On 28 October 2014 your office found the RIS on this matter compliant with the Government's RIS requirements (OBPR reference 16442). Since then, there have been some changes to the proposal which have required the RIS to be revised.

I believe the revised RIS meets best practice requirements and is consistent with the ten principles for Australian Government policy makers. In particular, I note that the RIS addresses the seven RIS questions:

1. What is the problem?
Too few individuals have a PCEHR so healthcare providers are making limited use of the PCEHR system. The majority of healthcare providers are not using the system and their participation is critical to its clinical value and benefits. Concerns with its design, usability and governance arrangements have also been identified by an independent review as being important contributors to the problem.

2. Why is government action needed?
The PCEHR system was implemented as a first step to overcome some of the issues facing healthcare, primarily the fragmentation of health information, and to help counter expected increases to the cost of delivering healthcare. There is steady criticism of the usability of clinical utility of the system and the value in participating in the system. Some significant design and policy changes need to be made in order to encourage participation by healthcare providers and accrue the expected benefits in a reasonable timeframe.

3. What policy options are you considering?
Four options are being considered – two are regulatory – and the analysis of the likely impacts of each options is adequate.

(i) Continuing with business as usual;
(ii) Enhancing business as usual with a public awareness campaign to increase the number of people registered (non-regulatory); and

(iii) Making the system opt-out for individuals with associated public awareness raising and education and training for healthcare providers, improving usability and changing the governance arrangements through creation of a statutory authority (regulatory); and

(iv) Implementing opt-out trials with targeted communications in the trial regions and education and training for healthcare providers, improving usability and changing the governance arrangements through creation of a statutory authority (regulatory).

4. What is the likely net benefit of each option?

(i) No change;

(ii) No significant improvement in use of the system and an additional cost to government for the campaign;

(iii) Under an opt-out model, almost all Australians will have a PCEHR that can be accessed by their healthcare providers. Healthcare provider organisations would be more likely to participate in the PCEHR system and contribute information to the system, thereby increasing the system's clinical value. This option would see a significant reduction in the regulatory burden on individuals and healthcare provider organisations, achieving an overall saving of $12.12 million over ten years. The creation of a statutory authority to govern all of eHealth would provide a level of accountability and transparency that would lead to public confidence. However, without conducting trials of implementation approaches and communication and education programs, these savings could be reduced and public confidence could be adversely affected;

(iv) In terms of the system's clinical value, this option would see similar benefits identified as option (iii) on a smaller scale since the opt-out model would operate in trial regions only, applying to a population of around 1 million individuals. The benefits in respect of the governance arrangements would be the same as option (iii). This option would see a short-term increase to regulatory burden on individuals and healthcare provider organisations at a cost of $412,245 in the trial period which would be up to nine months. However, this option would enable the Government to develop and implement a robust national opt-out system which includes effective communications and education.

5. Who will you consult and how will you consult them?

The Department undertook a national consultation process from July to September 2014 involving healthcare providers, individuals, jurisdictions and the IT industry. The consultations were undertaken by senior officers of this Department in person, at locations around Australia.

The consultations were aimed at obtaining stakeholder views on the implementation of the Government-commissioned PCEHR review recommendations, some of which are the subject of this RIS, including issues or risks for implementation and how these may be overcome. The outcomes of the consultations are influencing the system design, implementation schedule, and the planning for communication, education and risk management. Outcomes of the consultation have informed the analysis in this RIS.

6. What is the best option from those you have considered?

The option to best achieve the Government's objectives is to implement opt-out trials in selected areas in Australia, accompanied by targeted communications in the trial regions, and education and training for healthcare providers across Australia. These trials would be undertaken for up to nine months. This option would also change the governance arrangements through the creation of a statutory authority and would make changes to the usability of the system. While this option would see a total short-term cost to individuals and healthcare provider organisations of $412,245, it would, among other things, inform future decisions about the adoption of a national opt-out system and provide a greater capacity to improve accountability.

7. How will you implement and evaluate your chosen option?

The changes to governance and the way individuals can choose to participate in the PCEHR system would be implemented in stages, alongside a public awareness campaign and provision of

education, training and support. The opt-out trials will occur in 2016. A post-implementation review will be undertaken after the recommended changes have been in operation for a reasonable period of time.

I note that the RIS includes a description of the status of the RIS at each major decision point in the proposal's development. A short form RIS for changes to the PCEHR system was previously considered by the Government. This standard form RIS provides more detail for the Government's consideration of the proposed changes which will be implemented through changes to legislation and infrastructure.

I submit the RIS to the Office of Best Practice Regulation for formal assessment. I acknowledge that the OBPR will publish this letter together with the RIS.

Yours sincerely

Paul Madden
Deputy Secretary
30 March 2015