REGULATION IMPACT STATEMENT

Changes to the PCEHR system

1. INTRODUCTION

On 3 November 2013 the Australian Government commissioned an external review of the personally controlled electronic health record (PCEHR) system (the Review). The Review identified a number of issues regarding the system that present an impediment to individual and clinical uptake. In particular, the Review made recommendations concerning the model for individual participation, the governance arrangements and usability.

Implementation of the Review's recommendations will improve the credibility, usability and utility of the record for healthcare providers. These improvements will drive uptake, with healthcare providers more likely to support a system where the direct benefits are clear and the system is designed to sit within clinicians' existing workflows. Implementation will also expedite health benefits for individuals by enabling people to better manage their health. The number of avoidable admissions and adverse drug events will also be reduced.

The *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act) and possibly the *Healthcare Identifiers Act 2010* will need to be amended to support the changes.

A short form Regulation Impact Statement (RIS) for changes to the PCEHR system has been previously considered by the Government. This standard form RIS has been provided for the Government's consideration of the proposed changes in more detail which will be implemented through changes to legislation and infrastructure.

Background

On 1 July 2012 the Australian Government implemented the PCEHR system, supported by the PCEHR Act. It places the individual at the centre of their own healthcare by enabling access to important health information when and where it is needed, by individuals and their healthcare providers. A PCEHR is assembled using information created by a range of healthcare providers across the health sector to reflect an individual's healthcare journey.

Since its implementation more than 2.1 million individuals and more than 7,600 healthcare provider organisations have registered to participate in the PCEHR system. The system includes capacity to accept, store and share access to documents from and with any participating organisation and has more than 1.7 million clinical records, 70,000 individual-entered documents and over 192 million Medicare and Pharmaceutical Benefits Scheme claim records uploaded to the system. The privacy protections that apply to the system ensure individuals have strong protection of their records, and the security arrangements are subject to an ongoing work program to improve security, reduce risks and address threats in a rapidly changing cyber environment. There is an array of personal controls available to the individual to allow them to control access to their record to the extent that they prefer.

Participation in the PCEHR system is voluntary for individuals and organisations (healthcare provider organisations, contracted service providers, repository operators and portal operators). The system operates on an opt-in basis, which means that any person or organisation wishing to participate in the system needs to register.

2. RATIONALE FOR GOVERNMENT INTERVENTION

The annual Commonwealth costs of healthcare are forecast to increase by $27 billion to $86 billion by 2025 and over $250 billion by 2050.[1] Productivity improvements such as those that can be delivered by eHealth are needed to help counter the expected increases in the unit costs associated with the delivery of healthcare. Leveraging eHealth is one of the few strategies available to drive microeconomic reform to reduce Commonwealth health outlays.

The Australian Government implemented the PCEHR system as a first step towards overcoming some of the issues facing healthcare arising from the fragmentation of health information. Health information is spread across a vast number of different locations and systems. In many healthcare situations quick access to key health information about an individual is not always possible. Limited access to health information at the point of care can result in:

- a greater risk to patient safety (e.g. as a result of an adverse drug event (ADE) due to a complete medications history not being available – it is estimated that 2.5% of hospital admissions are due to ADEs[2]);
- increased costs of care and time wasted in collecting or finding information (e.g. when a general practitioner has to call the local hospital to get information because the discharge summary is not available – 36% of visits involve the clinician spending at least five minutes locating information[3]);
- unnecessary or duplicated investigations (e.g. when a person attends a new provider and their previous test results are not available – 10% of laboratory tests are avoidable through electronic health records[4]);
- additional pressure on the health workforce (e.g. needing to make diagnosis and treatment decisions with incomplete information); and
- reduced participation by individuals in their own healthcare management.

The PCEHR system has, however, not realised the full benefits of such a system in its first two years. While the PCEHR system has the potential to deliver real benefits, some significant design and policy changes need to be made in order to accrue these benefits in a reasonable timeframe.

Government has historically sponsored the development of infrastructure services like this to reduce the burden on business, and remove the possibility of creating further *rail gauge* issues. Ongoing refinements made by government to streamline these services will bring about even greater efficiencies, which can be leveraged and further innovations made possible for the benefit of all Australians.

3. THE PROBLEM

Participation

More than 2.1 million individuals have registered for a PCEHR. Since the vast majority of individuals don't have a PCEHR, healthcare providers generally lack any incentive to adopt and contribute to the system. As a result only 1.7 million clinical documents with key information have been uploaded to the system by clinicians and dispensers.

Governance

The PCEHR Review identified several issues related to governance of eHealth broadly and the PCEHR system in particular, namely:

[1] Australian Government's 2010 Intergenerational Report
[2] Aus NZ Health Policy 2009, Roughead et al.
[3] JAMA 2005, Smith et al.
[4] Health Affairs 2012, McCormick et al.

- governance processes around the PCEHR system did not adequately represent the industry, were overly bureaucratic in nature and did not effectively balance the needs of government and private sector organisations;
- engagement and consultation with some key stakeholders, including clinical stakeholders, has not been effective to date;
- there are currently two significant governance arrangements in place for eHealth and there are perceived benefits in reducing this to one; and
- there has been a lack of transparency in the decision-making process for the PCEHR system within the National E-Health Transition Authority (NEHTA) structure, whose role is to lead the uptake of eHealth systems of national significance.

The review of the PCEHR system found that governance for eHealth nationally is in need of significant change as it does not have the confidence of the industry. Multiple factors have contributed to this, including a significant broadening of the remit of NEHTA since its inception.

Further, eHealth governance is not representative of the users of eHealth. Although the PCEHR system directly affects healthcare providers (private and public), the medical software industry and individuals, the current governance predominantly comprises public organisations. A prime example of this problem is the NEHTA board which is made up of the heads of the Commonwealth, state and territory health departments.

Usability

The Review found that the system poses usability issues, such as:

- problems with the efficiency and effectiveness of eHealth applications in clinical systems and their poor fit within clinical practice workflow;
- complexity in user interfaces, and multiple provider registration systems;
- lack of integration across the broader eHealth infrastructure;
- inability to agree and adopt standards in a timely manner;
- technical compromises made to meet accelerated timeframes; and
- the absence of standard terminology.

These issues have affected use of the system by healthcare provider organisations.

4. OBJECTIVE OF GOVERNMENT INTERVENTION

The objective of the system continues to be to address information fragmentation by allowing a person to more easily access their own health information and make their health information securely accessible to healthcare providers involved in their care.

Making the system more useable and reliable is central to gaining the support and acceptance of healthcare providers and individuals, thereby leading to increased use and achievement of the identified benefits.

Changes to governance and the way individuals can choose to participate in the PCEHR system will be implemented in stages through to late 2017. Trials of participation arrangements, including an opt-out system, will be undertaken in a few selected regions in 2016 and inform a decision, and future approaches, for increasing individual participation in the system from late 2017.

The PCEHR Act will need to be amended to reflect such changes since it prescribes the components of the current governance arrangements and opt-in nature of individual participation.

5. OPTIONS

This section outlines the options for addressing the problems identified at section 3. Four options are considered:

- Option 1: Continuing with business as usual;
- Option 2: Implementing a public awareness campaign to improve uptake;
- Option 3A: 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 the creation of a statutory authority.
- Option 3B: Implementing participation trials, including opt-out, with targeted communications in the trial regions and education and training for healthcare providers, improving usability and changing the governance arrangements through the creation of a statutory authority.

5.1 Option 1: Continuing with business as usual

The status quo would not require any additional regulatory action or legislative change, but does not present a compelling business case. It could take a further 15 years to realise the benefits sought as it will take that long before a significant proportion of the population has a record, which is a key to increased use by healthcare providers. It is unlikely that healthcare providers will make use of the system until a significant proportion of the population has a PCEHR. This will result in limited content being contributed or accessed and minimal benefit being realised.

Individuals would continue to be able to register for a record if they choose. Many healthcare providers would continue to view the record as not clinically useful due to its limited content and customer coverage.

The Secretary of the Department of Health would continue to be the System Operator, delivering the system in cooperation with the following agencies:

- Department of Human Services which delivers certain components of the PCEHR system under agreement with the System Operator, and delivers other eHealth services such as the National Authentication Service for Health, the Healthcare Identifiers Service and the Health Professional Online Service that form part of the PCEHR infrastructure; and
  NEHTA, a company limited by guarantee and funded by the Australian Government and state and territory governments and whose board comprises heads of government health departments, delivers certain components of the PCEHR system under contract with the System Operator. It leads the uptake of eHealth solutions through the health system.

The System Operator would continue to be advised on the operation of the PCEHR system by two statutory committees – the Independent Advisory Council (representing individuals from peak stakeholder groups) and the Jurisdictional Advisory Committee (representing the health department of each jurisdiction). These committees report directly to the System Operator.

As part of business as usual activities and streamlining, improvements would be made to the system's access controls and the process for individuals to register and access their PCEHR. The Clinical Usability Program would work with healthcare providers and software vendors to continue to identify system usability improvements.

Stakeholders would continue to have concerns about the system's usability, transparency and accountability which may undermine their confidence and likelihood to participate.

5.2 Option 2: Implementing a public awareness campaign to improve uptake

This option would not require any regulatory action or legislative change.

The option would see the PCEHR system complemented by a public awareness campaign targeting all Australians. The intent of this campaign would be to raise community awareness of the PCEHR – its purpose, the information it can contain, how it can be used, who can use it and how it can improve healthcare.

Individuals would continue to be able to register for a record if they choose. During the *Medicare For All* campaign of 2013, which included promotion of the PCEHR, there was an increase of approximately 500 people a day registering using the consumer portal. This dropped back to the pre-existing levels once the campaign finished. Allowing for a campaign similar to the *Medicare For All* campaign but of 12 months' duration and assuming its direct focus on the PCEHR would result in greater effectiveness, it is estimated that an additional 273,000 people would register[5].

As described at option 1, as part of business as usual activities and streamlining, improvements would be made to the system's access controls and the process for individuals to register and access their PCEHR. The Clinical Usability Program would work with healthcare providers and software vendors to continue to identify system usability improvements.

It is considered, however, that many healthcare providers would continue to view the record as not clinically useful due to its limited content and customer coverage.

Stakeholders would continue to have concerns about the system's usability, transparency and accountability which may undermine their confidence and likelihood to participate.

5.3 Option 3A: 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

The opt-in approach of the system would be changed to an opt-out approach for individuals. Providing every Australian with a PCEHR without needing to take steps to register would be a fundamental step to delivering a world class PCEHR to the community. A record would be created for every eligible individual. That individual may or may not choose to access their record but healthcare providers would be able to access that record for healthcare purposes.

Individuals who wanted to access their PCEHR would need to first register for a myGov user identity and undertake a process to verify their identity. Once they gain access they would be able to fully exercise the access controls of the record. Experience over the past two years has shown that only about ten per cent of individuals who have a PCEHR access it and exercise their access controls. This rate has been used in the consideration of this proposal.

Individuals would have the option of opting out of the system before a record is created for them or by cancelling their record so that it can no longer be accessed or used by healthcare providers if they already have one. The individual would be able to opt back into the system at any time.

[5] This assumes that, over 12 months, there would be a 150% increase to the registrations achieved by the two month *Medicare For All* campaign.

National and international experience in opt-in/opt-out rates for eHealth record systems and other health programs indicates that around one per cent of individuals choose to opt-out[6]. This rate has been used in the consideration of this proposal. Implementation of opt-out nationally would be supported by an appropriate awareness raising campaign including about the benefits of the eHealth record system, how to set access controls, and details of how to opt-out if that is what someone chooses to do.

This shift in participation rates would give effect to behavioural changes in the healthcare provider industry, although participation by healthcare provider organisations will remain voluntary. Nearly all individuals would have a record so, combined with other measures to improve the usability of the system and the nature of information it contains, healthcare providers would be more likely to commit to using and contributing to the PCEHR system, thereby increasing the utility of the system by increasing the amount of clinically valuable information in a PCEHR.

This option would also see a major shift in expectations of the governance arrangements to address concerns raised by stakeholders regarding transparency, stakeholder representation and accountability.

The following changes would result in a simplified structure with which the industry and individuals could more easily interact, and would ensure more meaningful consultation is undertaken in the operation and management of the system and the future directions of eHealth more broadly.

A statutory authority would be established to have relative independence from government departments ensuring it is balanced and represents the needs of key stakeholders to facilitate eHealth delivery by the private health sector in partnership with the public health sector.

A governing board would comprise skills-based representatives reflective of key health stakeholders. Some members would have experience as healthcare providers, care recipients and leadership in governance. Others would have clinical safety, systems, technical and government expertise. The new entity would retain jurisdictional input and representation to reflect jurisdictions' interests as continuing national eHealth funders.

The new organisation's broad role would be the ongoing development and implementation of the national eHealth strategy, including PCEHR-related responsibilities arising from the Review. This would include coordinating and managing activities relating to national eHealth infrastructure, solution design, specification and, where necessary, standards development and working with other key agencies to ensure this work is carried out in a coordinated fashion and expected outcomes are delivered to the satisfaction of key stakeholders. It would also work to improve the usability of the system.

The new organisation would report directly to the Council of Australian Governments' Health Council.

The current statutory committees that report to the System Operator would be abolished and dedicated advisory committees would be established within the legislative framework establishing the new entity to ensure that the PCEHR system delivers on the following matters:

- clinical and technical;

[6] Research by McKinsey & Company, 2014. This research was undertaken on publicly available information and input from selected expert interviews on prominent examples of electronic health record systems around the world at different stages of evolution. The systems that operate on an opt-out basis use opt-out mechanisms that are comparable to those that would likely be used in the PCEHR system.

- jurisdictional;
- individual; and
- privacy and security.

These committees would have appropriate representational coverage and skills to represent the interests of key stakeholders and report directly to the board.

Assurance on the progress of eHealth would be provided to the Minister for Health through the establishment of an independent assurer who would report regularly and directly to the Minister. The purpose of this role would be to provide unfiltered advice to the Minister on the real progress on the implementation of the changes to the eHealth record system and stakeholder acceptance. The role would be fulfilled by an independent organisation with experience in the health sector and in providing assurance in the delivery of complex initiatives.

This option, together with other measures including:
- improvements to usability, including those described at option 1;
- the establishment of a core set of clinical information comprising current medications and adverse events, clinical measurements, and pathology and diagnostic imaging reports;
- improving education and training programs for healthcare providers; and
- re-focused incentives for healthcare provider organisations to participate in and use the system,

would significantly improve the clinical usability, credibility and utility of the record for healthcare providers and encourage buy-in of the system.

In this option the Government would not trial the methods of implementing opt-out and different methods of providing communications and education prior to national implementation. This would pose a risk of failing to properly communicate with the target audience, resulting in an increased number of individuals choosing to opt-out of having a PCEHR, and less organisations choosing to participate, potentially undermining confidence in the value of the system.

5.4 Option 3B: Implementing participation trials, including opt-out, with targeted communications in the trial regions and education and training of healthcare providers, improving usability and changing the governance arrangements through creation of a statutory authority

This option would require regulatory action and legislative change.

In selected areas of Australia (covering a total population of 1 million), based either on population size or type, trials of individual participation arrangements would be conducted, including an opt-out system, and targeted communications would be undertaken together with training for healthcare providers in these areas. The intent of these trials would be to test the opt-out arrangements and other innovative approaches for driving registration and participation in the system, identify appropriate methods of targeting and delivering critical information to key audiences, assess the effectiveness of the communications and education and training for healthcare providers, and inform future decisions about, and the optimal approaches for, driving individual participation in the system for individuals from late 2017. These trials would be evaluated over a period of up to nine months.

Outside the trial regions the PCEHR system would continue with business as usual and individuals would continue to be able to register for a record if they choose. General practitioners, pharmacists and aged care services would be provided with targeted education and training in the trial regions, and more broadly.

In trialling an opt-out system, a record would be created for every eligible individual in the trial except for individuals who choose to opt-out. Individuals may or may not choose to access their record but healthcare providers would be able to access that record for healthcare purposes. As described at option 3A, individuals would access their record by first registering for a myGov user identity and will need to go through an identity verification process to access their PCEHR and exercise their access controls. Experience indicates that about 10 per cent of individuals choose to access their PCEHR.

Individuals in the opt-out trials would have the option of opting out of the system before a record is created for them. In the case of individuals who already have one, they would continue to be able to cancel them. Individuals that opt-out would be able to opt back into the system at any time.

As outlined in option 3A, national and international experience in opt-in/opt-out rates for eHealth record systems and other health programs indicates that around one per cent of individuals choose to opt-out[7].

Trials of other innovative approaches for driving individual registration and participation in the system will also be conducted. The nature of these other trials has not yet been determined.

This shift in participation rates would give effect to behavioural changes in healthcare provider organisations in or providing care in the selected trial regions, although participation by healthcare provider organisations will remain voluntary. Nearly all individuals in the opt-out trials would have a record and individuals in the other trials would be more likely to have a PCEHR so, combined with other measures to improve the usability of the system and the nature of information it contains (as described at option 1), as well as targeted communications in the trial regions, education and training of healthcare providers, along with re-focused incentives, these healthcare providers would be more likely to commit to using and contributing to the PCEHR system.

This option would result in improvements to the clinical value of the system and would see a positive impact on healthcare providers across Australia in terms of system use.

This option would also see the same governance changes made as discussed at option 3A and would include the other measures described at option 3A including usability improvements, business as usual activities and streamlining.

Stakeholders that are not part of the trials may continue to have concerns about the value of participating in the system given that the majority of their patients will not have a record. This is despite the improvements to governance, clinical utility and usability of the system, and the availability of incentives and training.

6. IMPACT ANALYSIS

This section describes the impacts of the proposed options. An overview of the costs and benefits, stakeholders impacted and issues associated with each option is provided below.

6.1 Option 1: Continuing with business as usual

Maintaining the status requires no regulatory action by Government.

[7] Research by McKinsey & Company, 2014. This research was undertaken on publicly available information and input from selected expert interviews on prominent examples of electronic health record systems around the world at different stages of evolution. The systems that operate on an opt-out basis use opt-out mechanisms that are comparable to those that would likely be used in the PCEHR system.

The risk of adverse outcomes from poor use of the system is likely to persist under the status quo. Limited use of the system by healthcare providers will affect the amount of clinical information uploaded to a PCEHR. In the longer term the lack of information in the system would become a disincentive to participate in the system.

Impact on individuals

The regulatory burden on individuals who choose to register for an eHealth record would be unchanged. Any individual registering can apply through five channels – phone, online, in writing, in person at a Department of Human Services shopfront and at healthcare provider practices that provide assisted registration.

The impact of improvements to individual usability is not yet determined so they cannot be quantified.

Individuals who choose to have a PCEHR will continue to be able to share their health information with their healthcare provider organisations. However, few healthcare providers use the system as the value proposition is low, so PCEHRs will continue to contain a limited amount of clinically useful information.

Impact on healthcare provider organisations

If an organisation chooses to register to use the system, it needs to complete the registration process to use the system. Depending on the type of healthcare provider organisation, its needs in terms of start-up will vary.

A registered organisation is subject to the requirements of PCEHR Act and the participation agreement with the System Operator. The regulatory burden on individual providers who work in organisations participating in the PCEHR system would be unchanged as system participation is undertaken at the organisational level, not individually.

The regulatory burden on healthcare provider organisations that choose to register to participate in the PCEHR system would be unchanged.

If an organisation is registered, individual providers would continue to be subject to the requirements relating to uploading information to the PCEHR system and using PCEHR information in accordance with an individual's wishes.

Registered organisations may choose to assist individuals to register for a PCEHR. If an organisation chooses to provide this assisted registration service, it needs to obtain the necessary software from the Department, free of charge, and must comply with requirements specified in the PCEHR Rules regarding policy and record retention. In providing assisted registration, an employee of the organisation discusses with the individual the benefits of having a PCEHR and, with the individual's consent, makes a registration application for the individual. The regulatory burden on organisations that choose to provide assisted registration would be unchanged.

The impact of improvement to healthcare provider usability is not yet determined so they cannot be quantified.

Those organisations that choose to participate in the PCEHR system will continue to have access to their patients' PCEHRs (with their patient's agreement) and be able to upload health information to those PCEHRs. However, for reasons of usability, low individual participation rates and low healthcare provider organisation rates, PCEHRs will not be fully utilised by organisations and will contain limited information, and therefore will be of limited clinical value.

Impact on software vendors

The medical software industry is not obliged to deliver medical software that is compliant with the requirements of the PCEHR system. It develops software to meet the needs of its customers (healthcare providers). To date, vendors have been working to develop and deliver software that facilitates PCEHR access largely as a result of funding provided by NEHTA for software in general practice, pharmacy, public hospitals and aged care. Increased participation by healthcare provider organisations may increase the customer base of software vendors. If healthcare providers lose interest in the system because of low participation rates the industry is unlikely to exert pressure on software vendors to deliver PCEHR compliant software.

Impact on Government

The Government will continue to incur increasingly significant healthcare costs and will only begin realising the benefits of the PCEHR system, including a reduction in healthcare costs, when a majority of individuals have a PCEHR which will lead to an increase in the healthcare providers using the system.

6.2 Option 2: Implementing a public awareness campaign to improve uptake

This option requires no regulatory action by Government.

This option would see a negligible increase in the benefits realised from use of the system. Limited use of the system by healthcare providers will affect the amount of clinical information uploaded to a PCEHR. In the longer term the lack of information in the system would become a disincentive to participate in the system.

Impact on individuals

The costs and benefits to individuals are largely as described at option 1. There would be a regulatory cost to those extra people who sign up as a result of the public awareness campaign.

Table 1 identifies the total costs over 10 years from additional individuals registering in the PCEHR system.

Average time taken for individual to register[8]	11 minutes
Individual leisure time[9]	$27/hour
Average cost per application	$4.86
Number of additional individuals registering[10]	273,000
Total regulatory cost for individuals	**$1.33 million**

Impact on healthcare provider organisations

The costs and benefits to healthcare provider organisations are as described at option 1.

Impact on software providers

There is no impact on software vendors, as described at option 1.

Impact on Government

The Government will continue to incur increasingly significant healthcare costs and will only begin realising the benefits of the PCEHR system, including a reduction in healthcare costs, when a majority of individuals have a PCEHR which will lead to an increase in the healthcare

[8] Advice provided by Department of Human Services which manages the individual registration process
[9] Figure provided by the Office of Best Practice Regulation
[10] Based on current registration rates, it is expected that about 500,000 individuals will register each year.

providers using the system. This option would be only marginally more effective than option 1.

The impact on Government will be the cost of undertaking the public awareness campaign. This cost has not been quantified but is likely to be in the same order of magnitude as the *Medicare For All* campaign which was undertaken for two months in 2013 at a cost of $8 million. The proposed public awareness campaign, which would be undertaken over 12 months, would be expected to cost over $50 million.

There will also be a cost for Government to support an increase to the capacity of the system.

6.3 Option 3A: Making the system opt-out for individuals with associated public awareness raising and education and training of healthcare providers, improving usability and changing the governance arrangements through creation of a statutory authority

This option would require amendments to the PCEHR Act to:

- revise the current consent framework to reflect the opt-out nature of the system while still ensuring that individuals can ask that individual documents not be uploaded, and that healthcare providers remain subject to specified state or territory laws regarding the disclosure of certain types of health information;
- change the name of the PCEHR where necessary to simplify references to legal aspects such as terms and conditions, and compliance requirements;
- revise the function of the System Operator as necessary to reflect changes to the governance arrangements; and
- abolish the Independent Advisory Council and Jurisdictional Advisory Committee (this will also require amendment of the *Personally Controlled Electronic Health Records Regulation 2012*).

It would also require amendment to other legislation to:

- establish the new organisation as an inter-jurisdictional statutory authority and prescribe its function and operation; and
- establish the board and the four committees and specify their function and operation.

These amendments would result in a reduction to the volume of Commonwealth legislation.

Under this option the new organisation would be established under *Public Governance, Performance and Accountability Act 2013* (PGPA Act) rules or under its own primary legislation, as an inter-jurisdictional statutory authority that is a body corporate.

The key advantages in establishing the entity as a statutory authority are:

- A greater capacity to improve accountability, which could be imposed either under *Public Governance, Performance and Accountability Act 2013* (PGPA Act) rules or enabling legislation. This could include a requirement that the new eHealth entity submit a rolling work plan to the Australian Health Ministers' Advisory Council and the Council of Australian Governments Health Council for approval on an annual basis, detailing its planned work and priorities for the following three years. Additionally, any new statutory authority would be subject to the existing accountability mechanisms in the PGPA Act, such as the duty to keep the Ministers informed of its activities.
- A greater level of ministerial oversight, which could be statutorily imposed. Rules made under the PGPA Act could also confer State or Territory ministers with oversight of the entity.
- Ability to impose, through ministerial direction, adherence to particular standards and processes such as procurement, staff engagement, and organisational performance reporting.

- The agreed role/charter of a statutory authority and the associated governance bodies such as boards and committees would be set in law. This would allow for easier ongoing management of the entity.
- The Rules that the Commonwealth Finance Minister can make under the PGPA Act can be made (or amended if necessary) more expediently than the previous approach of passing enabling legislation through the Commonwealth Parliament (although they would still be subject to Parliament's disallowance process).
- Moving to a skills-based board (rather than retaining current jurisdictional directorship of the board) would alleviate a range of perceived and real conflict of interest issues.

The main disadvantages of this option are:
- potential adverse perceptions that this is increasing bureaucracy;
- establishing a statutory authority under primary legislation could take marginally longer than using a repurposed form of the NEHTA public company entity – approximately six to twelve months. To mitigate this disadvantage a new eHealth entity could be created through PGPA Act rules which would take approximately six to nine months; and
- without conducting trials to evaluate methods of implementing opt-out and different communications and education approaches, the Government may fail to properly target its audience which could adversely affect participation and public confidence, and could see a reduction to the estimated regulatory savings.

Impact on individuals

In an opt-out system, every eligible individual would automatically get a PCEHR without taking any action.

The move to an opt-out system would represent a significant reduction in current regulatory burden for the community. Individuals would no longer need to go through a registration process to get a PCEHR.

Table 2 identifies the total savings over 10 years from individuals not having to register in the PCEHR system.

Average time taken for individual to register[11]	11 minutes
Individual leisure time[12]	$27/hour
Average cost per application	$4.86
Number of individuals registering[13]	5,000,000
Total regulatory saving for individuals	**$24.30 million**

Those individuals who did not want a PCEHR would need to go through an opt-out process. There is no explicit cost or burden in having a PCEHR and an individual can choose the extent to which they use or access their PCEHR. However, some individuals may choose to opt-out if they have unique privacy sensitivities, such as high profile individuals or individuals who are involved in potentially violent domestic or custodial disputes. It is possible that some people may be uncomfortable with having a record but not sufficiently motivated to opt-out or to set controls to mitigate their concerns. There is some burden associated with this situation but it has not been quantified. It will be mitigated by ensuring the process for opting out or setting access controls is as simple as possible.

[11] Advice provided by Department of Human Services which manages the individual registration process
[12] Figure provided by the Office of Best Practice Regulation
[13] Based on current registration rates, it is expected that about 500,000 individuals will register each year.

Table 3 identifies the total cost over 10 years for individuals to opt-out of the PCEHR system.

Estimated time taken for individual to opt-out[14]	6 minutes
Individual leisure time[15]	$27/hour
Average cost per opt-out	$2.70
Number of individual opting out[16]	271,400
Total regulatory cost for individual	**$0.73 million**

If an individual does not have a PCEHR they will not gain the benefits that making their health information more easily accessible by their healthcare providers would achieve. However, it would in no way affect their eligibility for health services.

Individuals who want to access their PCEHR and fully exercise their access controls would need to go through a process to verify their identity with the System Operator. This process would closely resemble the current registration process.

Table 4 identifies the total cost over 10 years for individuals to obtain access to their PCEHR.

Estimated time taken for individual to obtain access[17]	11 minutes
Individual leisure time[18]	$27/hour
Average cost per application	$4.86
Number of individuals obtaining access[19]	2,686,860
Total regulatory cost for individuals	**$13.06 million**

The PCEHR would enable healthcare providers to make more informed decisions about an individual's care based on more complete information available in the individual's PCEHR, and would also see a reduction in adverse medical events and in the duplication of treatment and tests. With access to their key health information, individuals will be able to more actively participate in their own healthcare and will no longer need to remember all of their previous health information to repeat to each healthcare provider that treats them, and they will benefit from improved quality of healthcare and coordination of healthcare delivery.

The reduction in adverse medical events would see improvements to productivity and labour force participation since, over time, it would lead to improved treatment outcomes and less sick leave. This may increase the community's trust in the healthcare system.

The PCEHR system is also expected to reduce the time spent, cost and number of healthcare visits required by family members and their dependants, and therefore reduce their healthcare expenditure as families. This will result in a consequent increase in the disposable income of families.

The reductions in time taken in finding information and the performance of unnecessary investigations would result in improved productivity for the health workforce thus addressing some of the challenge faced by the Commonwealth in the increasing cost of healthcare.

[14] The opt-out process has not been decided but is expected to be much simpler than the registration process since it will not require the same extent of identity verification because there is a significant lower risk of privacy breach.
[15] Figure provided by Office of Best Practice Regulation
[16] Based on an annual opt-out rate of 1% of population – 230,000 in year 1; 1% of population growth (assume 2%) from year 2
[17] This is expected to closely follow the identity verification undertaken in the current registration process so the current average registration time has been adopted.
[18] Figure provided by the Office of Best Practice Regulation
[19] Based on current access rates, it is expected that about 10% of the population with PCEHRs would seek to get access to their PCEHR (27.14 million less 271,400 who opt out).

A PCEHR will be of particular benefit to individuals with chronic and complex conditions, older Australians, Indigenous Australians, mothers and newborn children, and individuals living in rural and regional areas, as they are more likely to access healthcare from numerous healthcare providers.

In addition, it would mean that patients and their families will be able to go anywhere in Australia to receive high quality and convenient healthcare, reducing the time and costs associated with undertaking duplicate tests or repeating information.

It is anticipated that benefits in health outcomes of families will be skewed towards vulnerable families as they currently face more challenges in accessing timely and appropriate healthcare and will have more to benefit from improved health outcomes. These people are also less likely to participate in an opt-in model as they are more likely to be challenged by the registration process. Vulnerable families may include Aboriginal and Torres Strait Islander families, family carers with a member who has a mental illness, families in which English is a second language, and families with low socio-economic status. These groups are expected to experience more pronounced benefits as the PCEHR system will help reduce the enormous burden carried by these families.

The impact of improvements to individual usability is not yet determined so they cannot be quantified.

Impact on healthcare provider organisations

The regulatory burden on healthcare provider organisations that choose to register to participate in the PCEHR system would be unchanged, as described at option 1.

The regulatory burden on individual providers who work in organisations participating in the PCEHR system would be unchanged, as described at option 1.

The move to an opt-out system would have a regulatory impact on those registered healthcare provider organisations that currently provide assisted registration to individuals because they would no longer spend any time assisting individuals to apply to register for a PCEHR. This would result in a savings.

Table 5 identifies the savings over 10 years from organisations no longer providing assisted registration to individuals.

Average time to provide assisted registration	8 minutes
Average salary of officer providing assisted registration[20]	$175,000
Average cost to provide service	$11.76
Number of individuals receiving assisted registration[21]	182,000
Total regulatory saving for organisations not providing assisted registration	**$2.14 million**

Opt-out participation by individuals would change the behaviour of the healthcare provider industry. Healthcare providers would increasingly utilise the system and realise its benefits in terms of availability of healthcare information to improve healthcare quality and delivery.

Participation for healthcare provider organisations would remain opt-in. There would be an indirect impact on healthcare provider organisations since opt-out participation for individuals will increase the value of the PCEHR system for providers. It is estimated that 20 per cent more healthcare provider organisations would register each year.

[20] This takes into account a $100,000 salary plus other operating labour costs and overheads.
[21] Based on current assisted registration rates, about 50 individuals register through assisted registration per day.

The governance changes would not have a direct regulatory impact on healthcare providers and organisations. However integrating the services and ensuring more appropriate stakeholder representation would see improvements to the usability of the system and an increase to the confidence in the system by healthcare providers. This would likely lead to more healthcare provider organisations registering to participate in the system which, in itself, would impact organisations as described above.

Table 6 identifies the cost over 10 years for an increased volume of organisations to register to participate in the PCEHR system.

Average time taken for organisation to register	2.5 hours
Average salary of officer completing application[22]	$175,000
Average cost per application	$220.50
Number of additional organisations registering[23]	2,400
Total regulatory costs for additional organisations to apply to register	**$529,200**

This option would improve the efficiency in the provision of health services. Healthcare providers would have access to more complete and consistent information to inform their healthcare decisions, resulting in a reduction in the time wasted duplicating tests and treatment and seeking information from their patients and other healthcare providers, and reducing the occurrence of medication errors.

The impact of improvements to healthcare provider usability is not yet determined so they cannot be quantified.

Impact on software vendors

There is no regulatory impact on software vendors, as described at option 1.

Impact on Government

This option will impose some cost and burden on the Government as there would be a new agency to administer, however, given the nature in which the entity would be established, it would provide better accountability and transparency which would allow the Government to achieve and deliver better outcomes.

There will also be a cost for Government to support an increase to the capacity of the system and to undertake the communication campaigns and training.

The Government would gain significant economic benefits through the health sector and individuals through:

- reducing hospital admissions;
- enabling improved individuals care including better management of chronic disease; and
- enabling a more efficient healthcare system.

[22] This takes into account a $100,000 salary plus other operating labour costs and overheads.

[23] Based on current registration rates, about 1,200 healthcare provider organisations will register each year. In an opt-out system it estimated an additional 20 per cent (240) organisations will register each year.

6.4 Option 3B: Implementing participation trials, including opt-out, with targeted communications in the trial regions and education and training of healthcare providers, improving usability and changing the governance arrangements through creation of a statutory authority

This option would require legislative amendments as described in option 3A, plus further amendments to the PCEHR Act to enable the system to operate on an opt-out basis in certain trial regions while ensuring it continues as an opt-in system in the remainder of Australia.

Trials of other innovative approaches for driving registrations and participation in an opt-in system would also be conducted.

The statutory authority would be established as described in option 3A.

While this option would result in an increase to short-term regulatory costs, it would enable the Government to develop a robust approach to implementing an opt-out system nationally to assure long-term savings.

Impact on individuals

The impact on individuals would be the same as under option 3A, however it would only affect individuals in trial regions. These individuals would no longer need to go through a registration process to get a PCEHR. Since the nature of the other trials has not yet been determined, a conservative approach has been taken in this costing to assume that the regulatory cost would apply to the maximum trial population.

Table 7 identifies the total savings from individuals in trial regions not having to register in the PCEHR system.

Average time taken for individual to register[24]	11 minutes
Individual leisure time[25]	$27/hour
Average cost per application	$4.86
Number of individuals registering[26]	22,000
Total regulatory saving for individuals	**$106,920**

As described in option 3A, any individuals who don't want a PCEHR would need to go through an opt-out process.

Table 8 identifies the total cost for individuals in trial regions to opt-out of the PCEHR system.

Estimated time taken for individual to opt-out[27]	6 minutes
Individual leisure time[28]	$27/hour
Average cost per opt-out	$2.70
Number of individuals opting out[29]	10,000
Total regulatory cost for individual	**$27,000**

[24] Advice provided by Department of Human Services which manages the individual registration process
[25] Figure provided by the Office of Best Practice Regulation
[26] Based on current registration rates, it is expected that about 500,000 individuals will register each year which represents about 2.2% of the population. By applying this percentage to the 1,000,000 individuals to be part of the trials, it is expected that 22,000 individuals would otherwise register.
[27] The opt-out process has not been decided but is expected to be much simpler than the registration process since it will not require the same extent of identity verification because there is a significant lower risk of a privacy breach.
[28] Figure provided by Office of Best Practice Regulation
[29] Based on 1 million individuals being opted in, minus 1% who choose to opt out

If an individual does not have a PCEHR they will not gain the benefits that making their health information more easily accessible by their healthcare providers would achieve. However, it would in no way affect their eligibility for health services.

As described in option 3A, individuals who want to access their PCEHR and exercise their access controls would need to go through an identity verification process.

Table 9 identifies the total cost for individuals in trial regions to obtain access to their PCEHR.

Estimated time taken for individual to obtain access[30]	11 minutes
Individual leisure time[31]	$27/hour
Average cost per application	$4.86
Number of individuals obtaining access[32]	99,000
Total regulatory cost for individuals	**$481,140**

The PCEHR would enable healthcare providers who are treating individuals from the trial regions to make more informed decisions about an individual's care based on more complete information available in the individual's PCEHR. However it would likely see a negligible reduction in adverse medical events and the duplication of treatment and tests. With access to their key health information, individuals will be able to more actively participate in their own healthcare and will benefit somewhat from improved quality of healthcare and coordination of healthcare delivery.

A PCEHR will be of particular benefit to individuals with chronic and complex conditions, older Australians, Indigenous Australians, mothers and newborn children, and individuals living in rural and regional areas, as they are more likely to access healthcare from numerous healthcare providers.

The impact of improvements to individual usability is not yet determined so they cannot be quantified.

Impact on healthcare provider organisations

The regulatory burden on healthcare provider organisations that choose to register to participate in the PCEHR system would be unchanged, as described at option 1.

The regulatory burden on individual providers who work in organisations participating in the PCEHR system would be unchanged, as described at option 1.

Opt-out participation in trial regions would, to some degree, change the behaviour of the healthcare providers who treat those individuals. These healthcare providers would increasingly utilise the system and realise its benefits in terms of availability of healthcare information to improve healthcare quality and delivery, and may feel compelled to register with the system to meet patient demand.

Participation for healthcare provider organisations would remain opt-in. There would be an indirect impact on healthcare provider organisations in trial regions and those providing treatment to individuals in trial regions, since opt-out participation will increase the value of the PCEHR system for these providers. It is therefore likely that additional healthcare provider organisations would register during the trials. Until the trial regions are selected it is

[30] This is expected to closely follow the identity verification undertaken in the current registration process so the current average registration time has been adopted.
[31] Figure provided by the Office of Best Practice Regulation
[32] Based on 990,000 individuals having a PCEHR

not possible to quantify how many additional organisations are likely to register so for the purpose of this proposal it is estimated that 50 additional organisations would register.

The governance changes would not have a direct regulatory impact on healthcare providers and organisations. However integrating the services and ensuring more appropriate stakeholder representation would see improvements to the usability of the system and an increase to the confidence in the system by healthcare providers. This would likely lead to more healthcare provider organisations registering to participate in the system which, in itself, would impact organisations as described above.

Table 10 identifies the cost of additional organisations registering to participate in the PCEHR system.

Average time taken for organisation to register	2.5 hours
Average salary of officer completing application[33]	$175,000
Average cost per application	$220.50
Number of additional organisations registering[34]	50
Total regulatory costs for additional organisations to apply to register	**$11,025**

This option would see negligible improvements to efficiency in the provision of health services.

The impact of improvements to healthcare provider usability is not yet determined so they cannot be quantified.

Impact on software vendors

There is no regulatory impact on software vendors, as described at option 1.

Impact on Government

This option will impose some cost and burden on the Government, including the cost to undertake the communication campaigns and training, and to support an increase to the capacity of the system.

The Government would gain negligible economic benefits through the health sector and individuals through:

- reducing hospital admissions;
- enabling improved individuals care including better management of chronic disease; and
- enabling a more efficient healthcare system.

The Government will continue to incur increasingly significant healthcare costs and will only begin realising the benefits of the PCEHR system, including a reduction in healthcare costs, when a majority of individuals have a PCEHR which will lead to an increase in the healthcare providers using the system.

7. CONSULTATION

The panel undertaking the PCEHR Review considered information from submissions invited from stakeholder groups, unsolicited feedback by interested parties and a series of interviews with key stakeholders.

[33] This takes into account a $100,000 salary plus other operating labour costs and overheads.

[34] Until the trial regions are selected it is not possible to quantify how many additional organisations are likely to register so for the purpose of this proposal it is estimated that 50 additional organisations would register.

There is evidence of strong support for the opt-out model. There are specific user groups that could potentially see significant benefits from having an eHealth record, including people with chronic and complex conditions, the elderly, Aboriginal and Torres Strait Islander peoples, and mothers and newborns. An opt-out model would help resolve the difficult registration process and enable people to realise the benefits of an eHealth record.

In terms of governance, the Review identified that stakeholders have little confidence in the current PCEHR system for a range of reasons including a lack of transparency, usability, complexity, accountability and proportional representation of its governance.

The Department undertook a national consultation process from 18 July to 9 September 2014 involving clinicians, individual representative groups, jurisdictions, the IT industry and private health and indemnity insurers. Consultation sessions were held in all capital cities (except Darwin) and Alice Springs, and were led by senior officers of the Department.

The consultations were aimed at obtaining stakeholder views on the intent of the PCEHR Review's recommendations, any issues or risks for implementation and how these may be overcome.

The key messages from the consultations were:

- broad support by individuals and providers for the concept of an opt-out national shared electronic health record;
- the move to opt-out will need strong, effective communication about what it means in terms of privacy, security, and where they can get further advice;
- healthcare providers support the move to opt-out as one of a range of things that need to happen to encourage adoption, including improvement in usability and content;
- individuals consider provider participation should also be opt-out given the importance of their participation;
- providers consider the minimum key content of a PCEHR is allergies, adverse events, a current medication list and transfer of care summaries, and pathology and diagnostic imaging results are very useful; and
- key information in the PCEHR, such as medications, must be current and easy to find – the biggest concern is around current usability.

The consultations have informed the development of this proposal and the impact analyses, and they will also influence the system design, implementation schedule, and the planning for communication, education and risk management.

8. RECOMMENDATION

The recommended option is option 3B because:

- it would achieve the Government's objectives and would, in the long-term, have a positive impact on the reputation and usefulness of the system;
- a majority of stakeholders support an opt-out model;
- it would inform future decisions regarding approaches for the adoption of a national opt-out system and the delivery of communications, and education and training for healthcare providers.

While option 3B would see a short-term increase in the regulatory impact on individuals and healthcare provider organisations in trial regions, with a net cost of $412,245, it would provide valuable information that would enable the Government to increase participation in and meaningful use of the PCEHR system in a manner that appropriately targets and educates its audience, enhances confidence in the system and sees long-term savings.

Regulatory Burden and Cost Offsets Estimates Table

Option 2

Average annual regulatory costs (from business as usual)				
Change in costs ($ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	$0	$0	$0.133	$0.133
Cost offset ($ million)	Business	Community organisations	Individuals	Total, by source
Agency	$21.7	$0	$0	-$21.7
Are all new costs offset? Yes, costs are offset				
Total (Change in costs – Cost offset) ($ million) = -$21.567				

This cost is offset by the regulatory savings of $21.7 million achieved by the National Industrial Chemicals Notifications and Assessment Scheme reforms.

Option 3A

Average annual regulatory costs (from business as usual)				
Change in costs ($ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	-$0.161	$0	-$1.051	-$1.212
Cost offset ($ million)	Business	Community organisations	Individuals	Total, by source
Agency	$0	$0	$0	$0
Are all new costs offset? Deregulatory—no offsets required				
Total (Change in costs – Cost offset) ($ million) = -$1.212				

Option 3B

Average annual regulatory costs (from business as usual)				
Change in costs ($ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	$0.011	$0	$0.401	$0.412
Cost offset ($ million)	Business	Community organisations	Individuals	Total, by source
Agency	-$21.7	$0	$0	-$21.7
Are all new costs offset? Yes, costs are offset				
Total (Change in costs – Cost offset) ($ million) = -$21.288				

This cost is offset by the regulatory savings of $21.7 million achieved by the National Industrial Chemicals Notifications and Assessment Scheme reforms.

9. IMPLEMENTATION AND REVIEW

New participation arrangements for individuals, a new governance framework and usability improvements are intended to take effect in stages, alongside a national education and communication campaign.

A post-implementation review will be undertaken after the recommended changes have been in operation for a reasonable period of time.