



Australian Government
Department of Health

SECRETARY

30 October 2015

Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Chairperson

Inquiry into Health Legislation Amendment (eHealth) Bill 2015

Thank you for your invitation to make a submission to the Senate Community Affairs Committee inquiry into the Health Legislation Amendment (eHealth) Bill 2015. The Department of Health submission is attached.

Yours sincerely

Martin Bowles PSM



Australian Government

Department of Health

**Submission to the Senate Standing
Community Affairs Legislation Committee:**

**Inquiry into the Health Legislation Amendment (eHealth)
Bill 2015**

October 2015

1. Background

The Health Legislation Amendment (eHealth) Bill was introduced into Parliament on 17 September 2015. It was referred to the Community Affairs Legislation Committee on 15 October 2015. This submission is made to provide additional information to the Committee as part of its inquiry.

The Bill will make amendments to the *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act), *Healthcare Identifiers Act 2010* (HI Act), *Privacy Act 1988* (Privacy Act), *Copyright Act 1968*, *National Health Act 1953* and *Health Insurance Act 1973* to:

- change the name of the personally controlled electronic health record (PCEHR) system to the My Health Record system;
- enable trials of opt-out participation for individuals to be undertaken and, if the trials prove successful at improving uptake of the system, enable opt-out to be implemented nationally;
- prepare for establishment of the Australian Commission for eHealth, which will be progressed separately through rules made under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act);
- revise the way permission to collect, use and disclose information is presented and include several new permissions necessary for effective operation of the PCEHR system and Healthcare Identifiers (HI) Service;
- introduce new civil and criminal penalties and make enforceable undertakings and injunctions available in both systems;
- remove unnecessary restrictions on sharing of healthcare provider organisation information;
- clarify that health-related disability, palliative care and aged care services are considered health services;
- apply mandatory data breach notification requirements equally to all participants in the My Health Record system; and
- revise the obligations of people who provide decision-making support.

On 13 and 14 October 2015 the Parliamentary Joint Committee on Human Rights and the Senate Standing Committee for the Scrutiny of Bills respectively, identified issues with the Bill with regard to their terms of reference. Each Committee sought the Minister for Health's advice. The Minister has since responded with this advice. Information is included in this submission to also address these issues.

2. Purpose of this submission

This submission provides additional information about five subjects that have been raised in media and by Parliament:

1. Impact of the Bill on human rights;
2. Privacy and security of the My Health Record system;
3. Proposed trials of opt-out participation arrangements;
4. Findings by the Scrutiny of Bills Committee; and
5. Consultation undertaken on opt-out trials.

3. Impact on human rights

On 13 October 2015 the Parliamentary Joint Committee on Human Rights released its *Twenty-ninth report of the 44th Parliament* (Human Rights Report) which included its examination of the Bill.

The central theme of the Human Rights Report in relation to the Bill is whether the proposed opt-out arrangements are:

- (i) necessary to achieve a legitimate objective; and
- (ii) proportionate, necessary and reasonable to achieving that objective.

A subsidiary theme is whether the civil penalties proposed under the Bill are, in effect, criminal for the purposes of international human rights law, and whether they limit the right to a fair trial.

For the reasons described below, the proposed opt-out arrangements are considered necessary to achieve the legitimate objective of improving health outcomes for Australians, and are considered proportionate, necessary and reasonable to achieving that objective. The proposed civil penalties are not criminal for the purposes of international human rights law and do not limit the right to a fair trial.

Opt-out arrangements

The PCEHR Act (to be renamed the My Health Records Act) has, and will continue to have, the objective of *improving health outcomes* by establishing and operating a national system for accessing individual's health information to¹:

- (a) help overcome the fragmentation of health information;
- (b) improve the availability and quality of health information;
- (c) reduce the occurrence of adverse medical events and the duplication of treatment;
and
- (d) improve the coordination and quality of healthcare provided to individuals by different healthcare providers.

Having a My Health Record is likely to improve health outcomes, making access to the right treatment faster, safer, easier and more cost effective:

- **faster** – because doctors, nurses and other healthcare providers will not have to spend time searching for past treatment information;
- **safer** – because authorised healthcare providers can view an individual's important healthcare information, including any allergies, reactions and vaccinations and the treatment including medications the individual has received;
- **easier** – because individuals will not have to remember the results of tests they have had, or all the medications they have been prescribed; and
- **more cost effective** – because healthcare providers won't have to order duplicate tests – e.g. when an individual visits a different GP whilst on holidays. The time necessary to provide treatment may also be reduced as an individual's health information will be available in one place. As a result, the cost of treatment may be reduced, freeing up healthcare resources for improving health outcomes in other areas.

¹ Section 3 of the PCEHR Act

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 due to a complete medications history not being available);
- 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);
- unnecessary or duplicated investigations (e.g. when a person attends a new provider and their previous test results are not available);
- 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.

Currently about 1 in 10 individuals have a My Health Record. There is overwhelming support for electronic health records from the consumer community, and currently the need for an active “opt-in” and registration process is considered an administrative barrier to consumers achieving better health outcomes through the electronic sharing of their health information. The current “opt-in” registration process could therefore be considered a barrier to the achievement of the human right to health, impacting on a consumers ability to access the benefits of faster, safer, easier healthcare offered through a national shared electronic health system.

Since the majority of individuals don’t have a My Health Record, healthcare providers generally lack any incentive to adopt and contribute to the system, thereby limiting the usefulness of the system. This means there are currently too few individuals and healthcare providers using the system for health outcomes to be significantly improved for the benefit of all Australians.

The *Review of the Personally Controlled Electronic Health Record*² (PCEHR Review) recommended moving to opt-out participation arrangements for individuals as the most effective way of achieving participation of both healthcare providers and individuals in the system, and through this delivering the objective of improving health outcomes. Opt-out arrangements are supported by consumers and a wide range of peak bodies representing healthcare providers and other stakeholders³.

Annual Commonwealth healthcare costs are forecast to increase by \$27 billion to \$86 billion by 2025, and will increase to over \$250 billion by 2050⁴. Improved health outcomes and productivity improvements such as those that can be delivered by eHealth are needed to help counter the expected increases in the healthcare costs. Leveraging eHealth is one of the few strategies available to drive microeconomic reform to reduce Commonwealth health outlays. Without these changes, the quality of healthcare available to all Australians may reduce in the future as costs become prohibitive.

² [Department of Health website](#)

³ See, for example, the comments from the Consumers Health Forum supporting opt-out which are extracted on page 28 of the PCEHR Review.

⁴ Australian Government’s 2010 Intergenerational Report

Without a move to opt-out participation arrangements, the required critical mass of registered individuals may not occur, or may be significantly delayed. As a result, the anticipated objective of improving health outcomes and reducing the pressure on Commonwealth health funding may not occur or may be significantly delayed. Under the current opt-in registration arrangements, a net cumulative benefit of \$11.5 billion is expected over 15 years to 2025. It is anticipated that the move to a national opt-out system would deliver these benefits in a shorter period.

National opt-out eHealth record systems have been implemented in a number of countries that are also subject to Human Rights Conventions including Denmark, Finland, Israel, England, Scotland and Wales. This supports the view that opt-out participation arrangements for eHealth record systems are proportionate, necessary and reasonable in relation to perceived limitations on individuals' right to privacy.

While the PCEHR Review recommended moving straight to national opt-out arrangements, the Government has decided to trial opt-out arrangements first to ensure that there is community acceptance and support of opt-out arrangements. In other words the trialling of opt-out arrangements provides the opportunity for the Australian community to consider their response to opt-out arrangements and determine whether from their perspective the arrangements are proportionate and reasonable measures to achieving the objective of improving health outcomes.

Individuals in the opt-out trials will be made aware they are part of an opt-out trial, how their personal information will be handled, and how to opt-out or adjust privacy control settings, so they can make an informed decision. Comprehensive information and communication activities are being planned for the opt-out trials to ensure all affected individuals, including parents, guardians and carers, are aware they are in an opt-out trial and what they need to do to participate, adjust privacy controls associated with their record, or to opt-out if they choose. This will include letters to affected individuals, targeted communication to carers and advocacy groups, extensive online and social media information, and education and training for healthcare providers in opt-out trial locations.

The eHealth Bill maintains the current strong and significant privacy protections under the current opt-in arrangements, and ensures they will apply under the proposed new opt-out arrangements (whether as part of a trial or under any future national implementation).

These protections include the ability to do the following for all people registered with the My Health Record system, including children and persons with disabilities:

- set access controls restricting access to their My Health Record entirely or restricting access to certain information in their My Health Record;
- request that their healthcare provider not upload certain information or documents to their My Health Record, in which case the healthcare provider will be required not to upload that information or those documents;
- request that their Medicare data not be included in their My Health Record, in which case the Chief Executive Medicare will be required to not make the data available to the System Operator;
- monitor activity in relation to their My Health Record using the audit log or via electronic messages alerting them that someone has accessed their My Health Record;
- effectively remove documents from their My Health Record;
- make a complaint if they consider there has been a breach of privacy; and

- cancel their registration (that is, cancel their My Health Record).

The PCEHR Act and system currently provide special arrangements to support children and vulnerable people to participate in the system by allowing authorised representatives to act on their behalf and protect the rights of children and people with a disability. Authorised representatives generally have parental responsibility for a child, or some other formal authority to act on behalf of the individual. Nominated representatives can also be appointed by an individual (or by their authorised representative) to help the individual manage their electronic health record. The concept of nominated representatives allows for a less formal appointment of another person to help an individual manage their electronic health record. Nominated representatives could be, for example, a family member, neighbour or friend who will generally not have any formal authority to act on behalf of the individual, but whom the individual appoints to assist them in managing their record.

Representatives are currently required to act in the best interests of the person they are representing, and have regard to any directions given by that person. In light of international changes in the treatment of individuals who require supported decision-making, recognising that one person cannot necessarily determine what is in the best interests of another person, the eHealth Bill provides that people providing decision-making support will instead need to give effect to the will and preference of the person to whom they provide decision-making support. Ensuring that representatives can continue to act on behalf of individuals (including children and persons with a disability) to help them to manage their record as part of opt-out is a privacy positive under the eHealth Bill. Authorised representatives will be able, for example, to opt-out the individual for whom they have responsibility from having an electronic health record, if this meets the will and preference of the person they are representing.

Finally, in relation to privacy, a move to opt-out is likely to improve privacy for individuals, including children and persons with a disability, in a number of ways. As noted in the Commonwealth's *Concept of Operations: Relating to the introduction of a personally controlled electronic health record system* (2011):

According to the Australian Medical Association (AMA), over 95% of GPs have computerised practice management systems. The majority of GPs with a computer at work used it for printing prescriptions recording consultation notes, printing test requests and Referral letters and receiving results for pathology tests electronically. Roughly one third of GPs keep 100% of patient information in an electronic format and the remainder of general practices use a combination of paper and electronic records. (pages 126-7)

Implementing opt-out participation arrangements is likely to increase the number of individuals with a My Health Record, and it is anticipated that this will result in the majority of healthcare provider organisations viewing records for their patients in the system and contributing clinical content to those records as part of the process of providing healthcare. Increased participation by healthcare providers, planned improvements in system functionality and ease of use, together with planned incentives to use the system, will lead to much greater use of the system in providing healthcare to individuals.

Increased use of the system is a privacy positive as it will reduce the use of paper records, which pose significant privacy risks. For example, where a patient is receiving treatment in a hospital's emergency department for a chronic illness, the hospital may request from the patient's regular doctor information about the patient's clinical history which is likely to be faxed to the hospital. The fax might remain unattended on the fax machine for an extended period of time before being placed into the patient's file, or the information may be sent to

the wrong fax number. Either of these things could lead to an interference with the patient's privacy should a third party read the unattended fax or incorrectly receive the fax. In contrast, under the My Health Record system, the patient's Shared Health Summary would be securely available only to those people authorised to see it. There are other similar scenarios where an increase in the level of use of the My Health Record system is likely to lead to a reduction in privacy breaches associated with paper-based records.

In summary, the combination of opt-out trials, extensive information and communication activities, and the continuation of the same strong personal controls mean that moving to opt-out participation arrangements for individuals is proportionate, necessary and reasonable for achieving the objective of improving health outcomes. Furthermore, increased registration and use of the My Health Record system is likely to increase individuals' privacy, especially compared to paper-based records that are still used to at least some degree by around two-thirds of healthcare providers.

Civil penalties

The maximum civil penalty that can be imposed under the Bill is 600 penalty units. This penalty is considered justified as the My Health Record system stores the sensitive health information of many individuals. The amount of health information stored and the number of individuals whose records are stored will increase significantly under opt-out arrangements.

Penalty levels must provide an appropriate deterrent to any planned or deliberate misuse of sensitive health information. In addition, penalties need to be proportionate to the potential damage that might be suffered by individuals if the health information in their My Health Record is misused.

The civil penalty levels imposed under the Bill can be contrasted to the existing Privacy Act:

- Under the Bill, the maximum civil penalty is 600 penalty units for a misuse of sensitive health information;
- Under the Privacy Act there are significantly higher civil penalties of up to 2,000 penalty units for serious or repeated misuse of personal information. This is despite the fact that the information in question might not be sensitive health information, and may only be less-sensitive personal information.

Given that the civil penalties available under the Privacy Act are considered appropriate, it is most unlikely that lower penalties under the Bill would be considered criminal in nature or would limit the right to a fair trial, especially where the penalty regime imposed by the Bill is designed to protect significantly more sensitive health information than is generally the case under the Privacy Act.

The Human Rights Report also queried:

- the differential between the maximum civil penalty amount and the maximum criminal penalty amount. The Bill provides for a higher level of civil penalty (600 penalty units) compared to the maximum criminal penalty (120 penalty units) as it is not necessary to have the same levels for each. Imposition of a criminal conviction has other implications that mean that higher penalty levels are not necessary. For example, a criminal conviction may result in imprisonment (up to two years) or restrictions on an individual's ability to travel; and

- the reversal of the burden of proof in proposed new section 26 of the HI Act. Proposed new subsections 26(3) and (4) provide exceptions to the prohibition against misusing healthcare identifiers and identifying information in subsection 26(1) of the HI Act. In doing so, subsections 26(3) and (4) reverse the burden of proof by providing that the defendant bears an evidential burden when asserting an exception applies. An evidential burden placed on the defendant is not uncommon. Similar notations to those used in the Bill exist in many other pieces of Commonwealth legislation (for example, subsection 3.3 of the *Criminal Code Act 1995* – where a person has an evidential burden of proof if they wish to deny criminal responsibility by relying on a provision of Part 2.3 of the Criminal Code). In accordance with the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*, the facts relating to each defence in proposed new subsections 26(3) and (4) of the HI Act are peculiarly within the knowledge of the defendant, and could be extremely difficult or expensive for the prosecution to disprove whereas proof of a defence could be readily provided by the defendant. A burden of proof that a law imposes on a defendant is an evidential burden only (not a legal burden), and does not completely displace the prosecutor’s burden. Proposed subsections 26(3) and (4) simply require a person to produce or point to evidence that suggests a reasonable possibility that exceptions in those provisions apply to the person.

4. Privacy and security

A range of legislative and technical mechanisms work together to provide the privacy framework for the current PCEHR system and will continue to be available when it is renamed the My Health Record system.

Legislative framework

Currently the authorisations in the PCEHR and the HI Act specify how and why an entity can collect, use or disclose certain information. The way these authorisations were written was complex and has caused some confusion, resulting in some entities being unsure what they could or could not do.

The Bill amends both Acts to set out the authorisations in a simpler way and make it easier to understand what entities can and cannot do with certain information.

There have been some changes to the authorisations in the HI Act. These are:

- clarifying that if an entity can disclose information they can also use the information – previously they could only disclose the information but it is impractical to disclose the information without using it;
- clarifying the authorisations needed for the HI Service Operator to keep a record of healthcare identifiers and related information such as requests for healthcare identifiers;
- allowing the HI Service operator to disclose an individual’s identifying information to a healthcare provider – this disclosure is required to support correct matching of an individual to their individual healthcare identifier but would only occur when the HI Service Operator is sure they have identified the correct person. This disclosure addresses problems in matching identities across organisations. Problems currently arise through different data entry protocols, such as use of full (e.g. Christopher or Joanne) or preferred name (e.g. Chris or Jo), and human errors, such as spelling mistakes;
- giving the HI Service Operator authority to collect, use and disclose an individual’s healthcare identifier for any My Health Record purposes – disclosure was previously limited to the System Operator, Chief Executive Medicare and other Departments or

participants in the system, and only in specific circumstances;

- allowing the System Operator to disclose a healthcare identifier to the individual or a responsible person as defined by the Privacy Act – previously only the HI Service Operator and healthcare providers were able to do this;
- explicitly authorising the HI Service Operator to collect a range of information about a healthcare provider – this was previously implied but not expressly authorised;
- clearly including the communication and management of health information as an authorised use and disclosure of healthcare provider’s identifying information;
- collecting of information from registration authorities to ensure information about healthcare providers is up to date; and
- supporting healthcare providers access information about their identifier.

Changes to the PCEHR Act are:

- explicitly authorising the System Operator to collect health information – previously an individual consented to healthcare providers uploading their information to the system and the System Operator’s authority to collect information was inferred from this consent;
- clarifying that information about an individual can be collected, used and disclosed to determine if they are eligible to be an authorised representative;
- clarifying that the Chief Executive of Medicare, Department of Veterans’ Affairs and Defence Department can collect information about an individual to assist the System Operator verify that person’s identity – previously only use and disclosure were expressly authorised; and
- removing the requirement, in an opt-out environment, for an individual to provide consent for information to be included in the record from a registered repository.

Privacy in an opt-out setting

In an opt-out setting, individuals who have a My Health Record created for them will have the same range of privacy positive options for protecting the information in their My Health Record that are available for those who opt-in under the current arrangements. In addition to the points outlined in section 3 Impact on Human Rights they will be able to opt-out of having a My Health Record before a record is created for them. Should they not opt-out, they will be able to:

- set access controls restricting access to their My Health Record (by healthcare provider organisations and representatives) entirely or restricting access to certain information in their My Health Record;
- request that their healthcare provider not upload certain information or documents to their My Health Record, in which case the healthcare provider will be required not to upload that information or those documents;
- request that their Medicare claim data not be included in their My Health Record, in which case the Medicare claim data will not be made available to the My Health Record System;
- monitor activity in relation to their My Health Record using the audit log or via electronic messages alerting them that someone has accessed their My Health Record;
- effectively remove documents from their My Health Record;
- make a complaint if they consider there has been a breach of privacy, and have this complaint investigated; and

- cancel their registration (that is, cancel their My Health Record).

In addition to the privacy controls described above, there are a range of technical controls used to safeguard information in the My Health Record system including:

- encryption of the information;
- authentication of people accessing the system;
- constant monitoring of accesses to My Health Records to detect suspicious or inappropriate behaviour;
- maintaining audit trails of access to records and making these available to individuals; and
- regular and rigorous security testing of the system.

Privacy Impact Assessments

A privacy impact assessment (PIA) analysing the potential privacy risks and impacts of implementing an opt-out approach for participation in the PCEHR system at a national level reflecting the recommendation of the PCEHR Review has been undertaken. It is published on the [eHealth website](#).

The PIA identified a number of key privacy risks relating to the opt-out approach, pointing out that:

- individuals must be made aware of how their personal information will be handled and how to opt-out or adjust privacy control settings so they can make informed decisions; and
- there is legislative authority for the use and disclosure of identifying information and healthcare identifiers.

The PIA made 46 recommendations to address these key privacy risks including:

- amendments to the *Personally Controlled Electronic Health Records Act 2012* and *Healthcare Identifiers Act 2010*;
- developing appropriate forms of communication to better inform and reach vulnerable and disadvantaged individuals;
- further consultation and publishing of the consultation and PIA reports to increase transparency about privacy risks and benefits of the opt-out participation approach; and
- re-designing the labelling, layout and explanation of various privacy control settings such that it is clear, neutral, explicit and easy for individuals to understand.

While this PIA relates to a national opt-out approach, the Department is preparing its response to the PIA in respect of the opt-out trials, and is taking steps to implement the recommendations. The PIA response is proposed to be published.

A follow up PIA specifically on the opt-out trials has commenced and is expected to be completed in November 2015.

Stakeholder feedback on privacy issues

In response to the *Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper*, released in May 2015 for consultation, the Department received

137 submissions. These submissions are published on the [eHealth website](#) (except those that were marked as confidential).

Among the comments and feedback provided, stakeholders expressed some concerns regarding violation of privacy and doctor-patient confidentiality, and emphasised:

- the need for appropriate protection of patient information to prevent misuse;
- the importance of considering patient access controls in terms of safety and quality of care versus protection of medical information; and
- the importance of ensuring representatives have authority to act for individuals have access.

Frequent comments made on the matter of communications to individuals in opt-out trials were that the information include the rights of consumers to choose to opt-out, identify the privacy and other implications of opting out, the benefits and risks of the PCEHR system, privacy and security information, how consumers can make complaints and that the process to opt-out be easy to use and accessible for all Australians including those with a disability or from a culturally or linguistically diverse background

Many submissions supported implementation of an opt-out system provided individuals were well informed about these matters. About 85 per cent of submissions that commented on opt-out gave full or conditional support to national opt-out participation, while about 98 per cent supported opt-out trials – supporters were equally individuals (including representative organisations) and healthcare providers.

5. Opt-out trials

What is opt-out?

The PCEHR system currently operates on an opt-in basis, which means that individuals have to register to get a record. When an individual registers for a record they consent to registered healthcare provider organisations sharing health information (subject to some exceptions) and choose whether or not their Medicare data can be uploaded.

Opt-out means that an individual would get a My Health Record without needing to register for one. An individual would not have to have a record, they would be able to advise they do not want one and would be able to opt-out of the system before one is created for them.

The Bill will authorise registered healthcare provider organisations and registered repository operators (such as Medicare) to upload the individual's health information to the My Health Record system. This will be subject to the same exceptions that apply in the current opt-in system. If an individual asks a healthcare provider not to upload certain information, the healthcare provider cannot upload it.

If an individual does not opt-out, a My Health Record would be created for them. If they decide they do not want a My Health Record after it has been created, they can cancel it. If an individual cancels their record no more health information would be collected in their My Health Record.

Trialling opt-out participation

Trials of opt-out participation will help determine if moving to a national opt-out system is an efficient way of increasing the value of the system to healthcare providers leading to greater

use of the system and in turn better healthcare.

Trials of opt-out arrangements are being conducted to:

- identify appropriate methods of targeting and delivering critical information about the My Health Record System to key audiences;
- assess the effectiveness of targeted communications, and education and training for healthcare providers; and
- test implementation approaches.

Trials of opt-out participation arrangements will be conducted in:

- North Queensland Primary Health Network area; and
- Nepean Blue Mountains Primary Health Network area.

The Minister will make My Health Records Rules to apply the opt-out arrangements to the selected areas. The Minister must consult with the Australian Health Ministers' Advisory Council (comprising the heads of each state and territory health department) before making these Rules.

The Bill provides that the Minister can make My Health Records Rules to implement opt-out nationally, but only if:

- the opt-out model has been applied to a trial; and
- the opt-out trial improves participation to a degree that it is improving the value of the My Health Record system.

An independent evaluation of the trials will be undertaken in 2016 and will inform consideration by the Government in early 2017 on whether to proceed to national implementation. The Minister will be required to consult with state and territory health ministers before making the Rules necessary to execute such a decision.

Outside of the opt-out trial locations, the My Health Record system will continue to operate on an opt-in basis in all other areas.

Creating My Health Records in opt-out trial areas

The process leading to the creation and filling of a record as part of the opt-out trials will include:

- a letter being sent to inform eligible participants about the trial including how to opt-out prior to the commencement of the opt-out period;
- information that the opt-out period will operate for eight weeks. Participants will be able to notify their preference to not have a record through online, telephone and in-person channels;
- a confirmation letter will be sent to participants who advise they do not wish to have a record;
- the System Operator will take two weeks to create the approximately 1 million records. This will include a reconciliation process to ensure that people who have chosen to opt-out of having a record or are no longer eligible do not have one created;
- participants will have approximately four weeks to set access controls before the record is able to be viewed or added to by healthcare providers;

- records will only start to be filled with information after the participant has had an opportunity to set access controls;
- the first time a participant accesses their record they will be provided with simple instructions to help them set access controls and notifications including contact details. They will also be able to set preferences such as the loading of Medicare information; and
- healthcare provider organisations will be able to access and upload information to the records at the conclusion of the four weeks provided for participants to set access controls.

The process has been developed to minimise the risk of a participant having a record created for them without their knowledge. Participants will be able to cancel their record at any time if they choose.

The process has also been designed to cater for those people who have difficulties in coping with bureaucratic processes to ensure it is highly accessible and easy to understand so that they are able to exercise their right to opt-out without unnecessary complexity. While phone and online channels are expected to cater for the majority of individuals, the Department of Health is working to ensure that alternative processes will be available to all individuals including those needing additional support or with limited documentation.

Risk

Even with all the communication activities and safeguards in place to ensure participants can exercise choice, there is a possibility that a person who is eligible for the opt-out trial remains unaware of the trials existence and has a record created for them (and information has flowed into the record and healthcare providers can view it) without their knowledge.

To minimise these circumstances the following mitigations will be in place:

Mitigation 1: Communication strategy to inform people about the opt-out trials

Individuals living in an opt-out trial location will be given a reasonable amount of time to learn about the My Health Record system, and decide whether or not to opt-out, before a My Health Record is created for them.

A communication strategy to inform people about the opt-out trials and what it means for them is currently being developed. Key features of this strategy are:

- Minister's launch of the My Health Record (subject to the Bill being passed);
- updating of the eHealth website to include information about the opt-out trials;
- updating of information about the My Health Record programme, including that which is specific to the opt-out trials;
- the inclusion of information and articles in consumer peak body/disease association specific newsletters about the My Health Record programme, and in particular information to assist carers of people who need assistance to manage their record;
- education and training for healthcare providers about the My Health Record Programme;
- a letter to each person living in an opt-out trial location prior to the commencement of the 'opt-out' period informing them of the trials and how to opt-out if they so choose;

- targeted information, content and articles for distribution to carers and other associations and advocate groups;
- a letter to each person who opts-out to confirm they have opted out of the My Health Record system during the opt-out period;
- tailored information to meet the specific needs of each opt-out trial location community, including the availability of accessible culturally and linguistically diverse materials, working with vulnerable groups and considering the needs of rural and remote communities; and
- working with the state/territory governments involved in opt-out trials to ensure the appropriate communication or action is taken in respect of individuals in protection or custody.

Mitigation 2: Ensuring the opt-out process is as simple as possible for as many people as possible

Individuals who choose to opt out will be able to do so online, in person or by phone. The opt-out process will be as easy as possible and address common challenges faced by people in engaging with government.

The process leading to the creation and filling of a record as part of the opt-out trial has been designed to ensure it is highly accessible, easy to understand and caters for those people who have difficulties in coping with administrative processes so that they are able to exercise their right to opt-out without unnecessary complexity.

While phone and online channels are expected to cater for the majority of individuals, the Department of Health is working to ensure that alternative processes will be available to all individuals including those needing additional support or with limited documentation.

Mitigation 3: Mechanisms to alert people to the creation or use of their record

Anyone who has a record has the ability through online, phone, walk-in or mail channels to request the cancellation of their My Health Record. To exercise this right they need to know that they have a record. For those who opt-in this is a given. For those who have a record created as a result of an opt-out process this is being designed through consultation with individuals.

There are no specific measures proposed or in place to alert someone who is unaware that they have a record that it exists or is being used. Options being considered are:

- a letter is sent to them upon initial creation of the record; and/or.
- the provision of notices for display in healthcare settings and community noticeboards advising people of the existence of the trial and what to do if they don't want a record (either before or after its creation).

Populating a My Health Record

As part of the opt-out trials, Medicare documents (Medicare Benefits Schedule and Pharmaceutical Benefits Scheme claims information, Australian Childhood Immunisation Register and Australian Organ Donation Register information) will begin flowing into automatically created records upon *first access* of the My Health Record (view, not upload) by a healthcare provider after the access control setting period has concluded and if an individual has not already set their preferences.

The first time an individual accesses their record they will be presented with information on default document preferences, notifications and access controls, this will include instructions on how to set these controls and what will happen if they do nothing (or what would have occurred if first access by an individual is after the access control setting period).

During the access control setting period (four weeks), healthcare providers will not have access to records and the uploading of Medicare or clinical documents will not occur. Following the end of this access control setting period, clinical document uploads will be permitted by the system.

Once a healthcare provider accesses (views) the record, this will trigger *first access* by a provider and if Medicare document preference settings have not already been applied by the individual, default settings will be applied to the record (which means all Medicare documents will be uploaded including two years' of historical documents).

6. Scrutiny of Bills

On 14 October 2015 the Senate Standing Committee on the Scrutiny of Bills released its Alert Digest No. 11 of 2015 which included its examination of the Bill.

The Committee sought advice regarding:

- certain matters that are proposed to be addressed in delegated legislation and whether it is appropriate to do so;
- imposing evidential burden on individuals;
- enabling legislative instruments to incorporate written instruments; and
- a Henry VIII clause (providing that delegated legislation may modify the operation of an Act).

Matters in delegated legislation

The Committee noted that proposed sections 20 and 25D of the HI Act broaden the power to allow for future regulations to be made allowing prescribed entities to collect, use, disclose and adopt identifying information and healthcare identifiers. In light of the explanation provided by the explanatory memorandum, the Committee left the question of whether the proposed approach is appropriate to the Senate as a whole.

In 2014 the HI Act was amended to allow use of healthcare identifiers as part of the Aged Care Gateway, which is a centralised online information resource for individuals seeking access to aged care services. The amendments permitted the verification of aged care clients' identities, and the creation and maintenance of uniquely identifiable aged care client records. Identity verification and the protection of both client privacy and the integrity of Commonwealth systems were enhanced through the use of healthcare identifiers. In the future, it is intended that (with appropriate consent), aged care clients registered in the Aged Care Gateway system (who are also registered in My Health Record system) will be able to make relevant components of their aged care client record (including assessment outcomes and a summary of their services plan) accessible to healthcare professionals (who are participating in the My Health Record system). Establishing the key building blocks such as adoption of the healthcare identifier in the Aged Care Gateway system was an important step to enabling appropriate access to health-related information.

Individuals who are recipients of health-related or health-reliant services, such as aged care, disability or cancer screening, are clients of the health system and are in a category where they would benefit from having a My Health Record. Under an opt-out system, they would have a My Health Record unless they choose to opt-out. The use of healthcare identifiers can enable an individuals' health information to be shared in a manner that enables high identity integrity across the services. In the same way that the Aged Care Gateway can utilise healthcare identifiers to ensure accurate identification of individuals and their aged care records, entities that provide other appropriate health-related services and their clients may be able to benefit from use of healthcare identifiers to accurately identify individuals and their records.

These entities could include, for example, the National Disability Insurance Agency (NDIA) and the national cancer screening registers, or other health related services that are not registered with a Healthcare Provider Identifier for their Organisation (HPI-O). Healthcare identifiers are an accurate identifier of an individual, and such entities and individuals may benefit from the entity being able to associate health-related records with an individual's healthcare identifier. In the future this may allow, for example, the viewing of certain disability or cancer screening information as part of an individual's My Health Record (as is planned in connection with the Aged Care Gateway). Currently, entities such as NDIA are not authorised to handle healthcare identifiers or identifying information as they are not healthcare providers within the meaning of the HI Act.

Proposed new sections 20 and 25D of the HI Act allow for future regulations to be made allowing prescribed entities to collect, use, disclose and adopt identifying information and healthcare identifiers. However, there are strict limits on the ability to make regulations for these purposes. In summary, regulations may only be made authorising the collection, use or disclosure of identifying information and healthcare identifiers for purposes related to the provision of healthcare or to assist people who, because of health issues including illness, disability or injury, require support.

The proposed new regulation-making powers have been designed to allow the appropriate collection, use, disclosure and adoption of healthcare identifiers and identifying information by entities like NDIA and the national cancer screening registers, without having to amend the Act each time a new entity needs to be authorised as was necessary with the Aged Care Gateway. Given that the NDIA and the national cancer screening registers may wish to handle identifying information and healthcare identifiers over the next couple of years to improve healthcare and health-related services supplied to individuals, the ability to authorise this in regulations will allow timely authorisation without the need to amend the HI Act each time.

Any regulations made authorising other entities to collect, use and disclose identifying information and healthcare identifiers will be subject to Parliamentary scrutiny and disallowance.

These changes also reflect the more holistic view of health services that is being taken through changes to the definition of "health service" in the *Privacy Act 1988*, and go directly toward enabling a more integrated and cooperative healthcare sector.

The Committee also noted that Part 1 of new Schedule 1 of the My Health Records Act provides for rule-making powers which would allow the Health Minister to make rules that will facilitate trials of an opt-out system for healthcare recipients. Further, it noted that Clause 2 of Part 1 of Schedule 1 includes a rule-making power which would allow the Health Minister to make rules to apply the opt-out participation arrangements nationally. Before

doing so the Minister would be required to consider the evidence obtained through the trials and any other matter relevant to the decision (subclause 2(2)) and to consult the Ministerial Council (subclause 2(3)).

The Committee noted that the explanatory materials made a strong case for undertaking trials of an opt-out system, however the Committee sought justification as to why it is appropriate to allow a Minister to implement opt-out nationally through a legislative instrument rather than the matter being considered by Parliament and the change being made through an amendment to the primary legislation.

The Bill ensures that strong and significant privacy protections will continue to exist under the current opt-in arrangements, and will apply under the proposed new opt-out arrangements (whether as part of a trial or under national implementation). These protections include the ability to do the following for all people registered with the My Health Record system:

- set access controls restricting access to their My Health Record entirely or restricting access to certain information in their My Health Record;
- request that their healthcare provider not upload certain information or documents to their My Health Record, in which case the healthcare provider will be required not to upload that information or those documents;
- request that their Medicare data not be included in their My Health Record, in which case the Chief Executive Medicare will be required to not make the data available to the System Operator;
- monitor activity in relation to their My Health Record using the audit log or via electronic messages alerting them that someone has accessed their My Health Record;
- effectively remove documents from their My Health Record;
- make a complaint if they consider there has been a breach of privacy; and
- cancel their registration (that is, cancel their My Health Record).

As part of the trials, arrangements for opting-out will be tested to ensure that individuals who do not wish to have a record are able to communicate that wish as simply and easily as possible. Opt-out trials will be accompanied by extensive information covering a range of channels, and targeted at all relevant individuals in the trial areas including healthcare recipients, parents, guardians and carers. If a Government decision is made to implement opt-out nationally, a similar strategy would precede the opt-out period ensuring that individuals are able to make an informed choice about whether or not to opt-out.

The Bill proposes that, before the Health Minister makes a decision to implement opt-out nationally, they must consult with the Ministerial Council – that is, the COAG Health Council. The states and territories are central to the success of the My Health Record system, regardless of whether the system is opt-in or opt-out, given that their public health systems will be one of the major healthcare provider participants in the system. If a decision is made to implement opt-out nationally, that decision will be of great interest to states and territories as it will also affect their citizens. In practice, national implementation of opt-out will not occur unless states and territories support the implementation.

Finally, any Rule made implementing opt-out nationally would be subject to Parliamentary scrutiny and disallowance.

Given that the privacy and security arrangements for registration apply equally to opt-in and opt-out arrangements, and the authorisations for collection, use and disclosure of information

necessary to implement opt-in and opt-out are clearly set out in the Act (opt-in) and in the Bill (opt-out), the parameters of the proposed opt-out arrangements are clear. This is true whether opt-out is implemented as part of a trial in limited geographic areas, or as part of implementing opt-out nationally. As noted above, there are significant privacy protections built into the design of the system, and there will be a comprehensive communications strategy as part of any move to opt-out.

Given these circumstances, the Department considers that Parliament has sufficient information in the Bill to assess the opt-out arrangements now, including whether the proposed opt-out arrangements appropriately balances the systemic and population-wide benefits of the My Health Record system with the important interest individuals have in managing the privacy of their health information. As a result, the Department considers that it is an appropriate delegation of power for the Bill to allow the Health Minister to make a Rule implementing opt-out nationally, provided that they first follow the procedural and consultation requirements in the Bill.

Evidential burden

The Committee noted that proposed section 26 provides that the use or disclosure by a person of any information obtained under the HI Act, or a healthcare recipient's or individual healthcare provider's healthcare identifier, is prohibited unless an exception in proposed subsections 26(3) or 26(4) applies. It further noted that significant civil and criminal penalties apply for contravention of this provision and that there is no justification in the explanatory memorandum for placing an evidential burden on the defendant. The Committee therefore sought advice as to the rationale for the proposed approach, including whether the approach is consistent with the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (September 2011).

Proposed new subsections 26(3) and (4) provide exceptions to the prohibition against misusing healthcare identifiers and identifying information in subsection 26(1) of the HI Act. In doing so, subsections 26(3) and (4) reverse the burden of proof by providing that the defendant bears an evidential burden when asserting an exception applies.

An evidential burden placed on the defendant is not uncommon. Similar requirements to those used in the Bill exist in many other pieces of Commonwealth legislation (for example, subsection 3.3 of the *Criminal Code Act 1995* – where a person has an evidential burden of proof if they wish to deny criminal responsibility by relying on a provision of Part 2.3 of the Criminal Code).

In accordance with the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*, the facts relating to each defence in proposed new subsections 26(3) and (4) of the HI Act are peculiarly within the knowledge of the defendant, or could easily be obtained by the defendant, and could be extremely difficult or expensive for the prosecution to disprove whereas proof of a defence could be readily provided by the defendant.

A burden of proof that a law imposes on a defendant is an evidential burden only (not a legal burden), and does not completely displace the prosecutor's burden.

Proposed subsections 26(3) and (4) simply require a person to produce or point to evidence that suggests a reasonable possibility that any of the exceptions in those provisions apply to the person.

The evidential burden in each of these circumstances covered by proposed subsections 26(3) and (4) can easily be met. In these circumstances, therefore, the imposition of an evidential burden on the defendant is reasonable.

Incorporation of written instruments

The Committee noted that proposed subsection 109(9) of the My Health Records Act allows the My Health Records Rules (delegated legislation) to incorporate other material which may change from time to time. The Committee has concerns with such provisions and sought advice as to whether a requirement that any material incorporated by reference be freely and readily available can be included in the Bill itself.

The materials that will most likely be incorporated in the My Health Records Rules are IT security-related documents, like the *National eHealth Security and Access Framework*, and registered healthcare provider organisations would be required to use software that is compliant with this framework if they wish to connect to the My Health Record system. These requirements are typically technical in nature and complex, detailing IT-related security measures. The requirements may quickly and at relatively short notice change to address emerging IT security threats. It is important to be able to deal with rapidly changing IT security threats in a responsive manner that also allows requirements to be enforced. If this does not occur, the security risks to the My Health Record system will increase given the large number of interconnecting healthcare provider organisations (currently more than 7,000 and expected to increase substantially with the trial of opt-out arrangements). A failure by healthcare provider organisations (or repository or portal operators) to comply with IT security requirements may put individuals' health information at increased risk.

While mentioned in the explanatory memorandum to the Bill as one of the types of document that may be incorporated by reference, at this stage it is considered less likely that Australian standards will be incorporated by reference into the My Health Records Rules.

As the Committee is aware, the power to incorporate material by reference is also constrained by principles relating to the sub-delegation of powers and the requirement that a legislative instrument must be within the clear authority of the enabling legislation. My Health Record Rules that incorporate material by reference must meet the requirements in section 109 of the Act (as amended by the Bill).

Where materials are incorporated into subordinate legislation by reference, it is important that affected entities and individuals be made aware of any proposed changes to the material incorporated given that it affects the content of the law. For this reason, amendments proposed in the Bill are designed to increase the ability of the System Operator of the My Health Record system to communicate electronically with all participants (registered healthcare provider organisations, contracted service providers, portal operators and repository operators) as well as individuals (that is, registered healthcare recipients) where this is appropriate. There would be no cost for the public associated with accessing IT security materials that are incorporated into the My Health Records Rules. In addition, other channels will also be employed to ensure affected parties are aware of any changes to materials that have been incorporated by reference. For example, publishing details on the System Operator's website and making hard-copies of the material available free of charge.

The Department of Health will make every effort to ensure that incorporating material by reference in My Health Records Rules is only done where necessary and appropriate.

Henry VIII clause

The Committee has noted that subitem 136(3) of the Bill makes express provision for rules (delegated legislation) made for the purpose of subitem 136(2) to modify the operation of the HI Act, PCEHR Act and Privacy Act. This provision is referred to as a ‘Henry VIII clause’, in that it may allow the Health Minister to modify the operation of the specified Acts by making rules. The Committee sought more information, and examples of possible circumstances in which the power could be needed, to assist the Committee in understanding why the clause is necessary.

Subitem 136(3) has been included in the Bill to allow the Minister to deal with any unintended or unforeseen circumstances that may arise in the future, in particular as part of transitional arrangements in relation to opt-out and in relation to changes of governance arrangements as governance mechanisms for the My Health Record system are moved out of the My Health Records Act and subordinate legislation and into rules proposed to be made under section 87 of the PGPA Act.

As the purpose of the provisions is to assist with unintended or unforeseen circumstances, it is difficult to provide specific examples of when the rule-making power may be used. However, possible circumstances may include where certain My Health Records Act governance mechanisms need to be retained for a short period after “governance restructure day” (as defined in the Bill) to ensure appropriate mechanisms remain in place until the Australian Commission for eHealth becomes fully operational.

Henry VIII clauses are not uncommon as part of transitional arrangements. Item 136 in the Bill is modelled on a very similar provision in the *Governance of Australian Government Superannuation Schemes Legislation Amendment Act 2015* – see Item 22 of Schedule 2 of that Act.

As a disallowable instrument, any Rules made under subitem 136(3) would be subject to Parliamentary scrutiny and would be open to disallowance. Subitem 136(4) limits the types of rules that the Minister is able to make under item 136.

7. Consultation on opt-out

Stakeholder consultation on the recommendations of the PCEHR Review was undertaken between July and September 2014.

Thirty-seven face-to-face workshops with large and small groups were held. A small number of group teleconferences with selected stakeholder groups unable to attend the workshop sessions also supplemented the consultations. The workshops included a range of stakeholders including individuals, healthcare providers, health software vendors, private health insurance providers, medical indemnity insurance providers, private hospitals and Indigenous community health workers. An online survey was also used to capture the views of stakeholders. A report on the consultation has been published on the [Department of Health website](#).

In May and June 2015 the *Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper* was available for public consultation. The Legislation Discussion Paper provided a plain English description of the proposed changes to the legislative framework to encourage discussion. 137 submissions were received. These are available on the [eHealth website](#) (except those that were marked as confidential). In addition, three stakeholder briefings were conducted with more than 100 representatives of stakeholder groups including

individuals and healthcare providers. The feedback received has informed the development of the legislative changes proposed by the Bill, and is also informing system and communications development, as well as planning for the trials of participation arrangements.

State and territory health ministers and their departments were given the opportunity to consider and provide feedback on exposure drafts of the Bill in July and August 2015.