Overview of submissions

Purpose

The purpose of this document is to provide an overview for governments of stakeholders' support of, or concerns about, the proposed legislative changes to the personally controlled electronic health record (PCEHR) system and Healthcare Identifiers Service.

This report identifies major themes and issues raised in the submissions. The report primarily focuses on the feedback that directly relates to the proposed legislative changes, but it also highlights issues raised about the system more broadly.

There is a wealth of information contained in the submissions which have been published to allow for deeper scrutiny, and they will be used to inform stakeholder engagement and implementation planning.

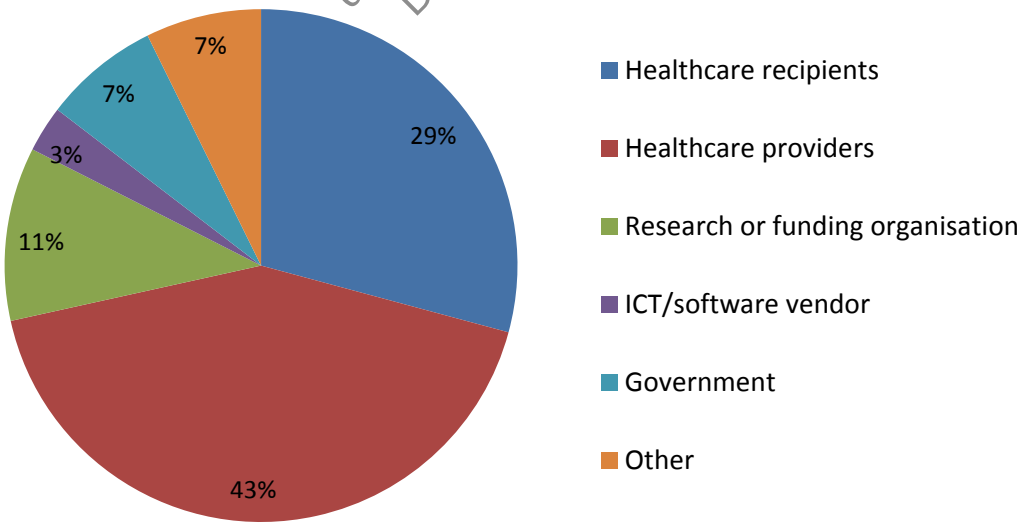
The report also identifies where the Department is revising is proposed legislative changes in response to the feedback received.

Overview

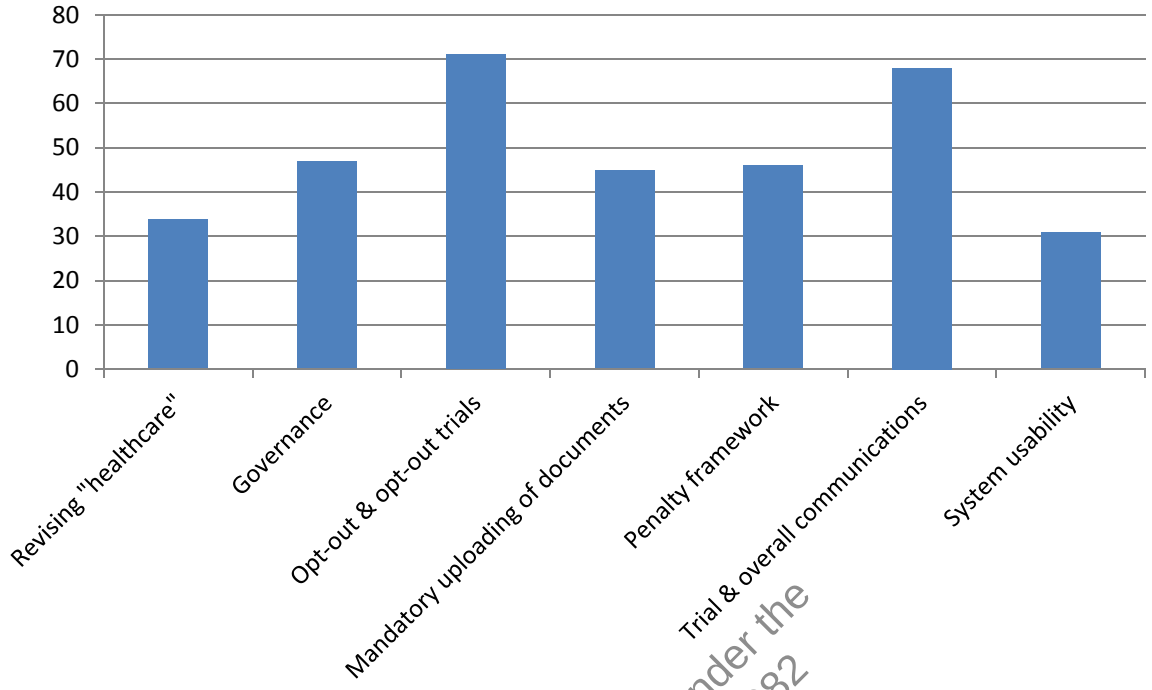
A total of 137 submissions were made on the *Electronic Health Record and Healthcare Identifiers: Legislation Discussion Paper*. Of these 128 submissions were published online and 7 submissions were confidential and were not published. There were 2 duplicate submissions.

The graphs below show the distribution of the responses and themes for each of the stakeholder groups identified.

Graph 1: Types of entities making submissions



Graph 2: Number of submissions addressing legislative & other issues



General comments

More than seventy submissions were openly supportive of an eHealth record system, acknowledging the benefits to healthcare recipients, healthcare providers and carers. Support was provided from a range of stakeholder groups including consumer, healthcare provider and carer representatives.

Less than ten submissions were critical of implementation of an eHealth record system objecting on the basis of privacy concerns. Criticism of an eHealth record system was largely from individuals.

Many of the remaining submissions did not express a position for or against an eHealth record system but commented on particular issues, generally implying support for the system.

Many of the submissions addressed issues relevant to the way the system is or should be that were not related to the proposed legislative changes. Almost every submission raised one or more questions for clarification. A notable number of submissions demonstrated some degree of misunderstanding as to how the PCEHR system currently operates.

Where submissions comment on other aspects of the PCEHR system or HI Service, those comments will be made available to departmental officers responsible for those aspects so that they can be taken into account for future development activities.

Revising “healthcare”

It is proposed that the definition of “healthcare” be clarified to remove doubt that it includes health related disability, palliative care or aged care services. It will include the assessment and treatment of injury, in addition to the assessment and treatment of illness and disability. It will permit regulations to be made to exclude specific activities from being considered part of healthcare.

Key issues raised in the submissions

Of about thirty submissions that commented on this proposal, most submissions clearly supported the proposed changes. Supporters were healthcare recipients, healthcare organisations, peak bodies and government agencies.

Some submissions requested further information about why this change was necessary and why aged care and disability services require specific mention, while two submissions made suggestions to further amend and expand the definition by including "preventative" and "psychosocial" activities.

Some submissions consider that this term should include a consumer's "wellness" and considered that health and fitness information captured by personal devices, such as a Fitbit, should be considered health information.

One private health insurance organisation did not support the change on the basis of concern that it would allow regulations to be made which would not allow them to access the PCEHR system.

Changes proposed to address issues

The definition of "healthcare" already includes preventative health measures, such as immunisations. There are concerns that including "psychosocial" activities would result in a much broader range of information being included and a wider array of organisations having access than intended.

Health and fitness information captured by personal devices does not need to be considered health information under the law to be able to be recorded and shared as part of an individuals' health record.

No legislative changes are proposed in response to the issues raised.

Governance

It is proposed that:

- an Australian Commission for Electronic Health (ACeH) be established as a new corporate Commonwealth entity through rules made under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act);
- the ACeH Board and its advisory committees include individuals with expertise in healthcare provision, consumer of health services, IT systems and innovation including health informatics, governance, clinical safety, and privacy and security; and
- the legislation provide flexibility for the Healthcare Identifiers Service Operator to be a different entity in the future.

Key issues raised in the submissions

Nearly 35 per cent of submissions commented on the establishment of ACeH. Comments mainly related to the need for representation of a wide range of stakeholders. Across the submissions it was suggested the ACeH Board and/or advisory committees include representation from stakeholder groups including:

- people with an intellectual disability or communication impairment (separate to other people with a disability);
- community service providers including aged care and disability services;
- rural and remote healthcare providers and consumers;
- a range of health professions including midwifery, optometry, dentistry and speech pathology;
- health information management (not exclusively technical in nature);
- research;
- user experience design and usability;
- private hospitals; and
- health insurers.

Some concerns were raised regarding individuals being assigned to the ACeH Board but not specifically tasked to represent particular groups. It was suggested that for stakeholders such as

consumers, a representative from a peak body may be more suitable than a specific individual to have a position on the ACeH Board.

Some submissions requested clarity and transparency around the process for appointment to the board and offered support regarding appointment of a suitable representative for their area.

Additional information on how ACeH would work with jurisdictions to ensure integrated systems and eHealth leadership was also requested in submissions.

There was some confusion around the appointment of an independent advisor to the Minister on the My Health Record. Some submissions understood that the independent advisor would be replacing the current Independent Advisory Committee which is intended to provide input to system design and operation from healthcare providers and consumers, and therefore such input would be absent.

The scope of ACeH's role was generally not commented on. Some submissions suggested it should be responsible for facilitating innovation to realise the potential of eHealth. One submission also suggested roles relating to clinical safety oversight and complaints handling should be handled by an independent organisation to ensure transparency.

Few submissions commented on the potential future transition of the HI Service Operator to another entity. Most of the submissions that provided comment were supportive of, and encouraged, flexibility being built into the legislation.

One submission did not support this proposal on the basis that it was unjustified and open-ended, and recommended that any change to the HI Service Operator be made not through subordinate legislation but as an amendment to the HI Act.

Changes proposed to address issues

The role of ACeH, the membership of its Board and advisory committees, and the process by which those members are to be appointed, are expected to be prescribed in rules made under the PGPA Act that would establish ACeH's legal basis. An implementation taskforce steering committee has been established to carefully consider these matters in consultation with key stakeholders. The subsequent recommendations will form the basis of the rule to establish the ACeH.

No legislative changes are proposed in response to the feedback received.

Opt-out & opt-out trials

It is proposed that trials of different participation models, including opt-out, be conducted to inform future Government decisions about maximising participation in the system, and that the legislation allow subordinate legislation to be made that would support the opt-out trial locations. This mechanism would allow opt-out to be implemented nationally should such a decision be made by Government.

It is also proposed that, since consent cannot be obtained in an opt-out system, the legislation provide authority for the registration of consumers who do not opt-out (or previously cancelled their PCEHR) and for healthcare provider organisations and Medicare to upload documents to a consumer's PCEHR.

Key issues raised in the submissions

National opt-out

About half of the submissions commented on national opt-out arrangements and, of these, about 85 per cent provided full or conditional support, representing a fairly even split between healthcare providers and consumers.

For those submissions providing conditional support, privacy and security of patient information was of highest concern to stakeholders, and the need for simple and extensive communication and

education was most frequently advised, particularly in relation to the needs of vulnerable people. The importance of evaluating opt-out trials to refine the system and supporting processes prior to national roll-out was also noted in some submissions.

Additional comments included:

- **Communication and education:** communication and education for consumers needs to be both extensive and simple. We should ensure sufficient information is available, including the implications of an opt-out system, to inform decisions on whether to opt-out, in language that is tailored for all Australians – including, but not limited to, people with limited literacy skills, intellectual disabilities and visual impediments, socially disadvantaged, and culturally and linguistically diverse populations.
- **Process of opting out:** needs to be easy. We should consider providing a range of options to opt-out in addition to a computer-based process. It is important to acknowledge the consumer's opt-out request.
- **System design:** a simplified login is needed for consumers. Further work is required into how data is received, structured and formatted. The system should be accessible for visually impaired people, and it should flag where a record has been amended or hidden.
- **Privacy and security:** concerns were expressed regarding violation of privacy and doctor-patient confidentiality. There should be appropriate protection of patient information to prevent misuse. It is important to consider patient access controls in terms of safety and quality of care versus protection of medical information. We must ensure authorised representative accessibility to a consumer's health information and ensure representatives have appropriate authority to act for consumers.
- **Interaction with state and territory laws:** some questions were raised as to the effect of local laws on the operation of opt-out trials in certain states.

One submission considered that an opt-out system would increase the risks associated with integrity of Medicare data.

Of the remaining submissions opposing national opt-out arrangements, the majority cited privacy and security concerns as the main reason. A few submissions opposed national opt-out due to concern for Australians with limited means or ability to comprehend communication and information regarding opt-out.

Questions raised were largely regarding accessibility of health information by authorised representatives, with one submission questioning the interaction with state-based guardianship laws. Clarification was also sought on data procedures when an individual chooses to opt-out after records have been created.

Opt-out trials

Submissions demonstrated overwhelming support for trialling opt-out arrangements, with many expressing the same concerns regarding privacy and targeted communication as for national roll-out.

Additional population groups were identified specifically in relation to trials that will require further consideration and targeted communication, including Aboriginal and Torres Strait Islanders, carer-dependent consumers, and consumers with a diminished capacity to make informed decisions.

Common feedback on opt-out trials included:

- both the opt-out trial duration and length of time to opt out, particularly for remote locations and people with intellectual disabilities, should be longer;
- strong support for targeted information, support, incentives and ability for wider scope of allied health professionals to upload records;

- trial sites should align with Primary Health Networks so they can better support healthcare providers in trial sites;
- trials should involve a large cross-section of Australians, for example, those in rural regions, culturally and linguistically diverse groups, Aboriginal and Torres Strait Islanders, and those with intellectual disabilities and visual impediments;
- opt-out arrangements should be trialled for healthcare as well as consumers in selected sites;
- concerns with using Medicare addresses to determine which individuals are in trial sites; and
- the need for clear communication to ensure an understanding of the arrangements for consumers who move into a trial site, or newborns born in trial sites, after trial commencement.

One submission suggested future education and awareness campaigns, encouraging consumers to revisit their PCEHR to check whether it is being used and populated.

Changes proposed to address issues

A robust and comprehensive communications campaign is critical for an effective trial of opt-out participation. Further, efforts must be made to provide support, including training and incentives, to the broad range of healthcare provider types. A contractor has been engaged for the provision of training materials for healthcare provider training and education, which will include training for healthcare providers in the trial sites. This is discussed in more detail in the section *Trial & other communications*.

In June 2015 Health Chief Executive Officers considered opt-out trial site selection and agreed on the criteria that should be used to guide the selection of the opt-out trial sites. The criteria for selecting trial sites includes that the location include a range of population groups including Aboriginal and Torres Strait Islanders and culturally and linguistically diverse communities, and has strong clinical networks such as Primary Health Networks. The criteria have been published at www.ehealth.gov.au.

State and territory health ministers have been invited to propose possible trial sites in their jurisdictions for opt-out participation arrangements, and the Department is considering the proposals provided.

The Department will engage an independent evaluator to undertake a robust evaluation of the participation trials to inform future decisions about, and optimal approaches for, increasing individual participation and meaningful use of the system.

In respect of the use of a Medicare address to identify trial participants, the Department recognises the issues associated with a Medicare address but considers that the risks are known and can be responsibly mitigated.

No legislative changes are proposed in response to the issues raised.

Mandatory uploading of documents

It is proposed that amendments be made to the *Health Insurance Regulations 1975* to require that payment for Medicare items relating to health assessments, comprehensive assessments, mental health plans, medication management reviews and chronic disease planning items depend on the uploading of specific documents to the PCEHR system.

These changes are not intended to have any adverse impact on individuals. Nor are the changes intended to override:

(a) personal controls that are available to individuals, such as the right to direct a healthcare provider to not upload a particular document; or

(b) a healthcare provider's discretion to not upload a particular document – e.g. because to do so may not be in the interests of the individual.

Care will be needed in linking payment to the uploading of certain documents to ensure these types of controls are not overridden.

Key issues raised in the submissions

About a third of submissions made comments about the proposal to link Medicare payments to the upload of information to the PCEHR system, and of these about 60 per cent of submissions were made by healthcare providers.

There were eight submissions supporting the proposal, by healthcare providers, consumers and a research or funding organisation. Some support was conditional on the ability of allied healthcare providers having the capability to upload documents and universal use of the system.

Six submissions objected to the proposal on the basis of potential adverse effects on the consumer and/or healthcare delivery given the sensitive nature of the information and the consumer's right to choose not to have the information uploaded.

Half of the submissions that commented on the mandatory uploading of documents asked questions or sought clarification about the proposal, how it would operate and what exemptions should be provided. Six submissions identified alternatives, such as:

- providing a rebate specifically for uploading summaries;
- that other clinically relevant information, or a note that the assessment was conducted, could be uploaded at the time of the assessment instead of the assessment;
- a rebate when a provider checks whether the consumer has a PCEHR and, if so, uploads documents to it.

Some submissions identified that alternatives were required for organisations that don't claim Medicare rebates. Two submissions proposed that hospitals should be similarly required to upload discharge summaries and that all Medicare and Pharmaceutical Benefits Scheme rebates should be dependent on uploads.

A few submissions noted that this proposal would change the medico-legal landscape and further legal consideration would be required.

While a few of the submissions that commented on this proposal considered that there should not be any exceptions to the requirement to upload documents, a majority of them consider that proposed exceptions that uploading would not be required if:

- the consumer does not have a PCEHR;
- the consumer instructs the provider not to upload the document;
- the consumer objects to the opinion set out in the document; and
- the provider considers that uploading the document could cause harm.

One submission considered that "when" general practitioners desert the PCEHR system, they will impose a significant fee on consumers who want their information uploaded to the PCEHR system.

A few submissions indicated that uploading would be more likely to occur if there was a dedicated Medicare item to account for the extra time taken to prepare/upload documents to a PCEHR.

Changes proposed to address issues

The Government will consider any changes to Medicare payments in the context of the current Medicare Benefits Schedule Review and the work of the Primary Health Care Advisory Group.

In response to the issues raised no legislative changes are proposed to be introduced at this time. The comments provided in these submissions will be considered in the development of the legislation.

Penalty framework

The discussion paper sought feedback on the question of penalties and whether:

- serious misuses of PCEHR information should be subject to criminal penalties while retaining civil penalties for less serious breaches; and
- misuse of healthcare identifiers should continue to be a criminal offense or whether civil penalties should be introduced for less serious breaches.

Key issues raised in the submissions

About a third of submissions commented on whether consideration should be given to increasing the range of enforcement and penalty options currently available for the misuse of PCEHR information and healthcare identifiers. Comments were mainly made by healthcare providers, but also included consumers, research and funding organisations, and state and Commonwealth Government agencies.

The submissions that provided comment on this matter were divided around support for criminal penalties, with half the submissions supporting criminal penalties for serious misconduct or unauthorised use or disclosure of information in the PCEHR system. Twenty per cent of the submissions commenting on this proposal opposed the introduction of criminal penalties. The remaining submissions did not provide a clear position on support for criminal penalties.

Those who supported the introduction of criminal penalties emphasised that these should only be applied to serious misconduct and not genuine or unintentional breaches. The proposed graduated framework was generally supported as it allowed for penalties appropriate to the situation.

Some healthcare provider peak bodies did not support the introduction of criminal penalties. They raised concerns that the introduction of criminal penalties would be a further deterrent to participation by healthcare providers. A medico-legal insurer also did not support criminal penalties.

Consumers and their representative peak bodies supported the introduction of criminal penalties. However, few submissions from these groups commented on this matter.

A Commonwealth Government agency supported criminal penalties in addition to civil penalties but noted that even without criminal penalties, the Office of the Australian Information Commissioner's powers such as complaint conciliation, enforceable undertakings and determinations provide a range of appropriate enforcement options.

Changes proposed to address issues

Given the degree of support for introducing criminal penalties, it is proposed that the enforcement options under the PCEHR Act and HI Act be aligned by providing for criminal penalties in addition to existing sanctions in the PCEHR Act, and civil penalties, enforceable undertakings and injunctions, in addition to current criminal penalties, in the HI Act. In line with normal practice, it is also proposed that civil penalties be more than those available under criminal provisions. This means that the civil penalties will be higher than currently available under the PCEHR Act, however they will be less than the maximum penalties set under the *Privacy Act 1988*.

Penalties will only be imposed if a person has intentionally contravened either Act. Penalties will not apply to individuals or entities that make a mistake, for example, if a healthcare provider accidentally opens the wrong PCEHR.

Other issues

Trial & overall communications

The most frequent issue raised in submissions was in relation to communications for the PCEHR system. A few submissions highlighted the failures of PCEHR communications to date, such as inconsistent information and general lack of promotion.

The most repeated comments on communications in relation to opt-out trials included:

- that information for consumers in trials 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, and how consumers can make complaints;
- that information be provided through various channels, not just mail, in various forms that are suitable to people with communication disabilities and who have low literacy skills, and is culturally and linguistically diverse;
- that consumer information be provided to healthcare providers to assist in their support of consumers;
- that information be suitable for consumers who require decision-making support, and help representatives assist in making those decisions;
- that support be provided to assist consumers in using the system and exercising access controls;
- that engagement with providers in trial sites commence as soon as possible, including training and education, to facilitate their participation in the system;
- that a guide for trials be developed for providers; and
- that clear information be provided to providers about their obligations.

Comments about overall system communications included, in addition to those matters listed above:

- that the system be suitable for a range of audiences (e.g. culturally and linguistically diverse, those with communication disabilities);
- that clear guidance information be provided regarding consumer use of the system, including access controls and the right to withdraw consent at any time for Medicare and provider uploads; and
- that clear guidance information be provided for providers on their obligation not to upload information at a consumer's instruction, and how that operates in practice.

Many submissions volunteered expertise, services and assistance to ensure communications are comprehensive and appropriate, and meet the needs of people, particularly consumers. Several submissions identified organisations that should be consulted in the development of communications material.

Response to issues

The Department will undertake a communications campaign to inform individuals in the trial sites about the trial. Education and training will also be provided to healthcare providers in the trial sites. A contractor has been engaged for the provision of training materials for healthcare provider training and education, which will include training for healthcare providers in the trial sites.

Communication activities will commence in advance of the opt-out trials to ensure individuals are fully informed about the benefits of eHealth, the privacy and security strengths of the system, and the process for opting-out if that is what they choose to do. Communication activities within the trial sites will be tailored to the information needs specific to that community. This will include the availability of accessible culturally and linguistically diverse materials, working with vulnerable groups and considering the needs of rural and remote communities.

No legislative changes are proposed in response to the issues raised.

System usability

A few submissions criticised the lack of useful information available in the PCEHR system and some submissions recommended alternative designs for the system.

Overall, the submissions highlighted the need for the system to:

- provide an easy to use login process and that a consumer portal should be made available independent of myGov which was considered overly complex;
- enable feedback and the reporting of clinical and non-clinical problems;
- be suitable to a range of audience needs, such as making it culturally and linguistically diverse and suitable for people with communication disabilities;
- enable uploads using the provider portal;
- include advanced care directives as they are considered a critical factor in care;
- keep pace with technology and be interoperable with mobile platforms, and support and encourage innovators such as app designers;
- enable a degree of access by researchers or inform consumers about how they can participate in research;
- better structure and present the information to make it more user-friendly and of more value to providers;
- better integrate with clinical systems to have less impact on workflows;
- make better use of alerts, such as making immediately clear whether someone has a pacemaker;
- engage with vendors to develop compliant software for other types of healthcare providers (e.g. allied health); and
- enable consumers to record additional types of information such as diet, alcohol consumption and smoker status.

A number of the submissions noted that this discussion paper was only consulting on legislative changes and that it was critical that consultation also be undertaken on the technical aspects of the system.

Response to issues

As part of the continued operation of the PCEHR system, improvements will be made to the system's access controls and the process for individuals to register and access their PCEHR.

Online and telephone channels will be provided for consumers to opt-out of the system, if they choose.

The system will continue to evolve and improve to be more user-friendly and better reflect the needs of consumers and healthcare providers.

Consultation and user testing of proposed system changes with consumers and various healthcare providers is planned prior to system changes being introduced.

No legislative changes are proposed in response to the issues raised

Next steps

The feedback on the Legislative Issues Paper and stakeholder consultations were taken into consideration in the development of the Health Legislation Amendment (eHealth) Bill 2015 which was introduced into Parliament on 17 September 2015, and is being taken into account in the development of subordinate legislation. Submissions are also informed the development of other components of the changes such as design of system changes, trial logistics and communications.