**EXPLANATORY STATEMENT**

**Issued by Authority of the Minister for Health**

***My Health Records Act 2012***

***My Health Records (Opt-out Trials) Rule 2016***

The *My Health Records Act 2012* (the Act) enabled the establishment of the My Health Record system (formerly referred to as the personally controlled electronic health record (PCEHR) system). The My Health Record system allows individuals and their healthcare providers to access their key health information online where and when they need it. A My Health Record is an electronic summary of an individual’s health records.

Due to the low numbers of healthcare recipients choosing to register with the My Health Record system, the Act was amended to allow for an opt-out model of participation to be trialed. Participation trials (including opt-out arrangements) are intended to inform future strategies for increasing uptake and meaningful use of the My Health Record system.

Schedule 1 to the Act:

* allows the Minister to make rules relating to an opt-out model;
* provides the authorisations necessary for opt-out trial regions to be selected;
* authorises the System Operator to collect, use and disclose identifying information and healthcare identifiers for healthcare recipients in order to register them for a My Health Record without the need for the healthcare recipient to first apply to be registered;
* authorises treating healthcare providers to upload health information to the My Health Record of a healthcare recipient, subject to any instructions from the healthcare recipient to not upload the information; and
* authorises healthcare provider organisations and other participants in the My Health Record system to collect, use and disclose health information in a healthcare recipient’s My Health Record as part of providing healthcare and for other authorised purposes.

The *My Health Records (Opt-out Trials) Rule 2016* (Opt-out Trials Rule) is made under subclause 1(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to theAct, which allow the Minister to make rules relating to opt-out trials.

The purpose of the Opt-out Trials Rule is to specify the classes of healthcare recipients who will participate in opt-out trials of the My Health Record system, unless they choose to opt‑out. The classes of healthcare recipients specified are those healthcare recipients who have a mailing address held by Medicare for correspondence with a specified postcode in Northern Queensland or in the Nepean Blue Mountains primary health network regions.

The Opt-out Trials Rule also specifies:

* the period of time a member of the prescribed class has to elect to not have a My Health Record created for them; and
* where the person is a member of the prescribed class and has not elected to opt-out of registration –the period of time the person has to make an initial election to not have their health information held by the Chief Executive Medicare disclosed to the System Operator.

Detail of the Opt-out Trials Rule is set out in the Attachment.

Subclause 1(3) of Schedule 1 to the Act provides that in making the Opt-out Trials Rule, the Minister must consult with the subcommittee to the Ministerial Council prescribed by the regulations. The Australian Health Ministers’ Advisory Council (AHMAC) is prescribed under regulation 5.1.1 of the *My Health Records Regulation 2012*. AHMAC was consulted about the proposed Opt-out Trials Rule in November 2015.

The Independent Advisory Council and Jurisdictional Advisory Committee were also consulted on the proposed Opt-out Trials Rule in November 2015. This consultation was undertaken in accordance with a current requirement of the Act (subsection 109(2)) which is proposed to be repealed around mid-2016.

All bodies supported the proposed Opt-out Trials Rule.

The Opt-out Trials Rule commences on the day after registration on the Federal Register of Legislative Instruments.

The Office of Best Practice Regulation has advised that a Regulation Impact Statement is not required (OBPR Reference 16442). A Regulation Impact Statement was prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to conduct opt-out trials, and is available at <http://ris.dpmc.gov.au/2015/07/21/proposed-changes-to-the-personally-controlled-electronic-health-record-system/>.

The Opt-out Trials Rule is a legislative instrument and is subject to the *Legislative Instruments Act 2003*.

**ATTACHMENT**

**Details of the** ***My Health Records (Opt-out Trials) Rule 2016***

**PART 1—PRELIMINARY**

1. **Name of Rule**

Rule 1 provides that the title of the Rule is the *My Health Records (Opt-out Trials) Rule 2016*.

1. **Commencement**

Rule 2 provides that the Opt-out Trials Rule takes effect on the day after the Rule is registered on the Federal Register of Legislative Instruments.

1. **Definitions**

Rule 3 provides the following definitions for terms in the Opt-out Trials Rule:

***Act***

References to the Act mean the *My Health Records Act 2012*.

***Medicare Address***

This term means the mailing address held by Medicare for correspondence with a healthcare recipient.

The note to rule 3 assists readers by making clear that other terms used in the Opt-Out Trials Rule are as defined in the Act.

**PART 2—TRIALS OF OPT-OUT REGISTRATION**

1. **Classes of healthcare recipients**

Rule 4 specifies the classes of healthcare recipients who will participate in opt-out trials of the My Health Record system, unless they choose to opt-out. The classes of healthcare recipients specified are those healthcare recipients who, on 3 March 2016, have a Medicare Address with a specified postcode in Northern Queensland or in the Nepean Blue Mountains primary health network regions.

Subclause 1(3) of Schedule 1 to the Act provides that in making the Opt-out Trials Rule the Minister must be satisfied that applying the opt-out model to the class, or classes, of healthcare recipients will provide evidence of whether the opt-out arrangements will result in participation in the My Health Record system at a level that provides value to those using the My Health Record system. As part of considering which areas were likely to provide the evidence required, the Minister consulted with states and territories and developed the following criteria for consideration as part of making a final decision:

* trial site population of approximately 250,000-500,000;
* clearly defined geographical area so there is no confusion as to whether people are included or not;
* ability to confine communications, including electronic media, to the site;
* demonstrated existing eHealth capabilities and utilisation of eHealth services across local health services including General Practice, pharmacy, aged care services, and at least one hospital;
* higher than average My Health Record uptake by providers;
* strong clinical networks with a demonstrated commitment to the success of the trial – including Primary Health Networks, Local Hospital Networks and any other relevant local health organisations within the trial site area;
* positive community engagement with, and local government commitment to, previous non-eHealth trials;
* not currently involved in, or minimal involvement with, other state, territory and/or Commonwealth run trial activities (for example, the National Disability Insurance Scheme);
* includes a range of population groups such as Aboriginal and Torres Strait Islander people, and people from culturally and linguistically diverse backgrounds; and
* at least one of the opt-out trial sites to include rural and/or remote areas.

The opt-out trials will be undertaken for individuals in a manner that retains the same access controls as are provided in the current opt-in system. While opt-out trials are being undertaken in the prescribed areas, the existing opt-in system of registration for healthcare recipients will continue to operate everywhere in Australia.

If the trials prove successful at improving both clinical and individual use of the system, the Minister may decide to implement the opt-out model nationally by making a rule under clause 2 of Schedule 1 to the Act. Before making a rule under clause 2 of Schedule 1, the Minister must consult with the Ministerial Council – that is, with the Council of Australian Governments Health Council.

1. **Period to opt-out of registration**

Subclause 5(1) of Schedule 1 to the Act provides that a healthcare recipient in opt-out trial areas may, by notice to the System Operator, elect not to be registered for a My Health Record.

Subparagraph 5(2)(c)(i) of Schedule 1 allows the Minister to make a rule prescribing the time within which a notice under subclause 5(1) must be given. Rule 5 prescribes the period within which a notice to opt-out must be given to the System Operator as commencing on 4 April 2016 and ending on 27 May 2016. After this period expires, healthcare recipients who are within the prescribed areas and who have not opted-out, will have a My Health Record created for them.

If a healthcare recipient who is a member of the prescribed class does not opt-out of registration with the My Health Record system within the prescribed time, they can still cancel or suspend their registration at any time after their My Health Record is created (under section 51(1) of the Act).

Healthcare recipients who have opted-out of registration may, if they wish, subsequently register themselves for a My Health Record under clause 6 of Schedule 1 to the Act.

A healthcare recipient registered under Schedule 1 to the Act will continue to have a My Health Record (including after the trials have finished) unless they or their representative cancel their registration under section 51 of the Act.

1. **Period within which to make initial election on disclosure of health information**

Under the opt-out model in Part 2 of Schedule 1 of the Act, the Chief Executive Medicare may at his or her discretion disclose health information held about relevant healthcare recipients (such as Medicare and Pharmaceutical Benefits Scheme information) to the System Operator for inclusion in the healthcare recipient’s My Health Record. Clause 13 of Schedule 1 to the Act provides that a healthcare recipient in the opt-out model may, by notice to the System Operator, elect not to have their Medicare health information made available to the System Operator. Subparagraph 13(2)(c)(i) of the Schedule allows for the Minister to make a rule stipulating the time within which such a notice must be given.

Rule 6 applies to healthcare recipients:

1. who are a member of a class of healthcare recipients prescribed under Rule 4; and
2. who have not elected to opt-out of registration within the period prescribed under Rule 5. That is, they have not opted-out during the period 4 April 2016 to 27 May 2016.

Under rule 6, if a healthcare recipient chooses to not have their health information held by the Chief Executive Medicare made available to the System Operator, the healthcare recipient’s election must be given to the System Operator within the period commencing on 28 May 2016 and ending on 14 July 2016.

After this period has expired, if a healthcare recipient has not given notice, the Chief Executive Medicare may disclose health information held about the healthcare recipient to the System Operator for inclusion in the healthcare recipient’s My Health Record.

After the period prescribed in rule 6, healthcare recipients may change their mind at any time and include, or not include, health information held by the Chief Executive Medicare about them in their My Health Record (see clause 13 of Schedule 1 to the Act).

If a healthcare recipient gives notice that they no longer wish to have Medicare health information included in their My Health Record, the Chief Executive Medicare must not disclose to the System Operator any further health information it holds about the healthcare recipient. However, any health information made available to the System Operator before the notice is given will continue to be available in the healthcare recipient’s My Health Record. Healthcare recipients may, if they wish, remove such documents from their My Health Record – see paragraph 4(e) of the *My Health Records Rule 2016.*

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***My Health Records (Opt-out Trials) Rule 2016***

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the Legislative Instrument**

The Legislative Instrument is part of a collection of rules that provide the detail necessary to support the operation of the My Health Record system, as established by the *My Health Records Act 2012* (the Act).

The Legislative Instrument will, in summary:

* prescribe the classes of healthcare recipients who will participate in opt-out trials of the My Health Record system, unless they choose to opt-out;
* prescribe the period of time within which a member of the prescribed classes of healthcare recipients must give notice to the System Operator if they do not wish to be registered and have a My Health Record created for them; and
* prescribe the time period within which a member of the prescribed classes of healthcare recipients, who has not opted-out, may make an initial election to not have their health information held by the Chief Executive Medicare disclosed to the System Operator.

**Human rights implications**

The Legislative Instrument engages the following human rights and freedoms:

*Right to health*

Article 12(1) of the *International Covenant on Economic, Social and Cultural Rights* provides for the right to the enjoyment of the highest attainable standard of physical and mental health.

The My Health Record system promotes the right to health by facilitating and improving the sharing of health information between treating healthcare providers, leading to quicker and safer treatment decisions and reducing repetition of information for patients and duplication of tests. Individuals are provided ready access to their own information, empowering them to make informed decisions about their healthcare.

The current opt-in participation arrangements have not effectively encouraged use of My Health Records by individuals and subsequently healthcare providers, and are creating a barrier to achieving the full benefits of the system for healthcare recipients. The Legislative Instrument enables the trial of opt-out participation arrangements. Healthcare recipients in prescribed areas will be registered and have a My Health Record created for them, unless they opt-out. Increased registration in opt-out trial areas, with the accompanying ability for treating healthcare providers to appropriately share health information for treatment purposes, will help improve the physical and mental health of registered healthcare recipients. Additionally, the opt-out trials are intended to inform future strategies for increasing uptake and meaningful use of the My Health Record system with the aim of achieving a greater standard of physical and mental health for all Australians.

*Protection of privacy and reputation*

Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR) prohibits unlawful or arbitrary interference with a person’s privacy and unlawful attacks on a person’s reputation. This right is also reflected in Article 22 of the *Convention on the Rights of Persons with Disabilities* (CRPD) and Article 16 of the *Convention on the Rights of the Child* (CRC)*.*

The right to privacy encompasses respect for informational privacy including the right to respect the storing, use and sharing of private information and right to control the dissemination of private information. The Legislative Instrument engages the right to privacy by prescribing a class of people to participate in an opt-out trial model of the My Health Record system, unless they opt-out.

The Instrument and the Act together counterbalance any limitation of the right to privacy by providing an opportunity for every healthcare recipient (or their representative) in the trial area to opt-out of registration and to ensure that a My Health Record is not created for them. Individuals who opt-out may later apply for registration, should they change their mind. Alternatively, healthcare recipients who do not opt-out and are registered are able to take advantage of a wide range of privacy protections as outlined below.

The Instrument allows a reasonable period of time (two months) for healthcare recipients to consider the benefits of the My Health Record system and their own preferences regarding their privacy and healthcare before making an informed decision as to whether they would like to opt-out of registration and having a My Health Record created. Under the Act, healthcare recipients who are registered may limit and restrict access to their My Health Record with control settings and may cancel or suspend their registration, should they so wish, as described below.

Healthcare recipients in opt-out trial areas need to be able to make informed decisions about the My Health Record system. 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 My Health 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 Instrument also ensures that healthcare recipients in opt-out trial areas who do not opt-out of registration have the opportunity to elect not to have any of their health information held by the Chief Executive Medicare made available to the System Operator for inclusion in their My Health Record. Individuals who initially elect not to have their Medicare health information included in their My Health Record may later have such information included, should they change their mind.

Opt-out trials offer an opportunity to tailor and refine the public awareness campaign for opt‑out areas which will include significant information about individuals’ options, privacy rights and how to exercise them. This will help ensure that, if a decision is later made to implement opt-out nationally, privacy aspects can be managed in the most appropriate and effective manner.

Strong privacy safeguards are in place, regardless of whether healthcare recipients are in an opt-in or opt-out area. People who are registered under opt-out arrangements will retain the same privacy protections as those registered under opt-in arrangements. These protections include the ability to do the following, including for 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).

Increased use of the system in opt-out areas is a privacy positive outcome as it will help 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, as will occur in opt-out trial areas, is likely to lead to a reduction in privacy breaches associated with paper-based records.

**Conclusion**

The Legislative Instrument is compatible with human rights because it advances the right to health. Any limitation of the right to privacy is proportionate, necessary and reasonable to achieving improved healthcare for Australians. Increased use of the My Health Records system, which will occur in opt-out trial areas, will result in a number of privacy positives compared to use of paper-based records.

**The Hon Sussan Ley MP**

**Minister for Health**