

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

My Health Records Act 2012

My Health Records (National Application) Rules 2017

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 or PCEHR system). The My Health Record system allows people 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 a person's health records.

The My Health Record system currently operates on an opt-in basis which means that a person needs to register in order to get a My Health Record.

The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) provide that an opt-out model will be implemented so that people no longer need to register; instead a My Health Record will be created for every eligible person unless they choose not to have one (i.e. opt-out).

Background

Due to the low numbers of people choosing to register for a My Health Record, the Act was amended in 2015 to allow for an opt-out model of participation to be implemented. Specifically, Schedule 1 to the Act allows the Minister to make rules to undertake trials of an opt-out model, and to implement opt-out nationally.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed risks to privacy, confidentiality and security.

In May 2017 the Government announced that the My Health Record will transition to national opt-out participation arrangements during 2018.

National Opt-out Rules

The National Opt-out Rules are made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the Act.

The purpose of the National Opt-out Rules is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, nationally. The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

Detail of the National Opt-out Rules is set out in the [Attachment](#).

Subsection 109(2) of the Act, together with regulation 5.1.1 of the *My Health Records Regulation 2012*, provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council (AHMAC) and the System Operator (i.e. the Australian Digital Health Agency). Consultation occurred in July and August 2017 and the System Operator and AHMAC supported the making of the proposed National Opt-out Rules.

Subclause 2(3) of Schedule 1 to the Act further provides that before making the National Opt-out Rules, the Minister must consult the Council of Australian Governments Health Council (CHC). CHC noted the making of the National Opt-out Rules in December 2017.

Public consultation on the concept of an opt-out My Health Record system has been undertaken:

- during July to September 2014 following the Personally Controlled Electronic Health Record Review, as reported in the *Report to the Commonwealth Department of Health on the public consultation into the implementation of the recommendations of the Review of the Personally Controlled Electronic Health Record*; and
- in May and June 2015 upon the release of the *Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper*.

Consumers support the concept of an opt-out model for the My Health Record system.

The National Opt-out Rules, with the exception of Part 3, commence on the day after registration on the Federal Register of Legislation. Part 3 will commence on a day to be specified by the Minister.

Regulation Impact Statements were prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally (published at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and as part of the Government decision to transition the My Health Record system to an opt-out system (published at ris.pmc.gov.au/2017/06/01/changes-my-health-record-system).

The National Opt-out Rules are a legislative instrument and are subject to the *Legislation Act 2003*.

Details of the *My Health Records (National Application) Rules 2017***PART 1—PRELIMINARY****1 Name of Rules**

Rule 1 provides that the title of the Rules is the *My Health Records (National Application) Rules 2017*. For the purposes of this document, the Rules are referred to as the National Opt-out Rules.

2 Commencement

Rule 2 provides for the commencement of the National Opt-out Rules.

With the exception of Part 3, which provides for the period in which people can choose to opt-out, the National Opt-out Rules take effect on the day after the Rules are registered on the Federal Register of Legislation. Of particular importance is the commencement of Part 2 which provides authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out.

Part 3 will take effect on a day that specified by the Minister in a notifiable instrument or if a day is not specified, 9 months after the Rules are registered on the Federal Register of Legislation. This approach provides the flexibility necessary as the exact timing for implementing opt-out is dependent on technological, communication and operational activities that need to be developed, planned and undertaken in parallel. It also provides certainty that Part 3 will take effect within a 9 month window. It is likely that the day specified for Part 3 to take effect will be in the first half of 2018. The opt-out period referred to in Rule 6 will begin upon the commencement of Part 3 and ends three months later.

3 Authority

Rule 3 identifies that the legal authority for making the National Opt-out Rules is provided by the *My Health Records Act 2012*.

4 Definitions

Rule 4 provides definitions of several terms used in the National Opt-out Rules. Of particular importance is the term *opt-out model* which is defined by Part 2 of the Rules. Other terms used in the Rules, such as *healthcare recipient*, are defined by the Act.

PART 2—APPLYING OPT-OUT MODEL TO ALL HEALTHCARE RECIPIENTS**5 Opt-out model applies to all healthcare recipients in Australia**

Rule 5 applies the opt-out model to all individuals in Australia. This means that Part 2 of Schedule 1 to the Act will begin operating and, in some cases replace existing provisions of the Act, on the day after the Rules are registered on the Federal Register of Legislation. A person cannot be registered unless they have been given an opportunity to opt out or have applied directly to register.

The Rules do not apply the opt-out model ‘afresh’ to individuals who have already been subject to opt-out arrangements. This means it does not apply to:

- people who were in the opt-out trial areas and did not opt-out, and who have since cancelled their My Health Record; or
- people who were in the opt-out trial areas and chose to opt-out.

The Rules do apply to people who previously applied for a My Health Record and have since cancelled their My Health Record. However, when deciding to register individuals as part of these opt-out arrangements, the System Operator will take cancelled My Health Records into account and decide not to register these people.

Rule 5 triggers the authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out (item 1 of subclause 8(1) of Schedule 1 to the Act provides this authority).

PART 3—REGISTERING HEALTHCARE RECIPIENTS

6 When healthcare recipients may elect not to be registered

People are entitled to choose to opt-out if they do not want a My Health Record (clause 5 of Schedule 1 to the Act refers), and the System Operator cannot register a person unless they have been given the opportunity to opt-out (clause 3 of Schedule 1 of the Act refers). In order to opt-out, a person must give notice to the System Operator in a particular manner. In practice, a person will be able to give this notice in a number of ways and at a time or period specified by the Minister, depending on their circumstances.

Rule 6 provides the arrangements by which a person can opt-out. Rule 6 will commence on a date to be specified by the Minister (this date will not be before March 2018). If the Minister does not specify a date, Rule 6 will commence 9 months after the National Opt-out Rules are registered on the Federal Register of Legislation.

If a person already has an Individual Healthcare Identifier (IHI)¹ they will be provided the opportunity to opt-out during the opt-out period. People who do not have an IHI at the commencement of the opt-out period will be provided the opportunity to opt-out prior to being assigned an IHI.

A person who is enrolled in Medicare² or has a Department of Veterans' Affairs (DVA) file number is automatically assigned an IHI. People who are not enrolled in Medicare or DVA but receive healthcare in Australia, such as international tourists, or people who want a pseudonymous IHI, can apply directly to the Healthcare Identifiers Service for an IHI.

National roll-out (subrules 6(2) and (3) refer)

Everyone who already has an IHI will be given the opportunity to opt-out during an opt-out period, and anyone who does not opt-out will have a My Health Record created for them.³

¹ Healthcare identifiers have been used since June 2010 and were established by the *Healthcare Identifiers Act 2010*. Healthcare identifiers are used for consistently identifying individuals and healthcare providers to, among other things, ensure patients are properly matched with their health records, and support the communication of health information between healthcare providers. The Chief Executive Medicare is currently responsible for operating the Healthcare Identifiers Service.

² In general, any person who resides in Australia is eligible to enrol in Medicare if they hold an Australian or New Zealand citizenship, have been issued with a permanent visa or have applied for a permanent visa. For detailed Medicare eligibility criteria, go to the [Department of Human Services website](#).

³ There are some exceptions. Despite having an IHI, not everyone will be included in this process – that is, they will not be given the opportunity to opt-out and will not be registered. For example, the System Operator will

Subrule 6(2) provides that the class of people specified in paragraph 6(3)(a) – those who have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice during the period specified in paragraph 6(3)(b) – the period commencing on the day this Part commences (i.e. the date to be specified by the Minister) and ending three months later (referred to as the opt-out period).

People who are part of the national roll-out will have three months in which to opt-out. This is considered a reasonable amount of time for people to receive information about the creation of My Health Records and take any action necessary.

If a person has been given the opportunity to opt-out, and they don't want to wait until the end of the opt-out period to get a My Health Record, they may choose to register. A My Health Record will be created for them immediately.

Ongoing (subrules 6(4) and (5) refer)

Anyone who gets an IHI after the beginning of the national roll-out will be given the opportunity to opt-out when they apply to enrol in Medicare or get an IHI, and anyone who does not opt-out will have a My Health Record created for them.⁴

Subrule 6(4) provides that the class of people specified in paragraph 6(5)(a) – those who do not have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice upon the event specified in paragraph 6(5)(b) – when they apply for something that results in them being assigned an IHI. In practice, a person is assigned an IHI when they apply to enrol in Medicare⁵ or create an IHI⁶.

Unlike national roll-out, the ongoing process does not provide individuals three months in which to opt-out; instead it provides a single point in time. This is because the ongoing process involves an individual taking an action to interact with a relevant Government service (i.e. enrolling in Medicare to requesting an IHI), and this interaction can be leveraged to ensure the person is directly informed about the My Health Record system and the need to opt-out during that interaction if they don't want a My Health Record created.

If an individual has parental or legal authority for another person (such as if they are a parent or guardian), or is found otherwise appropriate to act on behalf of another person, the individual may opt-out that other person. This capability will be available as part of the national roll-out and the ongoing process. Individuals aged 14 years and older will be able to opt themselves out. Individuals younger than 14 years will only be able to opt themselves out if they are able to provide evidence of their capacity to manage their My Health Record.

If a person does not opt-out at the time or during the period specified, the person can still cancel or suspend their registration at any time after their My Health Record is created (under subsection 51(1) of the Act). Conversely, if a person opts out, they may subsequently register for a My Health Record at any time (under clause 6 of Schedule 1 to the Act).

not register any person who previously had a My Health Record and cancelled it, who were part of the opt-out trials and opted out, who has a pseudonymous IHI, or whose registration may compromise the security or integrity of the system.

⁴ The System Operator will not register any person whose registration may compromise the security or integrity of the system.

⁵ The *Medicare enrolment application* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

⁶ The *Healthcare Identifiers Service Application to create or update an Individual Healthcare identifier* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

PART 4—HANDLING HEALTH INFORMATION FOR THE PURPOSES OF A HEALTHCARE RECIPIENT’S MY HEALTH RECORD

7 When healthcare recipients may elect not to have certain health information disclosed to System Operator

The Chief Executive Medicare holds the following health information (referred to as Medicare information) about individuals which may, at his or her discretion, be provided to the My Health Record System Operator to include in an individual’s My Health Record (clause 12 of Schedule 1 to the Act):

- Medicare Benefits Schedule claims information;
- Pharmaceutical Benefits Scheme claims information;
- information about organ and/or tissue donation decisions recorded by the Australian Organ Donor Register; and
- information about immunisations recorded by the Australian Immunisation Register.

People are entitled to choose not to include Medicare information in their My Health Record (clause 13 of Schedule 1 to the Act refers).

In order to choose not to include Medicare information in their My Health Record, a person must give notice to the System Operator at a particular time and in a particular manner.

Rule 7 provides the arrangements by which a person can choose not to include their Medicare information in their My Health Record, whether they are registered because they did not opt-out, or because they applied to register. Rule 7 will commence on the day after the National Opt-out Rules are registered on the Federal Register of Legislation.

The manner for choosing not to include Medicare information will be offered in one of two ways, depending on how a person has been registered for a My Health Record.

People who apply to register (subrules 7(2) and (3) refer)

Under an opt-out model, people can still choose to register at any time (clause 6 of Schedule 1 to the Act). This ensures that people who previously had a My Health Record and cancelled it, or who have opted out, can subsequently change their mind and get a My Health Record.

When a person applies to register⁷, they will be given the opportunity to choose not to include their Medicare information in their My Health Record.

Subrule 7(2) provides that the class of people specified in paragraph 7(3)(a) – people who, from the day after the National Opt-out Rules have been registered on the Federal Register of Legislation, have been registered – must give notice not to include their Medicare information upon the event specified in paragraph 7(3)(b) – when they apply to register for a My Health Record.

⁷ A person can apply to register online at the [My Health Record website](#), in person at a Medicare service centre, by phone on 1800 723 471, or in writing by completing the *Application to register for a My Health Record* form and sending it to the My Health Record System Operator.

People who are registered because they didn't opt-out (subrules 7(4) and (5) refer)

When a person does not opt-out and a My Health Record is created for them, they will be able to choose whether to include Medicare information in their My Health Record.

Subrule 7(4) provides that the class of people specified in paragraph 7(5)(a) – people who, from when Part 3 commences (i.e. the date to be specified by the Minister), have been registered because they didn't opt-out – must give notice not to include their Medicare information within the period specified in paragraph 7(3)(b) – from when they are registered until their My Health Record is first accessed.

It is important to understand that a person's Medicare information will, by default, automatically be included in the person's My Health Record unless the person has given notice not to include it. The transfer process by which Medicare information will be included in a My Health Record is triggered the first time someone accesses a My Health Record – either the person or their healthcare provider.

- If the person is the first to access their My Health Record they will, before the inclusion of any Medicare information, be guided through the various settings associated with the privacy of their My Health Record. This will be the opportunity to notify if they do not want their Medicare information included.
- If the person's healthcare provider organisation is the first to access a person's My Health Record, the Medicare information will be included in the My Health Record. This is because the transfer process has been triggered and no notice has been provided by the person not to include their Medicare information.

A person can change their mind at any time about whether or not to include Medicare information in their My Health Record. It is important to understand that if a person did not initially give notice not to include their Medicare information, and it has been included in their My Health Record, a subsequent decision not to include this information will only affect new information and will not affect the information already in their My Health Record. The person may choose to remove any Medicare information from their My Health Record.

Regardless of how people are registered for a My Health Record, if an individual has parental or legal authority for another person (such as if they are a parent or guardian), the individual may choose not to include that other person's Medicare information in that other person's My Health Record.

Statement of Compatibility with Human Rights

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

My Health Records (National Application) Rules 2017

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 made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the *My Health Records Act 2012* (the Act).

The purpose of the *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, to individuals nationally. This means that the My Health Record System Operator will create a My Health Record for all individuals unless they choose not to have one.

The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out – in this case, everyone who has a healthcare identifier;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

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 their healthcare providers, and are creating a barrier to achieving the full benefits of the system for individuals.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security. As a result, the Government decided to implement the My Health Record system as an opt-out system for individuals.

The Legislative Instrument enables opt-out participation arrangements for every eligible person across Australia. Increased registration, 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 individuals. This will increase 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* 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* and Article 16 of the *Convention on the Rights of the Child*.

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

The Legislative Instrument and the Act together counterbalance any limitation of the right to privacy by providing an opportunity for every individual (or their representative) across Australia 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, individuals who do not opt-out and are registered are able to take advantage of a wide range of privacy protections as outlined below.

As part of the roll-out of opt-out participation arrangements, the Legislative Instrument allows a reasonable period of time (three months) for individuals 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. In future, as new individuals become eligible, the opportunity to opt-out will be made available as part of the process for enrolling in Medicare, and individuals would be able to learn about the My Health Record system and decide whether they would like to opt-out in advance of enrolling in Medicare.

Under the Act, individuals 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.

Individuals need to be able to make informed decisions about the My Health Record system. Individuals will be made aware of the national opt-out arrangements, 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 to ensure all affected individuals, including parents, guardians and carers, are

aware of the opt-out arrangements, what they need to do to participate, how to adjust privacy controls associated with their My Health Record, or opt-out if they choose.

The Legislative Instrument also ensures that individuals 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.

Strong privacy safeguards are in place. People who are registered under opt-out arrangements will retain the same privacy protections as those previously 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 under opt-out arrangements 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 under opt-out arrangements, 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 Record system, which will occur as a result of opt-out arrangements, will result in a number of privacy positives compared to use of paper-based records.

The Hon Greg Hunt MP

Minister for Health