

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

My Health Records Act 2012

My Health Records Amendment (System Operator) Regulation 2016

The *My Health Records Act 2012* (My Health Records Act) provides for the establishment and operation of the My Health Record system (formerly referred to as the personally controlled electronic health record (PCEHR) system). The My Health Record system allows healthcare recipients 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 healthcare recipient's health records.

Subsection 112(1) of the My Health Records Act provides that the Governor-General may make regulations prescribing matters which are required or permitted by each Act, or matters which are necessary or convenient in order to carry out or give effect to each Act.

Section 14 of the My Health Records Act establishes that the My Health Record System Operator is either the Secretary of the Department of Health (paragraph 14(a)) or a body established by Commonwealth law that is prescribed by regulations to be the System Operator (paragraph 14(b)). There is currently no body prescribed by regulations for this purpose which means that the Secretary of the Department of Health is the System Operator.

The *My Health Records Amendment (System Operator) Regulation 2016* (the Regulation) amends the *My Health Records Regulation 2012* (the My Health Records Regulation).

The purpose of the Regulation is to amend the My Health Records Regulation to prescribe the Australian Digital Health Agency, as established by the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016*, to be the System Operator.

Details of the Regulation are set out in the [Attachment](#).

Subsection 112(3) of the My Health Records Act requires that the Minister consult the Ministerial Council before regulations are made. Further, subsection 14(2) of the My Health Records Act requires that such consultation must be undertaken before regulations are made for the purposes of paragraph 14(b) of the My Health Records Act. Accordingly, the Council of Australian Governments Health Council was consulted on the Regulation in February 2016 and it supported the making of the Regulation.

The My Health Records Act does not specify any other conditions that need to be met before the power to make regulations may be exercised.

The Regulation commences on the governance restructure day as defined by the *Health Legislation Amendment (eHealth) Act 2015*.

The Regulation is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT**Details of the *My Health Records Amendment (System Operator) Regulation 2016*****1. Name of Regulation**

This section provides that the title of the Regulation is the *My Health Records Amendment (System Operator) Regulation 2016*.

2. Commencement

This section provides that the Regulation takes effect on the governance restructure day as defined by the *Health Legislation Amendment (eHealth) Act 2012*. This is a day proclaimed by the Governor-General to be the governance restructure day for the purposes of the *Health Legislation Amendment (eHealth) Act 2012*.

3. Authority

This section provides that the Regulation is made under the *My Health Records Act 2012* (My Health Records Act).

4. Schedules

This section provides that each instrument that is specified in a Schedule to the Regulation is amended or repealed as set out in the applicable items in the Schedule concerned. Any other item in a Schedule to the regulation has effect according to its terms.

Schedule 1—Amendments to the *My Health Records Regulation 2012*

The items in the Schedule amend the *My Health Records Regulation 2012* (the My Health Records Regulation) as set out below.

Item 1

Item 1 inserts a new definition into regulation 1.1.3 to define the *Australian Digital Health Agency* for the purposes of regulation 2.1.1 (item 2 refers).

Item 2

Item 2 inserts regulation 2.1.1 into the My Health Records Regulation to prescribe that the Australian Digital Health Agency to be the My Health Record System Operator for the purposes of paragraph 14(b) of the My Health Records Act.

The Australian Digital Health Agency was established by the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016* on 30 January 2016.

The Australian Digital Health Agency is expected to be fully operation by 1 July 2016 and will be responsible for overseeing the operation and evolution of the national digital health capability.

Statement of Compatibility with Human Rights

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

My Health Records Amendment (System Operator) Regulation 2016

This Disallowable 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 Disallowable Legislative Instrument

The review of the personally controlled electronic health record system (now known as the My Health Record system) found that governance for digital health nationally is in need of significant changes as it does not have the confidence of the industry. Further, it is not representative of the potential users and potential beneficiaries of the digital health system.

New governance arrangements are being implemented which include the establishment of the Australian Digital Health Agency which will become the single accountable organisation for digital health in Australia.

The Disallowable Legislative Instrument will prescribe the Australian Digital Health Agency, as established by the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016*, to be the My Health Record System Operator.

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights as it does not raise any human rights issues.