

EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 160

Healthcare Identifiers Act 2010

Healthcare Identifiers Amendment Regulation 2012 (No. 1)

Subsection 39(1) of the *Healthcare Identifiers Act 2010* (HI Act) provides that the Governor-General may make regulations prescribing matters which are required or permitted by the HI Act, or matters which are necessary or convenient in order to carry out or give effect to the HI Act.

The HI Act implements a national system, the Healthcare Identifiers Service (HI Service), for assigning unique identifiers to consumers, healthcare providers and healthcare provider organisations for the purpose of healthcare. The HI Act sets out clear purposes for which healthcare identifiers may be used. Division 2A of Part 3 of the HI Act provides for the collection, use and disclosure of healthcare identifiers and identifying information for the purposes of the personally controlled electronic health record system (PCEHR) system.

The *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act) provides for the establishment and operation of the PCEHR system to provide access to health information relating to consumers' healthcare. From 1 July 2012 consumers will be able to register for a PCEHR, if they choose to do so, and will be able to control access to their PCEHR by healthcare provider organisations.

The purpose of the regulation is to amend the *Healthcare Identifiers Regulations 2010* to support the effective operation of the PCEHR system by:

- enabling facilitated registration;
- supporting the inclusion of Department of Veterans' Affairs (DVA) information in a consumer's PCEHR; and
- ensuring that the Healthcare Identifiers Service Operator (HI Service Operator) can share critical information with the PCEHR System Operator.

Section 22E of the HI Act provides that regulations may authorise a person to collect, use and disclose the identifying information and healthcare identifier of a consumer (or their authorised or nominated representative) or a healthcare provider as authorised by the PCEHR Act and as necessary in relation to the PCEHR system. The regulation authorises healthcare provider organisations to disclose to the PCEHR System Operator identifying information and the healthcare identifier of a consumer. This ensures that healthcare providers will be able to assist consumers in registering for a PCEHR.

Subsection 22D(1) of the HI Act provides that certain departments are authorised to collect, use and disclose identifying information and the healthcare identifier of a consumer for the purpose of including prescribed information in the consumer's PCEHR. Subsection 22D(3) provides that this authorisation applies only to information prescribed by the regulations and which a consumer has consented to being included in their PCEHR. The regulation authorises the DVA to include DVA claims information and Repatriation Pharmaceutical Benefits Scheme information in a consumer's PCEHR, subject to the consumer's consent.

Subsection 7(2) of the HI Act defines certain types of information about a healthcare provider and healthcare provider organisation as 'identifying information' to enable the HI Service Operator to perform its functions under the HI Act. With the implementation of the PCEHR system, the functions of the HI Service Operator have been expanded, so the regulation ensures that additional information on a healthcare provider and healthcare provider organisation is defined as identifying information and can therefore be disclosed to the PCEHR System Operator for PCEHR system purposes.

Details of the regulation are set out in the Attachment.

The proposals for the regulations were developed in consultation with a working group of representatives from Commonwealth, state and territory health departments, the Departments of Human Services and Veterans' Affairs and the National E-Health Transition Authority. The proposals took into account the outcomes from public consultation processes on several papers and ongoing workshops and targeted meetings.

Section 33 of the HI Act specifies that the Minister must consult the Ministerial Council before the Governor-General makes regulations. On 27 April 2012 the Minister for Health consulted the Standing Council on Health which agreed to the regulation without change.

The HI Act specifies no other conditions that need to be met before the power to make the regulation may be exercised.

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on the day after registration on the Federal Register of Legislative Instruments.

ATTACHMENT**Details of the *Healthcare Identifiers Amendment Regulation 2012 (No. 1)*****Section 1 – Name of regulation**

This section provides that the title of the regulation is *Healthcare Identifiers Amendment Regulation 2012 (No. 1)*.

Section 2 – Commencement

This section provides for the regulation to commence on the day after it is registered on the Federal Register of Legislative Instruments.

Section 3 – Amendment of *Healthcare Identifiers Regulations 2010*

This section provides that Schedule 1 of the regulation amends the *Healthcare Identifiers Regulations 2010* (the Principal Regulations).

Schedule 1 – Amendments**Items [1] and [2] – Regulation 3**

These items insert new definitions into section 3 of the Principal Regulations.

For example, ‘PCEHR Act’ is inserted to reflect that the amendments broaden the scope of the Principal Regulations to deal with matters associated with the PCEHR system in accordance with the *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act).

Item [3] – Paragraph 5(1)(c)

This item makes a typographical change to reflect the addition of new paragraph 5(1)(d) by Item [4].

Item [4] – After paragraph 5(1)(c)

This item inserts a new paragraph into subsection 5(1) to expand the meaning of ‘identifying information’ to include the status of the healthcare provider’s healthcare identifier, for example, whether it is active, deactivated or retired. This ensures the HI Service Operator can share critical information with the PCEHR System Operator for PCEHR system purposes.

Item [5] – Paragraph 5(2)(c)

This item makes a typographical change to reflect the addition of new paragraphs 5(2)(d) to (k) by Item [6].

Item [6] – After paragraph 5(2)(c)

This item inserts new paragraphs into subsection 5(2) to expand the meaning of ‘identifying information’ to include additional details, ensuring the HI Service Operator can share critical information with the PCEHR System Operator for PCEHR system purposes.

Under subsection 7(2) of the *Healthcare Identifiers Act 2010* (HI Act), certain information about healthcare provider organisations is defined as identifying information. Paragraph 7(2)(e) provides that regulations may prescribe other information for the purposes of this definition.

It is necessary that the following information be prescribed to be identifying information:

- the status of the healthcare provider organisation’s healthcare identifier, for example, whether it is active, deactivated or retired;
- to the extent it is not already covered by paragraph 7(2)(a) of the HI Act (that is, the name of the healthcare provider), the trading name of the healthcare provider organisation;
- the healthcare provider organisation’s service type (e.g. hospital or general practice);
- the names, personal and contact details and identifying numbers of the healthcare provider organisation’s Responsible Officer (the officer with day-to-day contact with the HI Service Operator to manage the healthcare identifiers of the organisation) and Organisation Maintenance Officer(s) (a delegate of the Responsible Officer);
- the identifying number assigned to the healthcare provider organisation’s Responsible Officer and Organisation Maintenance Officer(s) by the HI Service Operator;
- evidence of identity (EOI) details in relation to the healthcare provider organisation’s Responsible Officer and Organisation Maintenance Officer(s). EOI checks will be performed by the HI Service Operator or the Australian Health Practitioner Regulation Agency (AHPRA), depending on whether the Responsible Officer or Organisation Maintenance Officer is a healthcare provider registered by AHPRA (e.g. medical practitioners). EOI details may include whether a Responsible Officer or Organisation Maintenance Officer has undertaken an EOI process and, if so, whether the process was successful, the name of the organisation performing the EOI check and when the EOI was performed;
- the network address and technical requirements of the healthcare provider organisation that enables secure electronic messages to be sent to the organisation; and
- where a healthcare provider organisation (‘the first provider’) is part of a network hierarchy (that is, the first provider is a ‘seed organisation’ with subordinate network organisations, or is itself a ‘network organisation’, as defined in subsections 9A(3) and 9A(6) of the HI Act), the other healthcare

provider organisations that are linked to the first provider, and whether the first provider is a seed organisation or network organisation.

This information is necessary for the performance of the HI Service Operator's functions under a number of provisions in the HI Act, including:

- assigning healthcare identifiers to healthcare provider organisations;
- publishing professional and business details of a healthcare provider organisation to the healthcare provider directory; and
- enabling the PCEHR System Operator to create and maintain a database of healthcare provider organisations registered to participate in the PCEHR system for the purposes of section 56 of the PCEHR Act.

Paragraphs 5(3)(d) to (n) prescribe the information described above as identifying information in order to enable the HI Service Operator to carry out its expanded functions.

Item [7] – After regulation 8

This item inserts new section 12 to prescribe additional types of Commonwealth records under paragraph 22D(3)(a) of the HI Act that may be collected, used and disclosed.

Certain information held by DVA will be of value to the PCEHR system if it were included in a consumer's PCEHR, such as Repatriation Pharmaceutical Benefits Scheme information and DVA claims information. DVA claims information refers to claims relating to DVA programs operating under the *Veterans' Entitlements Act 1986*, the *Safety, Rehabilitation and Compensation Act 1988* and the *Military Rehabilitation and Compensation Act 2004*.

Subsection 22D(3) of the HI Act provides that regulations may be made to prescribe information for which Government departments are authorised to collect, use and disclose identifying information and the healthcare identifier of a consumer, for the inclusion of the prescribed information in the consumer's PCEHR, subject to the consumer's consent.

The new section 12 authorises DVA to collect, use and disclose a consumer's identifying information and healthcare identifier in order to include DVA claims information and Repatriation Pharmaceutical Benefits Scheme information in a consumer's PCEHR. This allows DVA to attach a healthcare identifier to the information so that it is included in the correct PCEHR.

This item also inserts new section 13 to enable facilitated registration of consumers by healthcare providers. Consumers will be able to register for a PCEHR using a variety of channels, one of which is referred to as facilitated registration. Facilitated registration is where a healthcare provider will assist a consumer to register for a PCEHR. This will require the healthcare provider to disclose identifying information and the healthcare identifier of the consumer to the PCEHR System Operator.

The HI Act does not authorise healthcare providers to collect, use or disclose a consumer's healthcare identifier to the PCEHR System Operator for this purpose.

The new section 13 authorises the healthcare provider, under paragraph 22E(d), to collect, use and disclose to the PCEHR System Operator identifying information and the healthcare identifier of the consumer undertaking registration.

The PCEHR System Operator is already authorised to collect, use and disclose the identifying information and healthcare identifier of a consumer as part of registration under section 22A of the HI Act.

This item also inserts new section 14 to support the registration of healthcare provider organisations.

When a healthcare provider organisation is registered by the PCEHR System Operator, it will be necessary to record the individual healthcare providers that are associated with that organisation. This will ensure that, for example, each time a healthcare provider accesses the PCEHR system on behalf of a healthcare provider organisation, their association with that organisation can be authenticated.

The HI Act does not authorise the collection, use or disclosure of a healthcare provider's healthcare identifier or identifying information for this purpose.

The new section 14 authorises the PCEHR System Operator, the HI Service Operator and healthcare provider organisations, under section 22E of the HI Act, to collect, use and disclose to a participant in the PCEHR system the healthcare identifier and identifying information of a healthcare provider.

**STATEMENT OF COMPATIBILITY FOR A BILL OR LEGISLATIVE
INSTRUMENT THAT RAISES HUMAN RIGHTS ISSUES**

Statement of Compatibility with Human Rights

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

Healthcare Identifiers Amendment Regulation 2012 (No. 1)

This Regulation 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 Regulations

The Regulation makes amendments to the *Healthcare Identifiers Regulations 2010* to support the additional processes and information flows that have arisen as a result of the personally controlled electronic health record (PCEHR) system as established by the *Personally Controlled Electronic Health Records Act 2012* (PCEHR Act).

The Regulation will:

- enable healthcare providers to assist consumers to register for a PCEHR (referred to as facilitated registration);
- support the inclusion of Department of Veterans' Affairs information in a consumer's PCEHR; and
- ensure that the Healthcare Identifiers Service Operator can carry out its functions and share critical information with the PCEHR System Operator.

Human rights implications

The Regulation engages the following human rights:

Right to Protection of privacy and reputation

Article 17 of the International Covenant on Civil and Political Rights guarantees protection from unlawful interference with a person's privacy and from unlawful attacks on a person's honour and reputation.

The Regulation prescribes circumstances, additional to those prescribed in the *Healthcare Identifiers Act 2010* (HI Act), in which identifying information and healthcare identifiers of consumers, their representatives and healthcare providers can be collected, used and disclosed. These additional circumstances are necessary for the operation of the PCEHR system and any unauthorised collection, use or disclosure of healthcare identifiers or identifying information is subject to the penalties and remedies set out in the HI Act, PCEHR Act and *Privacy Act 1988*.

Conclusion

The amendments made by this Regulation are compatible with human rights because they advance the protection of human rights, specifically the right to privacy.

Minister for Health, the Hon Tanya Plibersek MP