

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

Personally Controlled Electronic Health Records Act 2012

PCEHR (Assisted Registration) Rules 2012

The *Personally Controlled Electronic Health Records Act 2012* (the Act) enables the establishment of the personally controlled electronic health record (PCEHR) system. Section 109 of the Act provides that the Minister may make rules, known as PCEHR Rules, about matters that are required or permitted by the Act to be dealt with in the PCEHR Rules.

The purpose of the *PCEHR (Assisted Registration) Rules 2012* (Assisted Registration Rules) is to prescribe requirements for healthcare provider organisations that choose to assist consumers in applying for registration for a PCEHR, and to ensure the security of this manner of registration. The Assisted Registration Rules also prescribe a requirement of the System Operator to retain certain documents associated with assisted registration.

The Assisted Registration Rules form part of the collection of PCEHR Rules.

Consumers can currently register for a PCEHR using various channels and assisted registration will provide another channel. This manner of registration will encourage registration by a high proportion of vulnerable consumers (such as those in aged care and with chronic illness) who will benefit from having a PCEHR and who would be much more likely to apply to register with the support or assistance of their healthcare provider.

Participation in assisted registration by both healthcare provider organisations and consumers will be entirely voluntary. If a healthcare provider organisation chooses to provide assisted registration, it must comply with the Assisted Registration Rules in addition to the PCEHR Rules that currently apply (*PCEHR Rules 2012* and *PCEHR (Participation Agreements) Rules 2012*).

The Assisted Registration Rules require that a healthcare provider organisation providing assisted registration must:

- be registered with the System Operator;
- record consumer consent and retain this record for three years and/or provide it to the System Operator for retention for three years;
- use reasonable care in identifying a consumer before asserting the consumer's identity to the System Operator. Guidance on known customer models will be provided to organisations for this purpose;
- implement a policy that addresses certain matters associated with assisted registration, such as the manner of authorising and training employees to provide assisted registration; and
- inform the consumer about other channels for registration.

A healthcare provider organisation must comply with the PCEHR Rules in order to be and remain registered. If a healthcare provider organisation fails to comply with the PCEHR

Rules, it may result in a decision by the System Operator to cancel or suspend the registration of a registered healthcare provider organisation. Other sanctions may also be available against healthcare provider organisations that do not comply with the PCEHR Rules.

A healthcare provider organisation that chooses to provide assisted registration does not act on behalf of the System Operator.

The Assisted Registration Rules do not relate to the professional activities of healthcare providers. Professional obligations and professional bodies exist for this purpose. The Assisted Registration Rules only regulate matters necessary to support the making of an application for registration of identified consumers.

Detail of the Assisted Registration Rules is set out in the Attachment.

The Assisted Registration Rules commence on the day after registration on the Federal Register of Legislative Instruments.

The Assisted Registration Rules are a legislative instrument and are subject to the *Legislative Instruments Act 2003*.

Consultation

In September and October 2012, the Department consulted with the Office of the Australian Information Commissioner, the National E-Health Transition Authority, lead eHealth sites, representatives of stakeholder groups including healthcare providers, consumers, indemnity insurers and IT vendors on the proposed model for assisted registration which included legislative requirements. The Department also consulted with health organisations in the Northern Territory to align the proposed model more closely with the needs of the Northern Territory which has already implemented the *My eHealth Record* program. The model was revised following consultation to take account of stakeholder feedback and Assisted Registration Rules were drafted accordingly.

Section 109 of the Act requires that, before making PCEHR Rules, the Minister must consult the Jurisdictional Advisory Committee and Independent Advisory Council, although failure to consult these committees does not affect the validity of the PCEHR Rules.

The Independent Advisory Council and the Jurisdictional Advisory Committee were consulted on the proposed Assisted Registration Rules on 29 October 2012. Minor changes were made to the Assisted Registration Rules to reflect that healthcare provider organisations may choose to both store a consumer's consent and submit it to the System Operator for storage, and to ensure the Rules appropriately apply to the relevant parties.

ATTACHMENT**Details of the *PCEHR (Assisted Registration) Rules 2012*****PART 1—PRELIMINARY****1. Name of rules**

Rule 1 provides that the title of the rules is *PCEHR (Assisted Registration) Rules 2012*.

2. Commencement

Rule 2 provides that the Assisted Registration Rules commence on the day after they are registered on the Federal Register of Legislative Instruments.

3. Definitions

Subrule 3(1) defines particular terms used in the Assisted Registration Rules, including:

Assisted registration

This term describes the process whereby a healthcare provider organisation takes steps to assist a consumer to apply to be registered for a PCEHR. It is important to note that a healthcare provider organisation that provides assisted registration to consumers does not act on behalf of the System Operator.

The note to subrule 3(1) assists readers by making clear that other terms used in the Assisted Registration Rules have the same meaning as they have in the Act.

For the purpose of subrule 3(1), subrule 3(2) describes that the assisted registration process involves the provision of the consumer's identifying information, including their healthcare identifier, to the PCEHR System Operator (paragraph 3(2)(a)), and requires the organisation to check the identity of a consumer before asserting the consumer's identity to the System Operator (paragraph 3(2)(b)).

Subparagraph 3(2)(a)(i) makes clear that assisted registration is not only available to a consumer applying to register themselves but also to certain consumers claiming to be authorised representatives of a minor. In respect of applying to register a minor, the consumer must be listed on the same Medicare card as the minor (to demonstrate an existing relationship recognised by Medicare) (subsubparagraph 3(2)(a)(ii)(A)) and must make a declaration that they have parental responsibility for the minor (subsubparagraph 3(2)(a)(ii)(B)).

Subrule 3(2) does not affect the interpretation of the term ***authorised representative*** as defined by section 6 of the Act, rather it makes clear that only a subset of persons seeking to be an authorised representative of a person are eligible to apply to register that person through assisted registration.

Other types of persons seeking to be authorised representatives recognised by section 6 of the Act, such as a person authorised by an Australian law or court to act on behalf of another person, will not be able to register through assisted registration at this time.

PART 2—ASSISTED REGISTRATION

DIVISION 1— APPLICATION FOR REGISTRATION

Paragraph 15(f) of the Act specifies that a function of the System Operator is to register consumers and other participants in the PCEHR system, and to manage and monitor the system of registration.

The PCEHR system currently provides various channels for a consumer to apply to register for a PCEHR – phone, mail, online and in person.

4. Consumer registration

Rule 4 provides that the System Operator may make assisted registration available to consumers as a channel of consumer registration.

DIVISION 2— UNDERTAKING ASSISTED REGISTRATION

Subsection 109(3) of the Act provides that the PCEHR Rules may specify requirements relating to the PCEHR system that apply to consumers, and subsection 109(5) provides that the PCEHR Rules may specify requirements relating to registering a consumer.

5. Eligibility to undertake assisted registration

At this time, on the basis of technological capacity and the nature of consumer information currently held by them, only registered healthcare provider organisations will be permitted to provide assisted registration to consumers.

Rule 5 prohibits any person other than an employee of a registered healthcare provider organisation, who is authorised by that organisation for this purpose, to provide assisted registration to a consumer.

The note to this rule refers readers to the definition of *employee* in section 5 of the Act, making clear the scope of persons who are treated as employees.

The manner of authorising employees to provide assisted registration will be addressed in the organisation's policy, as required under paragraph 9(a).

6. Identification of consumer

Paragraph 41(1)(c) of the Act provides that the System Operator must decide to register a consumer if the System Operator is satisfied, having regard to the matters (if any) specified in the PCEHR Rules, that the identity of the consumer has been appropriately verified.

Paragraph 9(d) requires that an organisation providing assisted registration must implement a policy that reasonably addresses the process and criteria for identifying a consumer for the purposes of assisted registration. Guidance on identifying consumers will be published online by the System Operator to inform this policy.

Rule 6 requires that an employee must exercise reasonable care when identifying a consumer and must be satisfied that the consumer is the person making the application to register. This decision will be informed by the organisation's policy on identifying consumers, as described above. If the employee has verified a consumer's identity in accordance with its policy, it will be taken by the System Operator as being appropriate identity verification for the purposes of paragraph 41(a)(c) of the Act.

The concept of reasonable care is not defined and instead relies on the common meaning.

The employee must not knowingly or recklessly register a consumer fraudulently.

7. Consumer consent

Subsection 41(3) of the Act provides that the System Operator is not required to register a consumer if the consumer does not consent to the uploading of the consumer's health information to the consumer's PCEHR. This consent is subject to certain prescribed laws and any express advice by the consumer to a healthcare provider organisation not to upload certain information.

All current channels of registration are direct interactions with the System Operator which means that the consumer's consent is recorded by the System Operator. In the case of assisted registration, the System Operator is relying on the employee of the healthcare provider organisation to assert that the consumer has given consent for the application to be made to register **and** to the uploading of information to their PCEHR.

Relying solely on this assertion would leave the System Operator and the healthcare provider organisation vulnerable since there would be no auditable trail of the consumer's consent, for example, where a PCEHR is created for a consumer who has not (or claims to have not) consented.

Rule 7 will help mitigate the risk of identity fraud and provide traceability by requiring the healthcare provider organisation to record a consumer's consent in writing.

Subrule 7(2) provides that the consumer's consent must be recorded in the approved form. Paragraph 39(a) of the Act requires that, for a consumer to apply to the System operator for registration, the application must be made in the approved form. This form will be available in paper and electronic form, allowing the healthcare provider organisation to select the form most appropriate to their business.

This form which records the consumer's consent must be retained for audit purposes. The healthcare provider organisation can choose to store the form itself (in whatever manner chosen by the organisation) or it can be sent to the System Operator to be stored (subrule 7(3)). In cases the form must be retained for at least three years. The organisation may elect to store the form itself **and** send it to the System Operator, and may choose to store the form for a longer period.

If the organisation chooses to store the form, it will not be on the System Operator's behalf but for its own purposes.

If the organisation chooses to send the form to the System Operator, it must do so no more than 30 days after the consumer has given the consent (i.e. provided the completed form to the organisation) (paragraph 7(3)(b)).

The note to this rule refers readers to subsection 41(3) of the Act which provides that the System Operator is not required to register a consumer in the absence of consumer consent to upload information to the consumer's PCEHR.

8. Information for consumers

Rule 8 requires that a healthcare provider organisation that provides assisted registration to provide a consumer seeking to apply to be registered with information about other channels by which the consumer can apply to register.

This rule is intended to address circumstances where healthcare provider organisations may choose to charge a consumer for providing assisted registration.

The organisation will be unable to impose a charge under Medicare, however it may impose a charge outside Medicare for services they perform. This is a business decision of the organisation.

It is possible that charging for assisted registration could be a disincentive to some consumers to apply for registration. For example, low income patients may rely on assisted registration as the preferred option for registering for a PCEHR and may be unlikely to apply to register if it incurs a fee.

Rule 8 will therefore require all organisations that provide assisted registration to provide to consumers information about other channels of registration that are available to the consumer. This will ensure that the consumer will be aware of other options by which they can register.

DIVISION 3—SECURITY REQUIREMENTS

Subsections 109(3) and (4) of the Act provide that the PCEHR Rules may specify requirements relating to a range of matters, including administration and day-to-day operations and physical and information security.

9. Healthcare provider organisation policies

Rule 9 requires that a healthcare provider organisation that chooses to provide assisted registration for consumers must have in place a written policy that addresses certain matters in addition to those already required under rule 25 of the *PCEHR Rules 2012*.

Rule 25 of the *PCEHR Rules 2012* requires that, in order to be eligible to register, healthcare provider organisation must have in place a written policy that reasonably addresses the matters specified in those rules. In summary, those matters are:

- the manner of authorising persons within the organisation to access the PCEHR system, including the manner of suspending and deactivating the user account of any authorised person;

- the training that will be provided to persons before they are authorised to access the PCEHR system, including in relation to how to use the system accurately and responsibly, the legal obligations on healthcare provider organisations and individuals using the PCEHR system and the consequences of breaching those obligations;
- the process for identifying a person who requests access to a consumer's PCEHR and providing identification information to the System Operator, ensuring the organisation is able to satisfy its obligations under section 74 of the Act;
- the physical and information security measures of the healthcare provider organisation, including the procedures for user account management required under rule 27; and
- mitigation strategies to ensure PCEHR system-related security risks can be identified, acted upon and reported expeditiously.

Rule 9 specifies that the additional matters that must reasonably be addressed by the organisation's written policy are:

- the manner of authorising persons within the organisation to provide assisted registration to consumers on behalf of the organisation;
- the training that will be provided to persons before they are authorised to provide assisted registration;
- the manner of recording consumer consent and the process for handling that consent, i.e. whether it is retained by the organisation and/or sent to the System Operator and the associated process;
- the framework for identifying whether a consumer is a known customer. This may include the organisation's preferred model for being satisfied that a consumer is a known customer of the organisation, the preferred types of identity documents to be provided, and the steps to be taken if the employee of the organisation is uncertain about a consumer's identity. Guidance on identifying consumers will be published online by the System Operator to inform such policies.

The note to this rule makes clear that an organisation's written policy must be provided to the System Operator upon request. Such a request may relate to an organisation's current policy or the policy in force on a specified date.

Statement of Compatibility with Human Rights

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

PCEHR (Assisted Registration) Rules 2012

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 will provide detail necessary to support the operation of the personally controlled electronic health record (PCEHR) system, as established by the *Personally Controlled Electronic Health Records Act 2012* (the Act). Specifically, it will implement requirements to support the registration of consumers via a channel known as assisted registration, where a registered healthcare provider organisation assists a consumer to register for a PCEHR.

Human rights implications

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

Conclusion

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

**Minister for Health,
Hon Tanya Plibersek MP**