

## EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

*Personally Controlled Electronic Health Records Act 2012*

*PCEHR (Participation Agreements) Rules 2012*

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

The purpose of the PCEHR (Participation Agreements) Rules is to prescribe for the purposes of subsection 109(4A) of the Act a requirement that healthcare provider organisations, repository operators, portal operators and contracted service providers enter into a participation agreement in order to be, and remain, registered as a participant in the PCEHR system.

Each person wishing to participate in the PCEHR system as a healthcare provider organisation, repository operator, portal operator or contracted service provider will need to enter into a participation agreement with the System Operator. Entering into a participation agreement is a prerequisite to being registered as a participant in the PCEHR system. A person must continue to be a party to a participation agreement in order to remain registered as a healthcare provider organisation, repository operator, portal operator or contracted service provider.

Participation agreements will deal with a number of matters that are not covered by the Act or related subordinate legislation, including by granting the intellectual property licences necessary for the PCEHR system to operate as intended.

The form of the participation agreement for healthcare provider organisations is included in the Schedule to the Participation Agreements Rules. It is intended in the future that the Participation Agreements Rules will be amended or remade to include participation agreements for repository operators, portal operators and contracted service providers.

The Participation Agreements Rules do not relate to the professional activities of healthcare providers. Professional obligations and professional bodies exist for this purpose. The Participation Agreements Rules relate only to the requirement to enter into, and remain a party to, a participation agreement in order to be registered as a participant in the PCEHR system.

Detail of the Participation Agreements Rules is set out in the [Attachment](#).

The PCEHR (Participation Agreements) Rules commence on the day after registration on the Federal Register of Legislative Instruments.

The PCEHR (Participation Agreements) Rules are a legislative instrument and subject to the *Legislative Instruments Act 2003*.

## **Consultation**

The *PCEHR System: Proposals for Regulations and Rules* ('proposals paper') was released for public comment on 21 March 2012. The proposals were subsequently revised to address the submissions made on the proposals paper.

The Minister consulted with state and territory health ministers on 26 April 2012 to provide the opportunity to comment on the revised proposals paper, and the PCEHR Rules have been revised to address the feedback provided by health ministers.

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 was consulted on the PCEHR Rules on 19 July 2012.

In place of the Jurisdictional Advisory Committee, which had not yet been constituted, jurisdictions were consulted on the PCEHR Rules through the National Health Information and Performance Principal Committee, National Health Chief Information Officers Forum and National Health Information Regulatory Framework Working Group.

Submissions received in relation to these consultations were considered and incorporated where possible in finalising the Participation Agreements Rules.

Schedule 1 to the Participation Agreements Rules was the subject of consultation with industry stakeholders, including bodies representing healthcare providers and medical indemnity insurers. The consultation occurred on several occasions from March to July 2012. Schedule 1 was significantly revised as a result of this consultation.

**ATTACHMENT****Details of the PCEHR (Participation Agreements) Rules 2012****PART 1—PRELIMINARY****1. Name of Determination**

Rule 1 provides that the title of the determination is *PCEHR (Participation Agreements) Rules 2012* (the Participation Agreements Rules).

**2. Commencement**

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

**3. Definitions**

Rule 3 defines particular terms used in the Participation Agreements Rules.

The note to rule 3 assists readers by making clear that other terms used in the Participation Agreements Rules are as defined in the Act.

**PART 2—PARTICIPATION AGREEMENTS**

Subsection 109(4A) of the Act provides that the Participation Agreements Rules may require a person to enter into a specified kind of agreement in order to be, and remain a registered healthcare provider organisation, registered repository operator, registered portal operator or registered contracted service provider.

**4. Requirement to enter into a participation agreement**

Subrule 4(1) requires that a healthcare provider organisation, repository operator, portal operator or contracted service provider wishing to be registered in the PCEHR system (and remain registered) must enter into a participation agreement with the System Operator.

Under the Act, and the related *Healthcare Identifiers Act 2010*, there can be one or more healthcare provider organisations in a single legal entity. Subrule 4(2) clarifies if there is more than one healthcare provider organisation within a legal entity, it is only necessary to enter into a single participation agreement to cover all healthcare provider organisations within that legal entity that wish to participate in the PCEHR system.

Under section 38 of the Act, it is a function of the Chief Executive Medicare to seek to become a registered repository operator and, if registered, to operate a repository for PCEHR purposes. The repository proposed to be operated by the Chief Executive Medicare will contain health information such as Medical Benefits Scheme and Pharmaceutical Benefits Scheme information. That health information will be included in a registered consumer's PCEHR if the consumer consents to this occurring. Subrule 4(3) exempts the Chief Executive Medicare from having to enter into a participation agreement in relation to this repository. Instead, it is intended that

the Department of Human Services (representing Medicare) and the Department of Health and Ageing (representing the System Operator) will enter into an agreement (which is not a participation agreement). This is considered more appropriate due to the unique nature of the Chief Executive Medicare and its proposed repository.

Subrule 4(4) of the Participation Agreements Rules provides that the participations agreement, which healthcare provider organisations enter into with the System Operator, must use the terms which are specified in Schedule 1 to the Participation Agreement Rules. Schedule 1 has been developed following consultation and agreement with the representatives of healthcare providers and medical indemnity insurers.

### **SCHEDULE 1—PARTICIPATION AGREEMENTS FOR HEALTHCARE PROVIDER ORGANISATIONS**

The Participation Agreements Rules do not specify terms for participations agreements for registered repository operators, registered portal operators or registered contracted service providers. This is because some requirements relating to those participants is still under developments. Once these requirements are finalized, it is intended that the Participations Agreements Rules will be amended or remade to include participation agreements for those participants in the PCEHR Rules.

Schedule 1 sets out the form and content of the participation agreement which a healthcare provider organisation that wishes to register to participate in the PCEHR system must use.

**STATEMENT OF COMPATIBILITY FOR A BILL OR LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES**

**Statement of Compatibility with Human Rights**

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

**PCEHR (Participation Agreements) 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).

The Legislative Instrument will require participants in the PCEHR system to enter into a participation agreement with the System Operator.

**Human rights implications**

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

**Conclusion**

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

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