**EXPLANATORY STATEMENT**

**Issued by Authority of the Minister for Health**

***Personally Controlled Electronic Health Records Act 2012***

***PCEHR (Participation Agreements) Amendment (specified kind of agreement) Rule 2014***

**Purpose**

The purpose of the *PCEHR (Participation Agreements) Amendment (specified kind of agreement) Rule 2014* (the Amendment Rule) is to amend the *PCEHR (Participation Agreements) Rules 2012* (Participation Agreements Rules) to remove the requirement for a legally binding participation agreement for entities that are part of the Commonwealth and wish to participate in the PCEHR. The Amendment Rule also changes the kind of participation agreement for all non‑Commonwealth entities from a deed to a contract and removes the text of the participation agreement for healthcare provider organisations from the Participation Agreements Rules.

The Participation Agreements Rulesrequire healthcare provider organisations, repository operators, portal operators and contracted service providers that wish to participate in the personally controlled electronic health record (PCEHR) system, to enter into, and remain a party to, a participation agreement in order to be, and remain, registered as a participant in the PCEHR system.

Participation agreements deal with a number of matters that are not covered by the *Personally Controlled Electronic Health Records Act 2012* (the Act) or related subordinate legislation, including the granting of intellectual property licenses necessary for the PCEHR system to operate as intended. A participation agreement is executed in the form of a deed and creates enforceable legal obligations.

Commonwealth entities are currently unable to comply with the requirement to enter into a participation agreement with the System Operator, who is the Secretary to the Department of Health. This is due to the nature of the Commonwealth as a legal entity. Any Commonwealth participant in the PCEHR system would execute the participation agreement for and on behalf of the Commonwealth, however the System Operator executes participation agreements for and on behalf of the Commonwealth. This means the signatories would not be separate parties in a legal sense and no enforceable legal obligations would be created.

The Amendment Rule would require Commonwealth entities to enter into a memorandum of understanding with the System Operator in order to be registered as a participant in the PCEHR system. This would replace the current requirement for Commonwealth entities wishing to participate in the PCEHR system to enter into a legally binding participation agreement. This memorandum of understanding would, for all intents and purposes, be the same as the participation agreement used by non-Commonwealth entities.

Under the Amendment Rule all non‑Commonwealth entities wishing to participate in the PCEHR system will be required to enter into a contract with the System Operator rather than a deed. Changing the agreement from a deed to a contract will remove the complexities for entities associated with executing a deed and will simplify the application process.

At the time the Participation Agreements Rules were made it was unclear whether a participation agreement included considerations (i.e. benefits) to both parties. A contract cannot be created and be legally enforceable without considerations while a deed can, so it was decided that participation agreements would take the form of deeds.

It is now clear that the considerations of the agreement are that the entity receives the benefit of being permitted to use the PCEHR system, and the System Operator receives the benefit of the entity complying with the Act. For these reasons the participation agreement can be executed as a contract which means the parties to the agreement are not required to sign it for the terms to have effect, only that the applicant agrees to the terms. This will simplify the application process for entities applying to be registered as a participant in the PCEHR system.

Finally, the text of the participation agreement for healthcare provider organisations will be removed from the Participation Agreements Rules. This will allow the agreement to be varied as necessary without requiring an amendment to the Participation Agreements Rules.

The Participation Agreements Rules form part of the collection of PCEHR Rules. They do not relate to the professional activities of healthcare providers. Professional obligations and professional bodies exist for this purpose.

**Authority**

The Act enables the establishment of the 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.

Subsection 109(4A) of the Act provides that the PCEHR Rules may specify that a person must 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 contract service provider.

**Consultation**

Subsection 109(2) of the Act requires the Minister to consult with the Independent Advisory Council and the Jurisdictional Advisory Committee before making PCEHR Rules. It further provides that failure to consult these bodies does not affect the validity of such PCEHR Rules. These bodies were consulted on 2 June 2014 and they raised no concerns or issues.

The National Health Information Regulatory Framework Group, a jurisdictional subcommittee of the Australian Health Ministers’ Advisory Council, was instrumental in the development of the legislative framework to the PCEHR system. It was consulted on 2 June 2014 and raised no concerns or issues.

**General**

Detail of the Amendment Rule is set out in the Attachment.

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

The Amendment Rule is a legislative instrument and is subject to the *Legislative Instruments Act 2003*.

**ATTACHMENT**

**Details of the** ***PCEHR (Participation Agreements) Amendment (specified kind of agreement) Rule 2014***

**PART 1—PRELIMINARY**

1. **Name of Rule**

Rule 1 provides that the title of the Amendments Rule is *PCEHR (Participation Agreements) Amendment (specified kind of agreement) Rule 2014*

1. **Commencement**

Rule 2 provides that the Amendment Rule will take effect and amend the Participation Agreements Rules on the day after it is registered on the Federal Register of Legislative Instruments.

1. **Amendment of *PCEHR (Participation Agreements) Rules 2012***

Rule 3 provides that Schedule 1 will make amendments to the Participation Agreements Rules.

**SCHEDULE 1—AMENDMENTS**

**[1] Subrule 4(1)**

Subrule 4(1) specifies 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.

Item 1 amends subrule 4(1) to reference subrule 4(4) which specifies the kind of participation agreement to be entered into by Commonwealth and non‑Commonwealth entities (item 3 refers).

This amendment ensures that all entities applying to be a participant in the PCEHR system must enter into a participation agreement of some form.

**[2] Subrule 4(4)**

Subrule 4(4) currently provides that the participation agreement that must be entered into by healthcare provider organisations must use the terms prescribed in Schedule 1 to the Participation Agreements Rules. Schedule 1 sets out the terms of the healthcare provider organisation participation agreement and, on the signature page, specifies that the agreement is to be executed as a deed.

Item 2 substitutes a new subrule 4(4) to specify that a participation agreement must take the form of a contract, except if the person is a Commonwealth entity in which case the participation agreement must be in the form of a memorandum of understanding.

This amendment ensures that all entities applying to be a participant in the PCEHR system must enter into a participation agreement of some form, however it recognises that Commonwealth entities cannot enter into a legally enforceable agreement with the System Operator since both entities represent the Commonwealth. Changing the agreement from a deed to a contract will also remove the complexities for entities associated with executing a deed and will simplify the application process.

**[3] Schedule 1**

Schedule 1 to the Participation Agreements Rules currently contains the terms of the participation agreement that must be entered into by healthcare provider organisations, and it specifies that the agreement must be executed as a deed.

Clause 6 of the participation agreement as set out in Schedule 1 provides that the System Operator may vary the agreement but must give 28 days’ notice of any variation, must try to consult with affected organisations (that is, those that have already entered into an agreement), and must provide a written copy of the variation with an explanation for it. Entities may choose to terminate the agreement if they don’t agree with the variation.

Any variation to the agreement, since it forms part of the Participation Agreements Rules, would also necessitate an amendment to the PCEHR Rules. Therefore it would also require consultation with the Independent Advisory Council and the Jurisdictional Advisory Committee.

Item 3 removes the terms of the participation agreement from the Rules by removing Schedule 1. This will make it administratively simpler to vary the agreement but only where the need arises and only when the steps described at clause 6 have been taken.

**Statement of Compatibility with Human Rights**

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

***PCEHR (Participation Agreements) Amendment (specified kind of agreement) Rule 2014***

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 part of a collection of rules that provide the 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 Legislative Instrument will amend the *PCEHR (Participation Agreements)*

*Rules 2012* to require Commonwealth entities to enter into a participation agreement with the System Operator in the form of a memorandum of understanding, in order to be registered as healthcare provider organisations, repository operators, portal operators or contracted service providers. This recognises that a legal agreement executed by two Commonwealth entities does not create legally enforceable obligations as intended by the *PCEHR* (*Participation Agreements) Rules 2012*.

The Legislative Instrument will also amend the *PCEHR (Participation Agreements) Rules 2012* to provide that a participation agreement for non-Commonwealth entities must take the form of a contract instead of a deed, and the agreement which applies to healthcare provider organisations is no longer contained as a Schedule to the Rules.

**Human rights implications**

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

The Legislative Instrument does not make changes to the rights of consumers to choose whether to register for a PCEHR and to choose who can access their PCEHR, rather it modifies the registration requirements for entities to participate in the PCEHR system.

**Conclusion**

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

**The Hon Peter Dutton MP**

**Minister for Health**