



PCEHR (Participation Agreements) Rules 2012

Personally Controlled Electronic Health Records Act 2012

I, TANYA PLIBERSEK, Minister for Health, make these Rules under section 109 of the *Personally Controlled Electronic Health Records Act 2012*.

Dated 16th August 2012

TANYA PLIBERSEK
Minister for Health

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Part 1 Preliminary

1. Name of Rules

These Rules are the *PCEHR (Participation Agreements) Rules 2012*.

2. Commencement

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

3. Definitions

In these Rules, unless the contrary intention appears:

Act means the *Personally Controlled Electronic Health Records Act 2012*.

Participation agreement means an agreement between the System Operator and a person wishing to be registered as a participant in the PCEHR system that is described as a participation agreement (whether using that expression or an equivalent expression).

Note 1: Unless the contrary intention appears, terms used in these PCEHR (Participation Agreements) Rules have the same meaning as in the Act— see section 13 of the *Legislative Instruments Act 2003*. These terms include:
Chief Executive Medicare, healthcare provider organisation, participant in the PCEHR system, PCEHR, PCEHR system, registered contracted service provider, registered healthcare provider organisation, registered portal operator, registered repository operator and System Operator.

Part 2 Participation agreements

4. Requirement to enter into a participation agreement

- (1) For the purposes of subsection 109(4A) of the Act, a person must enter into, and remain a party to, a participation agreement with the System Operator in order to be and remain:
 - (a) a registered healthcare provider organisation;
 - (b) subject to subrule (3) – a registered repository operator;
 - (c) a registered portal operator; or
 - (d) a registered contracted service provider.
- (2) If there is more than one healthcare provider organisation within a legal entity, the legal entity may enter into, and remain a party to, a participation agreement in relation to each healthcare provider organisation within that entity that wishes to participate in the PCEHR system.
- (3) Paragraph (1)(b) does not apply to the Chief Executive Medicare in connection with operating a repository under subsection 38(1) of the Act.
- (4) The participation agreement for healthcare provider organisations must use the terms of agreement specified in Schedule 1.

Schedule 1 Participation agreement for healthcare provider organisations

(rule 4)

Heading, notes and summary of clause's operation ⁱ	Clause no.	Terms
Parties <i>Healthcare provider organisations will need to authorise an employee to be their contact person for the purposes of the PCEHR system, including in connection with this agreement. Under the PCEHR Rules, that contact person must be the "Responsible Officer" or "Organisation Maintenance Officer" (as defined in the HI Act) for the healthcare provider organisation.</i> <i>The contact person may or may not be the same person who executes this agreement on behalf of the healthcare provider organisation. This is a matter for the healthcare provider organisation.</i>	Parties: System Operator and Healthcare Provider Organisation	
	System Operator ("us", "we", "our")	Name The Commonwealth as represented by the Secretary of the Department of Health and Ageing as PCEHR System Operator ABN/ACN/ARBN Contact person Phone number Fax number E-mail address Postal address
	Healthcare Provider Organisation ("you", "your")	Name ABN/ACN/ARBN (if applicable) Contact person Phone number Fax number E-mail address Physical address Postal address
Background <i>There are no obligations on healthcare providers to upload a consumer's health information to the PCEHR system. If providers do not</i>	A	A.1
		The personally controlled electronic health records system (PCEHR system) is designed to place individuals at the centre of their own healthcare. It does this by enabling access to important health information when and where it is needed by consumers and their healthcare providers.
		A.2
		A range of private and public sector entities will participate in

consider it appropriate to upload information, they should not do so.

the PCEHR system, including healthcare provider organisations, repositories, portals and contracted service providers.

- A.3 Rights and obligations for participants are set out in a number of places including the PCEHR Act and the HI Act, regulations made under those Acts, and in participation agreements such as this one.
- A.4 The PCEHR system is a voluntary system for consumers and other entities, including healthcare provider organisations. Consumers and other entities wishing to participate will have to register. This agreement is for use between the System Operator and healthcare provider organisations. Individual healthcare providers will not need to register with the System Operator, or enter into a participation agreement. Instead, they will be authorised to use the PCEHR system through the registered healthcare provider organisations for which they supply, or from which they acquire, services.
- A.5 Signing this agreement is a precondition for any healthcare provider organisation wishing to be registered and participate in the PCEHR system.

Version number

B 1.00

Definitions and interpretation

1 Definitions and rules for interpreting this agreement are set out in clause 14.

Commencement and term

2 This agreement commences on the date it is executed and ends when it is terminated in accordance with clause 12.

System Operator responsibilities

- 3**
- 3.1 We will establish and operate the PCEHR system to help improve access to consumers' health information by consumers and their healthcare providers. However, the PCEHR system will not store all health information about a consumer and is not a replacement for your or your employees' clinical records.
- 3.2 We will operate the PCEHR system in a way that allows participating healthcare providers to upload clinical records, and access other records about a consumer, subject to any access controls the consumer or their representatives have set. We are not responsible for the quality or content of any records you, other healthcare providers or consumers upload.
- 3.3 We will endeavour to ensure the PCEHR system is available as required by consumers and participants in the PCEHR system. However, some parts of the PCEHR system, and

Note – “employee” is defined to have the same meaning as in the PCEHR Act. That definition is broad – it includes employees (as that term is normally used) as well as contractors and volunteers.

The PCEHR system is made up of a large number of computer and telecommunications systems. Many of these are outside the System

Operator's control. While measures have been taken to reduce the risk that these systems will be unavailable, it is impossible to guarantee continuous availability in all circumstances. This situation is no different to that which exists now for many systems including telecommunication, electricity and gas systems.

Where it is proposed to make changes to the PCEHR system, the System Operator will endeavour to consult with affected parties (including providers and medical software vendors) and seek advice as necessary from the Independent Advisory Council and Jurisdictional Advisory Committee. However, given the number of participants in the PCEHR system, it is impossible to guarantee that the System Operator will consult individually with every participant.

some inputs such as telecommunications services, are outside our control. We do not guarantee continuity of access to, or operation of, the PCEHR system.

- 3.4 Upon request, we will provide you with information about any times when the PCEHR system was unavailable.
- 3.5 The PCEHR system and its functionality will change over time. However, we will endeavour to consult with healthcare provider representatives about any significant changes, and any significant issues affecting the system's operation. Where a change in functionality requires a change to the terms of this agreement, clause 6 applies.
- 3.6 We must promptly notify you if our contact person, or their contact details, change.
- 3.7 We consent to you communicating with us electronically in connection with the PCEHR system.

Healthcare Provider Organisation responsibilities

In relation to clause 4.1, reasonable steps might, for example, include implementing protocols for using the PCEHR system.

For example, in relation to clause 4.4(a)(i), if it appears that a record belonging to one consumer has been incorrectly linked to another consumer's PCEHR.

The System Operator is under a legislative obligation to notify certain

- 4 4.1 You must take reasonable steps to ensure that you and your employees exercise due care and skill:
 - (a) so that any record you or your employees upload to the PCEHR system is, at the time the record is uploaded, accurate, up-to-date and not misleading or defamatory; and
 - (b) about whether any records you or your employees access via, or download from, the PCEHR system are accurate, up-to-date and fit for purpose.
- 4.1A The obligation in clause 4.1(a) does not extend to ensuring records are accurate or up-to-date to the extent that:
 - (a) the record being uploaded was created by an individual who was not, at the time the record was created, an employee of the uploading healthcare provider organisation; and
 - (b) there is nothing in the record that would indicate to a reasonable person that the record was not accurate or

things in specific circumstances – e.g., if there has been a data breach.

The term “compromised” is defined in clause 14 to include an unauthorised collection, use or disclosure of information in a consumer’s PCEHR and other events that may affect the security or integrity of the PCEHR system. For example, in relation to clause 4.4(a)(ii), if it appears that someone has hacked into the PCEHR system using your IT system or if you have discovered that one of your employees has accessed records in the PCEHR system when not authorised to do so under the PCEHR Act.

The consent in clause 4.5 is for the purposes of paragraph 9(1)(d) of the Electronic Transactions Act 1999.

up-to-date.

- 4.2 The uploading of a record to the PCEHR system does not relieve you or your employees of any obligations that may be applicable to keep clinical records about a consumer. Nor does it relieve you or your employees of other obligations that may exist, including any obligation to communicate health information to a consumer.
- 4.3 [Not used].
- 4.4 You must promptly notify us if:
- (a) you know or suspect that:
 - (i) there is a non-clinical, PCEHR system-related error in a record that has been accessed via, or downloaded from, the PCEHR system; or
 - (ii) the security of the PCEHR system has been compromised by your or one of your employees or by the use of your equipment;
 - (b) there is a material change in your legal structure, or you are involved in a merger or acquisition; or
 - (c) your contact person, or their contact details, change.
- 4.5 You consent to us communicating with you electronically in connection with the PCEHR system.

Uploading records

5

5.1 You acknowledge that:

- (a) section 45 of the PCEHR Act; and
- (b) regulations made under sub-sections 41(3) and (4) of the PCEHR Act,

place restrictions on the uploading of records to the PCEHR system.

Regulations to be made under the PCEHR Act will preserve some State and Territory laws that, for example, require express consent or written consent to upload (i.e., disclose) some types of health information. These State and Territory laws generally relate to communicable diseases. For example, it is proposed to preserve sections 110 and 111 of the Public Health Act 1997 (ACT) which prohibit the disclosure of information about notifiable diseases without the written

consent of the person to whom the information relates.

Section 45 of the PCEHR Act contains a number of other restrictions on the uploading of records including, for example, that records must not be uploaded to the PCEHR system where a consumer has advised that the record is not to be uploaded.

Changes to this agreement

- | | | |
|----------|-----|---|
| 6 | 6.1 | Due to changing technical and operational requirements, it may be necessary to vary the terms of this agreement from time to time. |
| | 6.2 | <p>If we consider it is necessary to vary these terms:</p> <p>(a) we will:</p> <p style="margin-left: 40px;">(i) give you at least 28 days notice of the changes; and</p> <p style="margin-left: 40px;">(ii) endeavour to consult with you; and</p> <p>(b) we will give you a written copy of any proposed new terms and an explanation of their purpose.</p> |
| | 6.3 | <p>If you do not agree to the new terms:</p> <p>(a) either party may terminate this agreement in accordance with clause 12; and</p> <p>(b) we may suspend or cancel your registration as a participant in the PCEHR system.</p> |

Given the likely number of participants in the PCEHR system, it is impossible to guarantee that the System Operator will consult individually with every participant.

Clauses 6.2 and 6.3 do not create a unilateral right for the System Operator to vary the terms of this participation agreement. Rather, if a healthcare provider organisation does not agree to new terms put forward by the System Operator (either by signing or otherwise accepting the proposed new terms), the agreement may be terminated by either party in accordance with clause 12. If the participation agreement is terminated, the System Operator may suspend or cancel the provider's PCEHR registration.

Intellectual property rights

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|----------|-----|--|
| 7 | 7.1 | <p>Subject to this clause 7, nothing in this agreement affects ownership of:</p> <p>(a) any intellectual property rights (IP rights) in material you upload to the PCEHR system; or</p> |
|----------|-----|--|

Where you own IP rights you will continue to own them. However, you need to

provide a licence to the System Operator which allows the System Operator to license other healthcare providers and participants to use the information as intended in the PCEHR system. The System Operator will also license you to use documents uploaded by other healthcare providers.

Before you upload a document in which someone else owns the IP rights, you need to get their permission to upload the document to the PCEHR system and to granting a licence to the System Operator so that the information can be shared. A standard form of words has been developed that can be used by non-participating providers to do this.

The references to “modify” and “adapt” are to ensure that records can be converted into the correct format to be displayed in the PCEHR system.

The words modify and adapt will not permit the System Operator or anyone else to change the clinical content of a record.

Under clause 7.3, you grant us a licence for the purposes of the PCEHR system. The purposes of the PCEHR system include the purpose of providing healthcare.

Under clause 7.4, we grant you a licence to use records uploaded by other healthcare provider organisations for the purposes of providing healthcare and other PCEHR purposes.

(b) any IP rights in the parties’ existing material.

7.2 You must only upload material to the PCEHR system where:

- (a) you own the IP rights in the material; or
- (b) the owner of the IP rights in the material has:
 - (i) agreed to the upload of the material; and
 - (ii) agreed to you granting us a licence on the terms in clause 7.3.

7.3 You grant us a perpetual, irrevocable, royalty-free and licence-fee free, worldwide, non-exclusive licence (including a right to sub-license) to use, reproduce, copy, modify, adapt, publish and communicate (including to other healthcare provider organisations and to organisations that store health information) material you have uploaded to the PCEHR system for the purposes of the PCEHR system.

7.4 We grant you a perpetual, irrevocable, royalty-free and licence-fee free, worldwide, non-exclusive licence (including a right to sub-license) to use, reproduce, copy, modify, adapt, publish and communicate material you have accessed via or downloaded from the PCEHR system for:

- (a) the purpose of providing healthcare; and
- (b) other purposes of the PCEHR system.

The licences in clauses 7.3 and 7.4 only apply for the specified purposes. They do not remove the need to comply with other laws that may also be applicable – e.g., in relation to confidentiality and privacy.

Assistance in relation to inquiries, etc

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8.1

At our request and on reasonable notice, you must provide reasonable assistance in relation to any inquiry, investigation or complaint, in connection with the PCEHR system conducted, handled or facilitated by us.

Assistance is necessary to ensure that, for example, unauthorised access to the PCEHR system can be effectively investigated and that consumer complaints can be dealt with quickly, efficiently and accurately.

Costs

9

9.1

Each party bears their own costs in complying with their obligations under this agreement.

Warranty

10

10.1

By executing this agreement, you warrant to us that, to the best of your knowledge, the information you have supplied in this agreement is accurate, complete, up-to-date and not misleading.

Resolving disputes

10A

10A.1

If the parties are in dispute, each party must continue to perform its obligations under this agreement.

10A.2

Neither party may commence legal proceedings relating to a dispute arising under this agreement until the dispute resolution process required by this clause has been followed. This clause 10A.2 does not prevent a party commencing legal proceedings for urgent interlocutory relief.

10A.3

A party claiming that there is a dispute must send the other party a written notice setting out the nature of the dispute.

10A.4

The parties must try to resolve a dispute notified under clause 10A.3 through direct negotiation, including by referring the matter to persons within the parties who have the authority to intervene and direct some form of resolution.

10A.5 If:

- (a) after 28 days from the date of the notice under clause 10A.3:

“Interlocutory relief” would include, for example, seeking an interim injunction preventing the other party doing something until a court had the opportunity to hear the matter in full.

- (i) the parties have not resolved the dispute; and
- (ii) the parties have not agreed to submit the dispute to mediation or some alternative dispute resolution procedure; or
- (b) the dispute has been submitted to mediation or some other form of alternative dispute resolution procedure, and the dispute is not resolved within 21 days of the submission, or a longer time agreed in writing by the parties,

either party may commence legal proceedings.

10A.6 Nothing in this clause 10A limits or restricts any function, power, right or entitlement of the System Operator under clause 12.3 or under the PCEHR Act or PCEHR Rules.

Liability

Under clause 11.3, we state that we are liable to you for any loss you suffer as a direct result of our negligence.

Under clause 11.4, the liability of one party to another is reduced to the extent that the other party contributed to the loss.

Clause 11.1 states that we are not liable for any loss that you suffer except as specified in clauses 11.3 and 11.4.

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|-----------|--|
| 11 | <p>11.1 Except as specified in clauses 11.3 and 11.4 we have no liability to you in respect of any loss that you might incur or suffer (including as a result of negligence) that is directly or indirectly related to your:</p> <ul style="list-style-type: none"> (a) use of; or (b) reliance upon; <p>the PCEHR system or health information accessed via or obtained from the PCEHR system; or</p> <ul style="list-style-type: none"> (c) disclosure of information accessed via or obtained from the PCEHR system. <p>11.2 In clause 11.1, “use” and “disclosure” include unauthorised use and/or disclosure by your employees.</p> <p>11.3 We are liable for any loss which you may incur or suffer as a direct result of any negligence by us.</p> <p>11.4 The liability of one party (the “first party”) to the other (the “other party”) for any loss will be reduced proportionately to the extent that:</p> <ul style="list-style-type: none"> (a) any deliberately wrongful, reckless, negligent or unlawful act or omission of the other party contributed to the loss; or (b) any failure by the other party to comply with its obligations under this agreement contributed to the loss. |
|-----------|--|

Termination

- 12**
- 12.1 You may terminate this agreement by giving us at least 7 days written notice.
- 12.2 This agreement will terminate immediately upon the cancellation of your registration as a participant in the PCEHR system.
- 12.3 We may terminate this agreement immediately by written notice to you if:
- (a) you do not agree to any changes to this agreement, proposed in accordance with clause 6, within the timeframe specified in any notice given under clause 6.2 (such notice being at least 28 days);
 - (b) you breach any provision of this agreement and fail to remedy the breach within 28 days after being given a written notice from us requiring you to do so;
 - (c) you breach a material provision of this agreement and, in our reasonable opinion, the breach is not capable of being remedied; or
 - (d) we do not agree with an assignment or a proposed assignment under subclause 13.3(a), including because we consider that the assignment may compromise the integrity or security of the PCEHR system. Where we terminate under this clause 12.3(d), and the assignment has already occurred, we will notify you and the organisation to which you assigned your rights and obligations.
- 12.4 Upon termination of this agreement:
- (a) your right to access the PCEHR system ceases immediately; and
 - (b) we may cancel your registration as a participant in the PCEHR system.
- 12.5 The following clauses survive termination of this agreement:
- (a) clause 7 (intellectual property);
 - (b) clause 8 (assistance in relation to inquiries, etc), but only for the term of this agreement and for a period of seven years following termination;
 - (c) clause 9 (costs);
 - (ca) clause 10A (resolving disputes), but only to the extent a dispute arises between the parties in connection with

a clause that survives termination under this clause 12.5;

- (d) clause 11 (liability);
- (e) clauses 12.5 (survival) and 12.6 (accrued rights); and
- (f) clauses 13.1 (jurisdiction), 13.2 (entire agreement), 13.6 (giving effect to this agreement) and 13.7 (severability),

and any definitions or other provisions necessary to give effect to these clauses.

- 12.6 Termination of this agreement does not affect any accrued rights or remedies of a party.

Miscellaneous

- 13**
- 13.1 This agreement is governed by the law in force in the Australian Capital Territory. Each party submits to the exclusive jurisdiction of the courts of that place.
 - 13.2 This agreement constitutes the entire agreement between you and us about its subject matter.
 - 13.3 Assignment and novation:
 - (a) assignment or novation by you:
 - (i) if you are the Crown in right of a State or Territory, you must notify us as soon as practicable of any assignment or proposed novation or assignment of your rights and obligations under this agreement to another healthcare provider organisation and give us the contact details of the organisation to which you assigned or propose novating or assigning your rights and obligations;
 - (ii) in all other cases, you must give us at least 14 days written notice of your intention to assign or novate your rights and obligations under this agreement and give us the contact details of the organisation to which you propose to assign or novate your rights and obligations; and
 - (iii) if we do not agree to the assignment, or the proposed novation or assignment, under clause 13.3(a)(i) or (ii) we have an absolute discretion to terminate this agreement in accordance with clause 12; and
 - (b) we may assign or novate our rights and obligations

The System Operator would not agree to an assignment or novation where, for example, the party to whom the agreement is to be assigned or novated is not capable of being registered as a healthcare provider organisation under the PCEHR Act.

Under paragraph 14(1)(b) of the PCEHR Act, a body established by a Commonwealth law may be prescribed as the System Operator. If this occurs, it may be necessary to novate this agreement to the new System Operator.

The ability to give notice of a change of System Operator is dependent on a number of factors outside the control of the current System Operator – e.g., Parliamentary and Government processes.

under this agreement to a body that takes over from us as the System Operator. If it is proposed that another body will take over from us as System Operator, we will endeavour to give you reasonable notice of the change.

- 13.4 Except where this agreement expressly states otherwise, a party may, in its discretion, give conditionally or unconditionally or withhold any approval or consent under this agreement.
- 13.5 This agreement may be executed in counter-parts. All executed counter-parts constitute one document.
- 13.6 Each party must, at its own expense, do everything reasonably necessary (including executing documents) to give full effect to this agreement and any transactions contemplated by it.
- 13.7 A term or part of a term of this agreement that is illegal or unenforceable may be severed from this agreement and the remaining terms or parts of the terms of this agreement continue in force.

Definitions and interpretation

- 14 14.1 Unless a contrary intention appears, the following definitions apply:

Compromised, in relation to the security of the PCEHR system, means:

- (a) a person has, or may have, contravened the PCEHR Act in a manner involving an unauthorised collection, use or disclosure of health information included in a consumer's PCEHR; or
- (b) an event has occurred or circumstances have arisen (whether or not involving a contravention of the PCEHR Act) that compromise, or may compromise, the security or integrity of the PCEHR system.

Consumer has the same meaning as in the PCEHR Act.

Contact person means, for each party, the person described in the relevant part of the "Parties: System Operator and Healthcare Provider Organisation" section of this agreement.

Contact details means, for each party, the contact details described in the relevant part of the "Parties: System Operator and Healthcare Provider Organisation" section of this agreement.

Employee has the same meaning as in the PCEHR Act.

Entity means:

- (a) a person; or
- (b) a partnership; or
- (c) any other unincorporated association or body; or
- (d) a trust; or
- (e) a part of an entity (under a previous application of this definition).

This is the same meaning that “entity” has under the PCEHR Act.

HI Act means the *Healthcare Identifiers Act 2010* (Cth).

Intellectual property rights or **IP rights** means all intellectual property rights including all copyright, all rights in relation to inventions (including patent rights), registered and unregistered trade marks and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

Loss means any liability, expense, loss, damage or cost of any kind (including legal costs on a full indemnity basis, whether incurred by or awarded against a party).

Participant in the PCEHR system has the same meaning as in the PCEHR Act.

PCEHR means personally controlled electronic health record.

PCEHR Act means the *Personally Controlled Electronic Health Records Act 2012* (Cth).

PCEHR Rules has the same meaning as in the PCEHR Act.

PCEHR system has the same meaning as in the PCEHR Act.

Personally controlled electronic health record has the same meaning as in the PCEHR Act.

System Operator has the same meaning as in the PCEHR Act.

The defined term “participant in the PCEHR system” includes registered healthcare provider organisations.

14.2 In this agreement, unless the contrary intention appears:

- (a) the singular includes the plural and vice versa;
- (b) another grammatical form of a defined word or expression has a corresponding meaning;
- (c) a reference to a statute or other law includes regulations and other instruments under it and

“PCEHRs” or “personally controlled electronic health records” are sometimes referred to as eHealth

records.

*As at 1 July 2012, the
System Operator is the
Secretary of the Department
of Health and Ageing.*

consolidations, amendments, re-enactments or
replacements of any of them;

- (d) a reference to a document includes the document as novated, altered, supplemented or replaced from time to time;
- (e) a reference to a person includes the person's permitted successors, substitutes (including, without limitation, persons taking by novation) and assigns;
- (f) a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority or agency or other entity;
- (g) a word or expression defined in the PCEHR Act has the meaning given to it in the PCEHR Act;
- (h) "including", "includes", "such as" and "in particular" do not limit the generality of the words which precede them or to which they refer;
- (i) any agreement, representation, warranty or indemnity by two or more parties (including where two or more persons are included in the same defined term) binds them jointly and severally;
- (j) any agreement, representation, warranty or indemnity in favour of two or more parties (including where two or more persons are included in the same defined term) is for the benefit of them jointly and severally;
- (k) a rule of construction does not apply to the disadvantage of a party because the party was responsible for the preparation of this agreement or any part of it; and
- (l) headings, footnotes and explanatory notes in the left hand column are for convenience and do not affect interpretation of this agreement.

14.3 The italicised notes in the left hand column have been provided for convenience, and are for information only. They do not form part of this agreement.

Signing page

Executed as a deed

DATED: _____

ⁱ The italicised notes in the left hand column have been provided for convenience, and are for information only. They do not form part of this agreement— see clause 14.3.