

National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 26 September 2024

Sam Mostyn AC Governor-General

By Her Excellency's Command

Mark Butler Minister for Health and Aged Care



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1 Name

This instrument is the *National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024.*

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information			
Column 1	Column 2	Column 3 Date/Details	
Provisions	Commencement		
1. The whole of this instrument	The day after this instrument is registered.	2 October 2024	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the National Health Act 1953.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceutical Benefits) Regulations 2017

1 Subsection 5(1)

Insert:

electronic medication chart system means a software system that:

- (a) is used for prescribing, and recording the administration of, pharmaceutical benefits to a person receiving treatment in or at:
 - (i) a residential care service at which the person is receiving residential care; or
 - (ii) an approved hospital; and
- (b) is accessible in real time by approved suppliers for the purposes of:
 - (i) viewing electronic prescriptions written in electronic medication charts within the system; and
 - (ii) recording the supply information mentioned in paragraph 45(2)(d) in such electronic prescriptions; and
- (c) meets any electronic medication chart system functionality requirements approved by the Secretary under section 12A.

2 Subsection 5(1) (subparagraphs (b)(i) and (ii) of the definition of electronic prescription)

Repeal the subparagraphs, substitute:

- (i) for prescriptions other than medication chart prescriptions—the form approved by the Secretary under subparagraph 40(2)(c)(ii); or
- (ii) for medication chart prescriptions—either the form approved by the Secretary under paragraph 41(5)(a), or the information requirements approved by the Secretary under paragraph 41(5)(b), for the purpose of writing an electronic prescription.

3 At the end of Division 2 of Part 1

Add:

12A Electronic medication chart system functionality requirements

For the purposes of paragraph (c) of the definition of *electronic medication chart system* in subsection 5(1), the Secretary may, in writing, approve electronic medication chart system functionality requirements to facilitate the safe and effective prescribing and supplying of pharmaceutical benefits using electronic medication charts.

4 After paragraph 41(1)(b)

Insert:

; and (c) if the prescription is an electronic prescription—the electronic prescription is written in an electronic medication chart using an electronic medication chart system.

2

5 Paragraph 45(2)(a)

Before "the approved supplier", insert "if the medication chart by which the prescription was written is not an electronic medication chart—".

6 After paragraph 45(2)(a)

Insert:

- (aa) if the medication chart by which the prescription was written is an electronic medication chart—the approved supplier:
 - (i) if subparagraph (ii) does not apply and subject to subsection (8)—has seen the electronic medication chart by which the prescription was written in an electronic medication chart system; or
 - (ii) in a case of urgency—has seen a copy of the electronic medication chart that complies with subsection (2A) and supplies the pharmaceutical benefit in accordance with subsection (2B); and

7 Paragraph 45(2)(c)

Omit "the approved supplier writes on the medication chart, or the copy of the chart, the following for the supply", substitute "if the medication chart by which the prescription was written is not an electronic medication chart—the approved supplier writes on the medication chart, or the copy of the chart, the following for the supply".

8 At the end of subsection 45(2)

Add:

- ; and (d) if the medication chart by which the prescription was written is an electronic medication chart—the approved supplier writes on the electronic prescription written in the electronic medication chart the following information for the supply:
 - (i) the approved supplier's name and approval number under section 16;
 - (ii) an identification number for the supply;
 - (iii) the date on which the pharmaceutical benefit is supplied.

9 After subsection 45(2)

Insert:

- (2A) For the purposes of subparagraph (2)(aa)(ii), a copy of an electronic medication chart complies with this subsection if the copy of the chart:
 - (a) meets so much of the information requirements approved for the electronic medication chart under paragraph 41(5)(b) as are specified, in writing, by the Secretary under subsection (9) of this section; and
 - (b) contains a date stamp showing the date and time when the copy was generated.
- (2B) For the purposes of subparagraph (2)(aa)(ii), the approved supplier:
 - (a) must supply the pharmaceutical benefit within 72 hours of the date and time stamped on the copy of the electronic medication chart in accordance with paragraph (2A)(b); and
 - (b) despite subsections (5), (6) and (7), must not:
 - (i) supply the pharmaceutical benefit more than once; or
 - (ii) supply more than the maximum quantity of the pharmaceutical benefit.

10 Subparagraphs 45(3)(a)(i) and (ii)

Repeal the subparagraphs, substitute:

- (i) starts on the day when the first prescription for a pharmaceutical benefit is written in the medication chart; and
- (ii) ends 6 months after the day mentioned in subparagraph (i); or

11 Subsection 45(3) (example)

Omit "30 November", substitute "11 December".

12 At the end of section 45

Add:

Matters in relation to electronic medication charts

- (8) For the purposes of subparagraph (2)(aa)(i), the electronic medication chart seen by the approved supplier:
 - (a) must include the information mentioned in subparagraph 41(2)(a)(iii) (about dose, frequency of administration and route of administration) that is written in the chart in respect of the person for whom the pharmaceutical benefit is prescribed; but
 - (b) does not need to include other information in the electronic medication chart about the administration of the pharmaceutical benefit to the person.

Information requirements for copies of electronic medication charts

(9) The Secretary may, in writing, specify information requirements for the purposes of paragraph (2A)(a).

13 Before subsection 61(1)

Insert:

Supplying a pharmaceutical benefit on the basis of a medication chart prescription if the medication chart is not an electronic medication chart

14 After paragraph 61(1)(a)

Insert:

(aa) the medication chart is not an electronic medication chart; and

15 After subsection 61(1)

Insert:

Supplying a pharmaceutical benefit on the basis of a medication chart prescription if the medication chart is an electronic medication chart

- (1A) An approved supplier commits an offence if:
 - (a) the approved supplier supplies a pharmaceutical benefit on the basis of a medication chart prescription; and
 - (b) the medication chart is an electronic medication chart; and
 - (c) the approved supplier does not keep the electronic prescription written in the electronic medication chart, or a copy of the electronic prescription, on which the approved supplier wrote the details referred to in

paragraph 45(2)(d) in relation to the electronic prescription, for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

Penalty: 0.2 penalty units.

Strict liability offences

16 Subsection 61(2)

After "subsection (1)", insert "or (1A)".

17 In the appropriate position in Part 9

Insert:

105 Application provisions relating to the National Health (Pharmaceutical Benefits) Amendment (Medication Charts) Regulations 2024

- (1) The amendment made by item 4 of Schedule 1 to the *National Health* (*Pharmaceutical Benefits*) *Amendment* (*Medication Charts*) *Regulations* 2024 (the *amending regulations*) applies in relation to an electronic prescription written on or after the commencement of the amending regulations.
- (2) The amendments made by items 5 to 9 and item 12 of Schedule 1 to the amending regulations apply in relation to the supply of a pharmaceutical benefit occurring on or after the commencement of the amending regulations.
- (3) The amendments made by items 10 and 11 of Schedule 1 to the amending regulations apply in relation to an electronic medication chart where the first prescription for a pharmaceutical benefit is written in the chart on or after the commencement of the amending regulations.
- (4) The amendments made by items 13 to 15 of Schedule 1 to the amending regulations apply in relation to the supply of a pharmaceutical benefit occurring on or after the commencement of the amending regulations.