National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 14 March 2024

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

OPC66654 - A

Contents

1 Name

This instrument is the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) 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
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 April 2024.	1 April 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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) (definition of *authority prescription*)

Repeal the definition, substitute:

authority prescription means a prescription that prescribes a pharmaceutical benefit and that:

(a) has been written in accordance with an authorisation under section 30; or

(b) has been authorised in accordance with authority required procedures that:

(i) are part of the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or

(ii) are part of the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit; or

(c) if neither paragraph (a) or (b) applies—has been authorised as part of the circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act.

2 Section 30

Repeal the section, substitute:

30 Variation of application of determination of maximum number of repeats or maximum number of quantity of units

(1) For the purposes of subsection 85A(3) of the Act, this section makes provision for authorising the variation of the application, in relation to persons included in a class of persons, of a determination under paragraph 85A(2)(a) or (b) of the Act.

(2) If:

(a) a practitioner included in a class of persons to which the determination applies proposes to write a prescription of one of the following kinds that is not in accordance with the determination:

(i) a prescription other than a medication chart prescription;

(ii) a medication chart prescription for a person who is receiving treatment in or at an approved hospital; and

(b) the practitioner provides the details of the proposed prescription to the Minister;

the Minister may authorise the variation of the application of the determination in relation to that practitioner and that prescription.

(3) If the Minister decides to authorise the variation, the Minister must allot a number to the prescription and tell the practitioner that number.

Note: For requirements to write the allotted number on the prescription, see sections 40 and 41.

3 Section 33 (heading)

Omit "**obtaining benefits by practitioners**", substitute "**practitioners other than approved medical practitioners**".

4 Before subsection 33(1)

Insert:

Application

(1A) This section applies to a practitioner who is not an approved medical practitioner.

How benefits to be obtained—lodging order with approved pharmacist

5 Subsection 33(1)

Omit "Act, a practitioner who is not an approved medical practitioner", substitute "Act and subject to this section, a practitioner".

6 Before subsection 33(3)

Insert:

Restriction—one order per month

7 Subsection 33(3)

Omit "who is not an approved medical practitioner".

8 After subsection 33(3)

Insert:

Restriction—stockpiling

(3A) A practitioner may obtain a pharmaceutical benefit that has a drug mentioned in an item of Schedule 1 to the *National Health (Prescriber Bag Supplies) Determination 2024* in the form mentioned in that item at a particular time only if, at that time:

(a) the quantity (if any) of pharmaceutical benefits that have that drug in that form that the practitioner has in the practitioner's possession and that the practitioner has previously obtained under this section is less than the maximum quantity set out in that item; and

(b) if the group number mentioned in that item is the same as the group number mentioned in another item—the quantity (if any) of pharmaceutical benefits that have the drug mentioned in the other item in the form mentioned in the other item that the practitioner has in the practitioner's possession and that the practitioner has previously obtained under this section is less than the maximum quantity set out in the other item.

Receipt for order

9 Paragraph 40(1)(i)

Repeal the paragraph, substitute:

(i) if the prescription is covered by paragraph (a) or (b) of the definition of ***authority prescription***—writes on it:

(i) each authority approval number for the prescription; or

(ii) the relevant streamlined authority code for the pharmaceutical benefit that is prescribed; and

10 Paragraph 40(1)(j)

After "'Regulation 24',", insert "'Reg 49', 'Regulation 49', 'Section 49',".

11 Subsection 40(1) (note)

Repeal the note, substitute:

Note 1: For paragraph (i), an authority prescription covered by paragraph (c) of the definition does not require an authority approval number to be a valid prescription, but an authority approval number may be needed for the special patient contribution to be payable by the Commonwealth under section 85B of the Act.

Note 2: For paragraph (j), section 49 of this instrument was previously regulation 24 of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

12 Subsection 40(5) (including the note)

Repeal the subsection.

13 Subparagraph 41(1)(b)(ii)

Omit "an authority prescription other than an authority prescription referred to in subsection (3A)", substitute "covered by paragraph (a) or (b) of the definition of ***authority prescription***".

14 At the end of subsection 41(1)

Add:

Note: For subparagraph (b)(ii), an authority prescription covered by paragraph (c) of the definition does not require an authority approval number to be a valid prescription, but an authority approval number may be needed for the special patient contribution to be payable by the Commonwealth under section 85B of the Act.

15 Subparagraph 41(3)(a)(i)

Omit ", unless the prescription is to be posted or delivered to the Minister or Chief Executive Medicare for authorisation".

16 Subsection 41(3A)

Repeal the subsection.

17 Section 57

Repeal the section.

18 In the appropriate position in Part 9

Insert:

104 Transitional provision relating to the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*

(1) This section applies in relation to prescriptions for the supply of pharmaceutical benefits written before 1 July 2024.

(2) Despite the repeal and substitution of section 30 by the *National Health (Pharmaceutical Benefits) Amendment (2024 Measures No. 1) Regulations 2024*:

(a) a practitioner may submit a prescription to the Minister in accordance with subsection 30(3) as in force immediately before 1 April 2024; and

(b) the Minister may make a variation under subsection 30(1) as in force immediately before 1 April 2024 in relation to the practitioner; and

(c) the prescription is taken to have been written in accordance with an authorisation under section 30 if the prescription is authorised in accordance with subsection 30(4) as in force immediately before 1 April 2024.

(3) If the Minister makes a variation in accordance with paragraph 30(4)(a), (b) or (c) as in force immediately before 1 April 2024, the practitioner is not required to comply with the following provisions in relation to the authorised prescription:

(a) paragraph 40(1)(i);

(b) paragraph 41(3)(a).