



National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019

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 03 October 2019

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*.

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	31 October 2019.	31 October 2019

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Section 5

Insert:

pharmaceutical benefit has a drug has the same meaning as in Part VII of the Act.

2 Paragraph 40(1)(d)

Repeal the paragraph, substitute:

- (d) identifies in the prescription the pharmaceutical benefit in accordance with subsection (2A); and

3 After subsection 40(2)

Insert:

- (2A) For the purposes of paragraph (1)(d), the PBS prescriber must identify in the prescription:

(a) if:

- (i) the prescription is prepared in accordance with paragraph (2)(a); or
(ii) the prescription is for the supply of a pharmaceutical benefit that has 4 or more drugs; or
(iii) the prescription is for the supply of a pharmaceutical benefit that is specified by the Secretary, in writing, for the purposes of this subparagraph;

the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit; or

(b) otherwise:

- (i) each drug that the pharmaceutical benefit has; and
(ii) if the PBS prescriber considers that it is necessary for the medical treatment of the person for whom the pharmaceutical benefit is to be supplied to identify a brand of the pharmaceutical item that the pharmaceutical benefit has—the brand of the pharmaceutical item.

- (2B) If subparagraph (2A)(b)(ii) applies, the brand of the pharmaceutical item must be listed after the drugs that the pharmaceutical benefit has.

- (2C) Subsection (2A) does not apply to the extent that it would be contrary to a law of a State or Territory that would otherwise apply.

4 Subsection 40(4)

Repeal the subsection, substitute:

- (4) For the purposes of paragraphs (2)(b), (c) and (d), a prescription must not be prepared using a computer program that:
- (a) operates, or may operate, to indicate on a prescription by default, for the purposes of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied; or

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- (b) if paragraph (2A)(b) of this section applies to the prescription—operates, or may operate, to indicate on a prescription by default a brand of the pharmaceutical item that the pharmaceutical benefit has.

5 Subparagraph 41(2)(a)(i)

Repeal the subparagraph, substitute:

- (i) particulars to identify the pharmaceutical benefit in accordance with subsection (2A); and

6 After paragraph 41(2)(e)

Insert:

- (ea) if paragraph (2A)(b) of this section applies to the prescription—the section of the chart is not completed using a computer program that operates, or may operate, to indicate on a prescription by default a brand of the pharmaceutical item that the pharmaceutical benefit has; and

7 After subsection 41(2)

Insert:

- (2A) For the purposes of subparagraph (2)(a)(i), the PBS prescriber must write in the section of the chart:
- (a) if:
- (i) the prescription is prepared by handwriting the prescription on the section of the chart; or
 - (ii) the prescription is for the supply of a pharmaceutical benefit that has 4 or more drugs; or
 - (iii) the patient is receiving treatment in or at a residential care service and the medication chart is not an electronic medication chart; or
 - (iv) the prescription is for the supply of a pharmaceutical benefit that is specified by the Secretary, in writing, for the purposes of this subparagraph;
- particulars sufficient to identify the pharmaceutical benefit; or
- (b) otherwise:
- (i) each drug that the pharmaceutical benefit has; and
 - (ii) if the PBS prescriber considers that it is necessary for the medical treatment of the patient to identify a brand of the pharmaceutical item that the pharmaceutical benefit has—the brand of the pharmaceutical item.
- (2B) If subparagraph (2A)(b)(ii) applies, the brand of the pharmaceutical item must be listed after the drugs that the pharmaceutical benefit has.
- (2C) Subsection (2A) does not apply to the extent that it would be contrary to a law of a State or Territory that would otherwise apply.

8 At the end of Part 9

Add:

102 Transitional provision relating to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*

- (1) This section applies in relation to a prescription for the supply of a pharmaceutical benefit that is written before 1 November 2020.
- (2) Despite the amendments of section 40 made by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*, a prescription that is not a medication chart prescription is taken to have been written in accordance with section 40 if the prescription is written in accordance with that section as in force immediately before 31 October 2019.
- (3) Despite the amendments of section 41 made by Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*, a prescription that is a medication chart prescription is taken to have been written in accordance with section 41 if the prescription is written in accordance with that section as in force immediately before 31 October 2019.