



PB 17 of 2023

**National Health Legislation Amendment
(Conditions of Approval for Approved
Pharmacists) Instrument 2023**

I, Mark Butler, Minister for Health and Aged Care, make the following instrument.

Dated 19 April 2023

Mark Butler
Minister for Health and Aged Care

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1 Name

- (1) This instrument is the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023*.
- (2) This instrument may also be cited as PB 17 of 2023.

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 June 2023.	1 June 2023

Note: This table relates only to the provisions of this instrument as originally made.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 subsections 92A(1A) and 100(2) of 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Main amendments

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

1 Before section 1

Insert:

Part 1—Preliminary

2 Subsection 1(1)

Omit “of approval”.

3 Section 4 (note)

Repeal the note, substitute:

Note 1: The Minister may, after investigation and report by the appropriate Committee of Inquiry, suspend, further suspend or revoke the approval of a pharmacist if the Minister is satisfied that the pharmacist has, in relation to or arising out of the approval, been guilty of conduct which is an abuse of that approval (see section 95 of the Act). Any conduct of an approved pharmacist that is a contravention of the conditions specified in section 92A of the Act shall be deemed to be conduct that is an abuse of the pharmacist’s approval for the purposes of section 95 of the Act (see subsection 92A(3) of the Act).

Note 2: The dispensing of drugs and medicinal preparations is also regulated under State and Territory laws.

4 Section 5 (after the heading)

Insert:

Note 1: A number of expressions used in this Determination are defined in the Act, including the following:

- (a) pharmacist (see subsection 4(1) of the Act);
- (b) premises (see subsection 4(1) of the Act);
- (c) prescription for the supply of a pharmaceutical benefit (see subsection 4(2) of the Act);
- (d) supply of pharmaceutical benefits at premises (see subsection 4(3) of the Act).

Note 2: Under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act. The expression National Law used in this instrument is defined in that Act.

5 Section 5

Insert:

Act means the *National Health Act 1953*.

approval number, for an approved pharmacist in respect of particular premises, means the pharmacist’s approval number under section 16 of the Regulations in respect of those premises.

approved pharmacist has the same meaning as in Part VII of the Act.

arrangement includes a contract, agreement or understanding, written or oral, and whether or not legally enforceable.

brand has the same meaning as in Part VII of the Act.

continued dispensing prescription, for a supply of a pharmaceutical benefit in accordance with subsection 89A(1) of the Act (supply without prescription), means the prescription referred to section 3.03 of the *National Health (Continued Dispensing) Determination 2022* in relation to the supply.

deferred supply authorisation has the same meaning as in the Regulations.

dispensing step: each of the following is a **dispensing step** in the dispensing of a pharmaceutical benefit:

- (a) if the benefit is to be supplied on the basis of a prescription (other than a medication chart prescription), repeat authorisation or deferred supply authorisation—reviewing the prescription, repeat authorisation or deferred supply authorisation;
- (b) if any of the following apply to the benefit—preparing the benefit:
 - (i) the benefit is a listed brand of a pharmaceutical item and the quantity of the benefit is less than a pack quantity of the listed brand of the pharmaceutical item;
 - (ii) the benefit requires the admixture of ready-prepared ingredients;
 - (iii) the benefit is an extemporaneously-prepared pharmaceutical benefit;
- (c) if the benefit is to be supplied other than on an order lodged under section 33 of the Regulations (prescriber bag supplies)—generating, and affixing to the packaging for the benefit, a label that displays the following:
 - (i) for a benefit other than an extemporaneously-prepared pharmaceutical benefit or a benefit that is to be supplied in accordance with the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*—the brand of the pharmaceutical item in the benefit;
 - (ii) if paragraph 40(2A)(b) or 41(2A)(b) of the Regulations applied to the prescription or continued dispensing prescription for the supply of the benefit—each drug that the benefit has;
 - (iii) the form (if any) and quantity or number of units of the benefit;
 - (iv) directions for use of the benefit in accordance with the instructions of the PBS prescriber who wrote the prescription or continued dispensing prescription for the supply of the benefit;
 - (v) the name of the person for whom the prescription or continued dispensing prescription for the supply of the benefit was written;
 - (vi) the date the benefit is dispensed;
 - (vii) the address of the premises at which the benefit is dispensed;
 - (viii) the name of the pharmacy situated at those premises (the **dispensing pharmacy**);
 - (ix) if subsection 64(1) of the Regulations applies to the benefit—the full cost of the benefit;
- (d) if required by section 52 of the Regulations—preparing a repeat authorisation for the benefit;
- (e) recording the dispensing of the benefit in the dispensing pharmacy's system for recording the dispensing of pharmaceutical benefits.

Note 1: For paragraph (a), a prescription may be in the form of a paper-based prescription or an electronic prescription (see section 39 of the Regulations).

Note 2: For subparagraphs (c)(ii), (iv) and (v), a prescription may be in the form of a paper-based prescription, an electronic prescription or a medication chart prescription (see section 39 of the Regulations).

Note 3: For subparagraph (c)(iii), the form of a pharmaceutical benefit may be determined by reference to strength, type of unit, size of unit or otherwise, and may be such as to require the addition of a substance or substances to the drug so that it will be suitable for administration in a particular manner or at a particular strength (see subsections 85(3) and (4) of the Act).

electronic prescription has the same meaning as in the Regulations.

extemporaneously-prepared pharmaceutical benefit has the same meaning as in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*.

listed brand has the same meaning as in Part VII of the Act.

6 Section 5 (definition of *medication chart prescription*)

Omit “*National Health (Pharmaceutical Benefits) Regulations 2017*”, substitute “Regulations”.

7 Section 5

Insert:

pack quantity has the same meaning as in Part VII of the Act.

paper-based prescription has the same meaning as in the Regulations.

PBS prescriber has the same meaning as in Part VII of the Act.

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

pharmaceutical item has the same meaning as in Part VII of the Act.

pharmacy means a business in the course of the carrying on of which pharmaceutical benefits are supplied.

record form has the same meaning as in Part VII of the Act.

8 Section 5 (definition of *reference time*)

Repeal the definition.

9 Section 5

Insert:

registered pharmacist means an individual who is registered under the National Law in the pharmacy profession.

Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017*.

repeat authorisation has the same meaning as in the Regulations.

10 After section 5

Insert:

5A Application of this Determination

This Determination applies to the dispensing and supply of a drug or medicinal preparation if:

- (a) the supply of the drug or medicinal preparation is to be a supply of a pharmaceutical benefit under Part VII of the Act (other than a supply taken, because of subsection 99(2A), (2AB) or (2B) of the Act, to be a supply otherwise than under Part VII of the Act); or
- (b) it is purported that the supply of the drug or medicinal preparation is to be a supply of a pharmaceutical benefit under Part VII of the Act (other than a supply taken, because of subsection 99(2A), (2AB) or (2B) of the Act, to be a supply otherwise than under Part VII of the Act).

Note 1: For example, this Determination does not apply to the dispensing and supply of a drug or medicinal preparation if:

- (a) the drug or medicinal preparation is not a pharmaceutical benefit; or
- (b) both:
 - (i) the drug or medicinal preparation is supplied on the basis of a prescription; and
 - (ii) the person presenting the prescription requests that the drug or medicinal preparation not be supplied as a pharmaceutical benefit under Part VII of the Act.

Note 2: For example, this Determination does not apply to the dispensing and supply of a pharmaceutical benefit if:

- (a) the person to whom the pharmaceutical benefit is supplied is not covered by subsection 86(1) of the Act (entitlement to receive pharmaceutical benefits); or
- (b) the following circumstances apply:
 - (i) the pharmaceutical benefit is supplied on the basis of a prescription;
 - (ii) the pharmaceutical benefit is determined, under subsection 85(7) of the Act, to be a relevant pharmaceutical benefit for the purposes of section 88A of the Act (prescription of certain pharmaceutical benefits authorised only in certain circumstances);
 - (iii) the writing of the prescription was not authorised as mentioned in that section.

11 Before section 6

Insert:

Part 2—Conditions

12 Section 6

Omit “dispensing prescriptions for pharmaceutical benefits and in supplying”, substitute “dispensing and supplying”.

13 Paragraph 6(c)

Omit “Pharmaceutical Society of Australia’s Code of Ethics for Pharmacists 2017, as existing at the reference time”, substitute “Code of Ethics for Pharmacists (2017), published by the Pharmaceutical Society of Australia on 1 February 2017”.

14 Paragraph 6(d)

Omit “Pharmaceutical Society of Australia’s Professional Practice Standards 2017, as existing at the reference time”, substitute “Professional Practice Standards – Version 5 – June 2017, published by the Pharmaceutical Society of Australia in June 2017”.

15 Section 6 (examples and note)

Repeal the examples and note, substitute:

- Note 1: The following are examples for subparagraph (d)(i) of ways that a patient could ensure that an approved pharmacist has ready access to the patient's medication history:
- (a) the patient having all medications, including pharmaceutical benefits, dispensed at or from a single approved premises for the pharmacist;
 - (b) the patient providing the pharmacist with the patient's record forms (if any);
 - (c) the patient authorising the transfer of the patient's medication history to the approved pharmacist.
- Note 2: The Code of Ethics for Pharmacists (2017) and the Professional Practice Standards – Version 5 – June 2017 could in 2023 be viewed on the Pharmaceutical Society of Australia's website (<https://www.psa.org.au>).

16 Section 7

Omit "Pharmaceutical Society of Australia's National Competency Standards Framework for Pharmacists in Australia 2017, as existing at the reference time", substitute "National Competency Standards Framework for Pharmacists in Australia 2016, published by the Pharmaceutical Society of Australia in 2016".

17 Section 7 (note)

Repeal the note, substitute:

- Note: The National Competency Standards Framework for Pharmacists in Australia 2016 could in 2023 be viewed on the Pharmaceutical Society of Australia's website (<https://www.psa.org.au>).

18 Sections 8 and 9

Repeal the sections, substitute:

8 Ensuring other pharmacists at approved premises comply with conditions

An approved pharmacist that is approved in respect of particular premises must ensure that a registered pharmacist:

- (a) who is not an approved pharmacist in respect of those premises; and
 - (b) who dispenses pharmaceutical benefits at those premises;
- complies with the conditions set out in this Determination.

9 No purported supply of pharmaceutical benefits at or from unapproved premises

Purported supply at unapproved premises

- (1) An approved pharmacist must not purport to supply a pharmaceutical benefit at premises that are not approved premises for the pharmacist.

Note: A reference to the supply of pharmaceutical benefits at premises is a reference to the supply of pharmaceutical benefits to people who are at the premises when the supply is made (see subsection 4(3) of the Act).

Purported supply from unapproved premises

- (2) An approved pharmacist must not purport to supply a pharmaceutical benefit from premises that are not approved premises for the pharmacist.

10 Requirements for supply of pharmaceutical benefits at or from approved premises—dispensing steps

- (1) An approved pharmacist must not supply a pharmaceutical benefit at or from approved premises for the pharmacist if a requirement in this section is not met in relation to the dispensing of the benefit.

Benefit must be at approved premises when dispensing steps performed

- (2) The benefit must be at the approved premises when each dispensing step in the dispensing of the benefit is performed.

Registered pharmacist must dispense or supervise dispensing

- (3) A registered pharmacist must dispense, or directly supervise the dispensing of, the benefit.

Registered pharmacist must be physically present at approved premises when dispensing steps performed

- (4) The registered pharmacist dispensing, or directly supervising the dispensing of, the benefit must be physically present at the approved premises when each dispensing step in the dispensing of the benefit is performed.

11 Requirements for supply of pharmaceutical benefits at or from approved premises—prescriptions other than medication chart prescriptions

- (1) An approved pharmacist must not supply a pharmaceutical benefit at or from approved premises for the pharmacist if:
 - (a) the benefit is supplied on the basis of a prescription that is not a medication chart prescription; and
 - (b) the requirement in subsection (2) is not met in relation to the dispensing of the benefit.

- (2) The registered pharmacist dispensing, or directly supervising the dispensing of, the benefit must, when the step mentioned in paragraph (a) of the definition of ***dispensing step*** in section 5 is performed, see the prescription at the approved premises.

Note: For supplies of pharmaceutical benefits without prescriptions, see the following:

- (a) subsection 89A(1) of the Act and section 46 of the Regulations (supply without prescription);
- (b) section 33 of the Regulations (prescriber bag supplies);
- (c) section 48 of the Regulations (supply before surrender of written prescription).

12 Advances not to be sought, and claims for payment not to be made, for purported supplies or supplies contravening section 10 or 11

Advances

- (1) An approved pharmacist must not seek an advance under subsection 99AB(1) of the Act in relation to:
 - (a) the purported supply of a pharmaceutical benefit as mentioned in subsection 9(1) or (2) of this Determination; or

- (b) the supply of a pharmaceutical benefit if the supply contravened subsection 10(1) or 11(1) of this Determination.

Claims for payment

- (2) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to:
 - (a) the purported supply of a pharmaceutical benefit as mentioned in subsection 9(1) or (2); or
 - (b) the supply of a pharmaceutical benefit if the supply contravened subsection 10(1) or 11(1).

Note: Section 99 of the Act does not authorise payment in respect of the supply of a drug or medicinal preparation by an approved pharmacist at or from premises in respect of which the pharmacist is not approved (see paragraph 99(3)(b) of the Act).

13 Deferred supply authorisations to be prepared only at approved premises

- (1) This section applies to the preparation by an approved pharmacist of a deferred supply authorisation.
- (2) The approved pharmacist must ensure that the authorisation is prepared by, or under the direct supervision of, a registered pharmacist who is physically present at premises that are approved premises for the approved pharmacist.

14 Approval numbers not to be used in connection with unapproved premises

An approved pharmacist must not use, or allow the use of, the pharmacist's approval number in respect of particular premises in relation to:

- (a) the dispensing of a pharmaceutical benefit at any other premises; or
- (b) the purported supply of a pharmaceutical benefit at or from any other premises; or
- (c) the preparation of a repeat authorisation at any other premises; or
- (d) the preparation of a deferred supply authorisation at any other premises.

Note 1: For example (for paragraphs (a) and (b)), an approved pharmacist must not affix (or allow to be affixed) a label to a pharmaceutical benefit purportedly supplied by the approved pharmacist if:

- (a) the label displays the approval number allotted in respect of premises that are approved premises for the pharmacist; and
- (b) the benefit is dispensed at, or purportedly supplied at or from, premises other than those approved premises for the pharmacist.

Note 2: For example (for paragraph (c)), an approved pharmacist must not mark (or allow the marking) on a repeat authorisation the approval number allotted in respect of premises that are approved premises for the pharmacist if the repeat authorisation is prepared at premises other than those approved premises for the pharmacist.

Note 3: For example (for paragraph (d)), an approved pharmacist must not mark (or allow the marking) on a deferred supply authorisation the approval number allotted in respect of premises that are approved premises for the pharmacist if the deferred supply authorisation is prepared at premises other than those approved premises for the pharmacist.

15 Approved pharmacists not to enter into certain arrangements

An approved pharmacist must not enter into an arrangement with the owner or operator of another pharmacy business for the supply by the approved pharmacist of pharmaceutical benefits to persons presenting at that pharmacy business.

Part 3—Application, saving and transitional provisions**16 Application of amendments made by the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023***

- (1) Despite the amendments of this Determination made by Schedule 1 to the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023*, this Determination continues to apply, as if those amendments had not been made, in relation to an approved pharmacist to whom subsection (2) applies during the period mentioned in subsection (3) for the pharmacist.
- (2) For the purposes of subsection (1), this subsection applies to an approved pharmacist if, immediately before 1 June 2023, the Pharmaceutical Services Federal Committee of Inquiry was inquiring into a matter that concerns the services or conduct of the pharmacist.
- (3) For the purposes of subsection (1), the period for the pharmacist begins on 1 June 2023 and ends at the end of the day on which the Committee:
 - (a) gives its report in relation to the matter to the pharmacist; or
 - (b) gives the pharmacist notice in writing that the inquiry has terminated.

Schedule 2—Consequential amendments

National Health (Chemotherapy Prescribing) Special Arrangement 2020

1 Subsection 12(1)

Omit “*National Health (Pharmaceutical Benefit) (Condition of approval for approved pharmacists) Determination 2017*”, substitute “Regulations”.

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

2 Section 34A

Repeal the section, substitute:

34A Conditions for approved pharmacists do not apply to infusions and certain related pharmaceutical benefits

The *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* does not apply to the dispensing or supply of:

- (a) an infusion; or
 - (b) a pharmaceutical benefit mentioned in Schedule 2 for which the manner of administration is injection or intravesical;
- that is supplied under this Special Arrangement.

3 After section 41

Insert:

41A Paragraph 99(3)(b) of the Act does not apply to infusions and certain related pharmaceutical benefits

Paragraph 99(3)(b) of the Act does not apply to the supply of:

- (a) an infusion; or
 - (b) a pharmaceutical benefit mentioned in Schedule 2 for which the manner of administration is injection or intravesical;
- under this Special Arrangement.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

4 Section 25

Repeal the section, substitute:

25 Conditions for approved pharmacists do not apply to certain HSD pharmaceutical benefits

The *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* does not apply to the dispensing or supply of an HSD pharmaceutical benefit if:

- (a) the manner of administration of the benefit is injection or extracorporeal circulation; and
- (b) the benefit is not a community access medication; and
- (c) the supply is a special arrangement supply of the benefit.

5 After section 30

Insert:

30A Paragraph 99(3)(b) of the Act does not apply to certain HSD pharmaceutical benefits

Paragraph 99(3)(b) of the Act does not apply to a special arrangement supply of an HSD pharmaceutical benefit if:

- (a) the manner of administration of the benefit is injection or extracorporeal circulation; and
- (b) the benefit is not a community access medication.

National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017**6 Section 18**

Repeal the section, substitute:

18 Conditions for approved pharmacists do not apply

The *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* does not apply to the dispensing or supply of a pharmaceutical benefit if the benefit is supplied to an approved Aboriginal health service under this special arrangement.