

PB 36 of 2024

National Health Legislation (Repeal and Consequential Amendments) Instrument 2024

I, Nikolai Tsyganov, as delegate for the Minister for Health and Aged Care, make the following instrument.

Dated 27 March 2024

Nikolai Tsyganov Assistant Secretary Pricing and PBS Policy Branch Technology Assessment and Access Division Department of Health and Aged Care



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1 Name

- (1) This instrument is the National Health Legislation (Repeal and Consequential Amendments) Instrument 2024.
- (2) This instrument may also be cited as PB 36 of 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Note: This table relates only to the provisions of this instrument as originally made.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 sections 84AF, 84AK, 85, 85A, 85B, 88, 92A, 93, 93AB, 100 and 101 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Repeals

1 Repeals of instruments

Repeal the following instruments:

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

National Health (Listing of Pharmaceutical Benefits) Instrument 2012

National Health (Prescriber bag supplies) Determination 2012

Schedule 2—Amendments

National Health (Chemotherapy Prescribing) Special Arrangement 2020

1 Section 4

Omit "an infusion or related chemotherapy benefit under the *National Health* (*Efficient Funding of Chemotherapy*) Special Arrangement 2011", substitute "a dose of a chemotherapy drug or related pharmaceutical benefit under the *National Health* (*Efficient Funding of Chemotherapy*) Special Arrangement 2024".

2 Subsection 5(1)

Omit "(1)".

3 Subsection 5(1) (definition of authorised prescriber)

Omit "section 9 or 9A of the National Health (Listing of Pharmaceutical Benefits) Instrument 2012", substitute "section 12 of the National Health (Listing of Pharmaceutical Benefits) Instrument 2024".

4 Subsection 5(1) (definitions of chemotherapy medication chart, chemotherapy medication chart prescription, chemotherapy pharmaceutical benefit and electronic chemotherapy medication chart prescription)

Repeal the definitions.

5 Subsection 5(1)

Insert:

electronic medication chart prescription means a medication chart prescription prepared, in electronic form, in a software system that is used for prescribing and recording the administration of medicines to persons receiving treatment in, at or from a hospital.

6 Subsection 5(1) (definition of electronic medication chart system)

Repeal the definition.

7 Subsection 5(1) (definitions of eligible private hospital patient and eligible public hospital patient)

Repeal the definitions, substitute:

eligible private hospital patient means a person who:

- (a) is, or is to be treated as, an eligible person; and
- (b) is receiving treatment at or from a private hospital.

Note: Under subsection 4(1A) of the Act, the phrase *eligible person* has the same meaning as in the *Health Insurance Act 1973*.

eligible public hospital patient means a person who:

- (a) is, or is to be treated as, an eligible person; and
- (b) is receiving treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge.

Note: Under subsection 4(1A) of the Act, the phrase *eligible person* has the same meaning as in the *Health Insurance Act 1973*.

8 Subsection 5(1) (definition of *infusion*)

Repeal the definition.

9 Subsection 5(1) (definition of medication chart)

Repeal the definition, substitute:

medication chart has a meaning affected by subsection 8(2).

10 Subsection 5(1) (definitions of participating hospital authority and related pharmaceutical benefit)

Omit "2011", substitute "2024".

11 Subsection 5(2)

Repeal the subsection.

12 Paragraphs 6(2)(a) and (b)

Omit "or", substitute "and".

13 Sections 8 and 9

Repeal the sections, substitute:

8 Method of prescribing pharmaceutical benefits

- (1) An authorised prescriber for a pharmaceutical benefit may write a prescription for supply of the pharmaceutical benefit to an eligible private hospital patient or eligible public hospital patient under this Special Arrangement by completing a section of a medication chart, in accordance with section 41 of the Regulations as modified by this section, that also directs the special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit to the patient under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*.
- (2) A medication chart referred to in subsection (1):
 - (a) is not required to be in a form approved under paragraph 41(5)(a) of the Regulations or meet the information requirements approved under paragraph 41(5)(b) of the Regulations; and
 - (b) is taken to be a medication chart for the purposes of the Regulations despite paragraphs 41(4)(a) and (b) of the Regulations.
- (3) For an electronic medication chart prescription:
 - (a) paragraph 41(2)(c) of the Regulations does not apply; and
 - (b) the authorised prescriber must approve the prescription in the electronic system used to write the prescription; and

(c) paragraph 104(3)(b) of the Regulations does not apply.

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

Section 30 of the Regulations applies in relation to a prescription written under this Special Arrangement as if a reference to a person receiving treatment in or at an approved hospital included a reference to a person receiving treatment from an approved hospital.

14 Subsections 10(3) and (4)

Repeal the subsections, substitute:

- (3) Subsections 45(2) to (7) of the Regulations apply to a supply made under this Special Arrangement as if a reference to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital.
- (4) For a supply made on the basis of an electronic medication chart prescription:
 - (a) paragraph 45(2)(c) of the Regulations does not apply; and
 - (b) the participating hospital authority, approved hospital authority for a private hospital or approved pharmacist must verify the supply and the date of supply in the electronic system used to write the prescription; and
 - (c) section 61 of the Regulations applies as if the reference to the details referred to in paragraph 45(2)(c) of the Regulations included a reference to the verification required by paragraph (b) of this subsection.

15 Sections 11 and 12

Repeal the sections, substitute:

11 Modified application of rules

For the purposes of item 32 of the table in clause 1 of Schedule 1 to the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*, an electronic medication chart prescription is taken to be a paper-based prescription.

National Health (Electronic National Residential Medication Chart Trial) Special Arrangement 2018

16 Section 4 (definition of Rules)

Repeal the definition, substitute:

Rules means the National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022.

17 Section 4 (definition of telephone authority required pharmaceutical benefit)

Repeal the definition.

18 Section 4 (definition of *Transitional eNRMC Conformance Register*)

After "Australian Digital Health Agency", insert "as existing on 19 March 2024".

19 Section 4 (definition of written authority required pharmaceutical benefit)

Repeal the definition.

20 Section 8

Repeal the section.

21 Subsection 10(2)

Omit "item 23 of the table in", substitute "item 25 of the table in clause 1 of".

22 Subsection 10(3)

Repeal the subsection, substitute:

- (3) For the purposes of subsection (2), the kind of supply of a pharmaceutical benefit is a supply using software made available by Fred IT Group Pty Ltd (ABN 68 109 546 901) and which is:
 - (a) a supply where writing the prescription for the supply required authorisation by the Chief Executive Medicare under section 19 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (not including where writing the prescription was taken to have been authorised); or
 - (b) a supply of a pharmaceutical benefit having a drug (within the meaning of Part VII of the Act) that is referred to in Schedule 8 of the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*).

National Health (Growth Hormone Program) Special Arrangement 2015

23 Subsection 4(1) (definition of *main listing instrument*)

Repeal the definition.

24 Section 9A

Repeal the section.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

25 Section 6

Insert:

General statement for drugs for the treatment of hepatitis C has the same meaning as in the Listing Instrument.

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26 Section 6 (definition of Listing Instrument)

Omit "2012 (PB 71 of 2012)", substitute "2024 (PB 26 of 2024)".

27 Section 6 (definition of medication for the treatment of hepatitis C)

Repeal the definition, substitute:

medication for the treatment of hepatitis *C* means medication mentioned in the table in clause 3 of the General statement for drugs for the treatment of hepatitis C.

28 At the end of section 7

Add:

(7) To avoid doubt, a person is not an authorised prescriber, within the meaning of this instrument, for an HSD pharmaceutical benefit only because the person is authorised in accordance with section 12 of the Listing Instrument to write a prescription for the supply of the pharmaceutical benefit.

Note:

A supply of an HSD pharmaceutical benefit is not a special arrangement supply of the benefit unless the supply was prescribed by an authorised prescriber for the benefit (see section 13 of this instrument).

29 Paragraph 8(7)(a)

Omit "2011", substitute "2024".

30 Section 14

Repeal the section.

31 Subsection 15(3)

Omit "section 10", substitute "section 13".

32 Subsection 16(2)

Repeal the subsection, substitute:

- (2) Section 19 of the Listing Instrument applies to the prescription as if:
 - (a) a reference to Part 1 of Schedule 4 to that instrument were a reference to Schedule 3 to this instrument; and
 - (b) a reference to an authorised prescriber were a reference to an authorised prescriber within the meaning of this instrument.

33 Paragraph 29(1)(c)

Omit "the quantity of the benefit supplied is more than a multiple of a pack quantity of the benefit", substitute "neither paragraph (a) or (b) applies to the quantity of the benefit supplied".

34 Section 50 (note)

Omit "Listing Instrument", substitute "National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)".

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

35 Section 5 (subparagraph (c)(i) of definition of dispensing step)

Omit "2011", substitute "2024".

36 Section 5 (definition of extemporaneously-prepared pharmaceutical benefit)

Omit "2012", substitute "2024".

National Health (Price and Special Patient Contribution) Determination 2022

37 Paragraph 8(1)(c)

Repeal the paragraph, substitute:

- (c) either:
 - (i) writing the prescription has been authorised in accordance with section 19 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*; or
 - (ii) if the circumstances are not ones in which writing the prescription requires authorisation—the prescription satisfies the requirements of subsection (2).

38 Subsection 8(2)

Repeal the subsection, substitute:

- (2) A prescription satisfies the requirements of this subsection if:
 - (a) the prescription or details of the prescription are submitted to the Chief Executive Medicare; and
 - (b) the Chief Executive Medicare authorises the prescription for the purposes of payment of the special patient contribution and allots a number to the prescription; and
 - (c) the allotted number is written on the prescription.

National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023

39 Section 6 (definition of *Listing Instrument*)

Omit "2012", substitute "2024".

40 Subsection 8(2)

Omit "section 10", substitute "section 13".

41 Subsection 8(2) (note 2)

Omit ", section 9 of the Listing Instrument and section 14 of the HSD Special Arrangement", substitute "and section 12 of the Listing Instrument".

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