



**PB 32 of 2022**

**National Health (COVID-19 Supply of  
Pharmaceutical Benefits) Special Arrangement  
Amendment (Extension for Receipt  
Requirements and Hospital Supplies)  
Instrument 2022**

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I, Adriana Platona, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 29 March 2022

Adriana Platona  
First Assistant Secretary  
Technology Assessment and Access Division  
Department of Health

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## 1 Name

- (1) This instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement Amendment (Extension for Receipt Requirements and Hospital Supplies) Instrument 2022*.
- (2) This instrument may also be cited as PB 32 of 2022.

## 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. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	31 March 2022
2. Schedule 1	The day after this instrument is registered.	31 March 2022
3. Schedule 2	1 April 2022.	1 April 2022

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

### ***National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020***

#### **1 Section 4**

Omit “2022”, substitute “2023”.

#### **2 Subsection 18(1) (definition of *repeal date*)**

Omit “2022”, substitute “2023”.

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## Schedule 2—Amendments commencing 1 April 2022

### *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*

#### 1 Section 5

Repeal the section, substitute:

#### 5 Simplified outline of this instrument

This instrument makes a special arrangement for the supply of pharmaceutical benefits by approved hospital authorities based on a digital image of a paper-based prescription, or a copy of a paper-based prescription.

This instrument also modifies arrangements for supplies of pharmaceutical benefits in relation to written acknowledgement of receipt of the benefits and signatures for records of supplies of the benefits on pharmaceutical benefits prescription record forms.

Note: Part VII of the Act, and regulations or other instruments made for the purposes of that Part, have effect subject to this instrument (see subsection 100(3) of the Act).

#### 2 Subsection 6(1)

Repeal the following definitions:

- (a) definition of *approved hospital authority dispenser*;
- (b) definition of *approved medical practitioner*;
- (c) definition of *approved pharmacist*;
- (d) definition of *approved supplier*.

#### 3 Subsection 6(1)

Insert:

*Medicare/DVA copy* has the same meaning as in the Regulations.

*pharmacist/patient copy* has the same meaning as in the Regulations.

#### 4 Subsection 6(1)

Repeal the following definitions:

- (a) definition of *phone attendance*;
- (b) definition of *Poisons Standard*;
- (c) definition of *telehealth attendance*.

#### 5 Subsection 6(2)

Omit “, the *Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021*,”, substitute “or”.

#### 6 Subsection 6(2)

Omit “or the *Therapeutic Goods Act 1989*”.

## 7 Divisions 1 and 2 of Part 2

Repeal the Divisions, substitute:

### **Division 2—Supplies of pharmaceutical benefits by approved hospital authorities based on paper-based prescriptions**

#### **9 Application of Division**

- (1) This Division applies to the supply of a pharmaceutical benefit by an approved hospital authority based on a paper-based prescription.

Note: For a hospital authority to be approved under section 94 of the Act in respect of a hospital, the dispensing of drugs and medicinal preparations at that hospital must be performed by or under the direct supervision of a medical practitioner or pharmacist (see subsection 94(5) of the Act).

- (2) However, this Division does not apply to the supply of a pharmaceutical benefit mentioned in subsection (1) if:
- (a) the prescription is a medication chart prescription; or
  - (b) under a law of the State or Territory in which the benefit is to be supplied, the benefit may not be supplied on the basis of:
    - (i) a digital image of a prescription; or
    - (ii) a copy of a prescription.

Note: For the supply of a pharmaceutical benefit on basis of a medication chart prescription, see section 45 of the Regulations.

#### **10 Modified application of section 44 of the Regulations—supplies on first presentation of prescription**

- (1) The requirement in subparagraph 44(3)(a)(ii) of the Regulations for the prescription for a supply of a pharmaceutical benefit to be given to the pharmacist or practitioner by whom, or under whose supervision, the benefit will be dispensed is taken to be met if:
- (a) a digital image of the prescription, or a copy of the prescription, is instead given to the pharmacist or practitioner; and
  - (b) if the prescription is or would be an authority prescription—the requirements in subsection (2) are met for the prescription.
- (2) The requirements in this subsection are met for a prescription if:
- (a) if the pharmaceutical benefit prescribed has a relevant streamlined authority code:
    - (i) the PBS prescriber who wrote the prescription informs the pharmacist or practitioner of that code before the benefit is supplied; or
    - (ii) the code is displayed on the digital image of the prescription, or the copy of the prescription (as applicable); or
  - (b) otherwise:
    - (i) the Minister or the Chief Executive Medicare has notified (orally or by other means) the PBS prescriber who wrote the prescription that each relevant authorisation will be given; and
    - (ii) the PBS prescriber informs the pharmacist or practitioner of that notification before the benefit is supplied.



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Note: A paper-based prescription prepared in duplicate in accordance with paragraph 40(2)(a) or (b) of the Regulations will include a part on which the words “pharmacist/patient copy” appear and a part on which the words “Medicare/DVA copy” appear.

## **11 Modified application of section 51 of the Regulations—repeated supplies of pharmaceutical benefits**

- (1) This section applies if:
  - (a) an approved hospital authority supplies a pharmaceutical benefit on the basis of a paper-based prescription as mentioned in section 10 of this instrument; and
  - (b) subsection 51(4) of the Regulations applies to the benefit.
- (2) The requirements in each of paragraphs 51(4)(b) and (c) of the Regulations for the supplier of the benefit to write the words “immediate supply necessary” on, and to sign, the Medicare/DVA copy of the prescription are taken to be met if the pharmacist or practitioner by whom, or under whose supervision, the benefit will be dispensed instead writes those words on, and signs:
  - (a) the digital image of the prescription, or the copy of the prescription (as applicable); or
  - (b) a print-out of a digital image of the prescription.

## **12 Modified application of section 52 of the Regulations—repeat authorisations**

- (1) Subsection 52(3) of the Regulations, modified by this section, applies if:
  - (a) an approved hospital authority supplies a pharmaceutical benefit on the basis of a paper-based prescription as mentioned in section 10 of this instrument; and
  - (b) subsequent supplies of the pharmaceutical benefit can be made under the prescription at the time of the supply mentioned in paragraph (a); and
  - (c) one of the following applies:
    - (i) the prescription contains a direction to supply the benefit more than once;
    - (ii) a deferred supply authorisation that contains a direction to supply the benefit more than once is attached to the prescription;
    - (iii) a repeat authorisation that contains a direction to supply the benefit more than once is attached to the prescription.
- (2) The requirements in subparagraph 52(3)(a)(iii) of the Regulations for the approved hospital authority to:
  - (a) attach the repeat authorisation prepared under paragraph 52(3)(a) of the Regulations to the pharmacist/patient copy of the prescription; and
  - (b) give the repeat authorisation and pharmacist/patient copy to the person to whom the benefit is supplied;are taken to be met if the approved hospital authority instead:
  - (c) attaches the repeat authorisation to a print-out of the digital image of the prescription, or the copy of the prescription (as applicable); and
  - (d) retains both:
    - (i) the repeat authorisation; and

- (ii) the print-out of the digital image of the prescription, or the copy of the prescription (as applicable).

### **13 Modified application of section 53 of the Regulations—deferred supply authorisations**

- (1) Subsection 53(3) of the Regulations, modified by this section, applies if:
  - (a) an approved hospital authority supplies a pharmaceutical benefit on the basis of a paper-based prescription as mentioned in section 10 of this instrument; and
  - (b) defers, in accordance with subsection 53(2) of the Regulations, the supply of one or more pharmaceutical benefits directed to be supplied by the prescription.
- (2) The requirement in subparagraph 53(3)(c)(i) of the Regulations for the approved hospital authority to mark on the pharmacist/patient copy and the Medicare/DVA copy of the prescription, across the wording relating to the pharmaceutical benefit the supply of which is being deferred, the words “original supply deferred”, is met if the approved hospital authority instead writes those words on:
  - (a) the digital image of the prescription, or the copy of the prescription (as applicable); or
  - (b) a print-out of the digital image of the prescription (if applicable).
- (3) The requirement in subparagraph 53(3)(c)(ii) of the Regulations for the approved hospital authority to attach the deferred supply authorisation prepared by the approved hospital authority (under paragraph 53(3)(a) of the Regulations) to the pharmacist/patient copy is met if the approved hospital authority instead:
  - (a) attaches the deferred supply authorisation to a print-out of the digital image of the prescription, or the copy of the prescription (as applicable); and
  - (b) retains:
    - (i) the deferred supply authorisation; and
    - (ii) the print-out of the digital image of the prescription, or the copy of the prescription (as applicable).
- (4) If the approved hospital authority writes the words “original supply deferred” on the digital image of the prescription, the print-out referred to in paragraph (2)(b) of this section must be of the digital image including that writing.

### **14 Keeping documents—authorised hospital authorities**

If:

- (a) an approved hospital authority supplies a pharmaceutical benefit:
  - (i) on the basis of a paper-based prescription as mentioned in section 10 of this instrument; or
  - (ii) as a repeated supply as mentioned in section 11 of this instrument; or
  - (iii) on the basis of a repeat authorisation prepared in accordance with section 12 of this instrument;
  - (iv) on the basis of a deferred supply authorisation prepared in accordance with section 13 of this instrument; and
- (b) the supply is of a kind specified in an item of the following table;

the approved hospital authority must keep a document specified in the item for at least 2 years from the date of supply.

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**Documents to be kept for supplies**

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<b>Item</b>	<b>Kind of supply</b>	<b>Document</b>
1	Both of the following apply in relation to the supply: (a) the supply was the first or only supply of a pharmaceutical benefit authorised by the prescription; (b) a CTS claim is made for the supply	The digital image of the prescription, or a print-out of the digital image, or the copy of the prescription (as applicable)
2	Both of the following apply in relation to the supply: (a) the supply was on the basis of a repeat authorisation or a deferred supply authorisation; (b) a CTS claim is made for the supply	The repeat authorisation or deferred supply authorisation
3	After the supply, there are no remaining supplies of pharmaceutical benefits that are authorised by the prescription	The digital image of the prescription, or a print-out of the digital image, or the copy of the prescription (as applicable)

Note: For the requirement to produce documents relating to supplies of pharmaceutical benefits for which amounts are paid by the Commonwealth, see section 99ABB of the Act.

## **15 Keeping documents—PBS prescribers**

If a PBS prescriber has written a prescription and has given an approved hospital authority a digital image of the prescription, or a copy of the prescription, the PBS prescriber must keep the prescription for at least 2 years from the date of the prescription.

## **8 Division 3 (heading)**

Repeal the heading, substitute:

### **Division 3—Receipt of pharmaceutical benefits**

#### **9 Section 16**

Omit “(1)”.

#### **10 Section 17**

Omit “(1)”.

#### **11 Section 17A**

Omit “(1)”.

#### **12 After section 17A**

Insert:

**17B Continued application of Special Arrangement as in force before 1 April 2022**

This Special Arrangement, as in force immediately before 1 April 2022, continues to apply on and after 1 April 2022 in relation to the supply of a pharmaceutical benefit made under this Special Arrangement before 1 April 2022.