

## **EXPLANATORY STATEMENT**

### *National Health Act 1953*

#### *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021*

PB 137 of 2021

### **Authority**

Subsection 100(1) of the *National Health Act 1953* (the Act) provides that the Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

- a) who are living in isolated areas: or
- b) who are receiving treatment in circumstances in which the supply of pharmaceutical benefits under general arrangements is inadequate for that treatment; or
- c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under these arrangements.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

### **Purpose**

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement). The Amendment Instrument extends the date of repeal of the Special Arrangement by three months, so it is repealed at the start of 1 April 2022.

The Amendment Instrument also updates references to refer to the *Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021* (the 2021 3C Determination), which replaces the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020* (the 2020 3C Determination).

### **Background**

As part of the COVID-19 National Health Plan, temporary Medicare Benefits Schedule (MBS) items allowed doctors, nurses, midwives and mental health professionals to deliver services via telehealth or telephone services. These arrangements are described in the 2020 3C Determination, which will cease on 31 December 2021.

From 1 January 2022, patient access to certain general practitioner (GP), specialist and allied health telehealth and telephone services will be continued, as described in the 2021 3C Determination.

In support of the telehealth measure, and as an interim measure while electronic prescribing capability has been implemented nationally, the Special Arrangement was developed under the Act to provide a patient who is confined to their home access to Pharmaceutical Benefits Scheme (PBS) medicines through 'Image Based Prescription for Medicine Supply'. To minimise disruption across the community pharmacy sector caused by the Christmas period, and whilst the vast majority of community pharmacies are still fulfilling commitments under the COVID-19 vaccination program, the Special Arrangement will again be extended from being repealed from 1 January 2022 to 1 April 2022.

The Special Arrangement can still operate as intended in spite of the changes to available telehealth and telephone service items in the 2021 3C Determination. This is because the primary intention of the Special Arrangement is to provide an alternative COVID-19 safe method of prescribing medications.

The PBS is established under the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

The Special Arrangement applies to all pharmaceutical benefits available for supply under Part VII of the Act, other than Schedule 8 and 4 medicines, such as opioids, unless specifically permitted under the relevant state or territory law. These are high-risk medicines that pose significant risks to the community including misuse and diversion. Urgent supply of these medicines can otherwise be provided under existing provisions in section 48 of the *National Health (Pharmaceutical Benefits) Regulations 2017*.

The Special Arrangement assists in protecting people most at-risk in the community from exposure to COVID-19. It is available to all patients who have had a telehealth or telephone attendance with their prescriber, as described in the 2021 3C Determination.

Division 2 of the Special Arrangement allows prescribers to provide a copy or a digital image of a patient's prescription as part of a telehealth or telephone attendance, as described in the 2021 3C Determination, to a pharmacy of the patient's choice via email, text message or fax, enabling the pharmacy to supply the required medicines, in the absence of a paper-based prescription (image based prescribing).

Division 3 of the Special Arrangement allows the supply of a pharmaceutical benefit without acknowledgement from the patient wherever it is impractical for them to sign the prescription (for example where the patient is concerned about transmission of COVID-19 by using the pharmacy pen). This is because of potential contamination risks of people in the pharmacy using pens to sign for this purpose in the current COVID-19 environment.

Pharmacists are still expected to ask patients to acknowledge receipt of the pharmaceutical benefit where practical, however pharmacists are not required to sign on the patient's behalf where it is not practical do so (for example, the pharmacist supplying medicine from an image based prescription). This measure should be used as an exception, not a rule, and pharmacists are required to use their professional judgement in these circumstances and implement localised processes for vulnerable patients.

Division 3 also removes the requirement for an approved supplier to sign a pharmaceutical benefits prescription record, but only where the record is not handwritten and it is not

practicable for the patient to obtain the approved supplier's signature due to concerns relating to the transmission of COVID-19.

The Special Arrangement will be repealed at the start of 1 April 2022.

### **Consultation**

The Department of Health (the Department) has consulted with State and Territory governments through the Electronic Prescribing Working Group (EPWG) regarding this fourth extension of this interim measure. States and Territories indicated a preference for the Special Arrangement to temporarily continue to minimise disruption across the community pharmacy sector at this time of the year, and whilst the vast majority of community pharmacies are still fulfilling commitments under the COVID-19 vaccination program.

The Department also consulted with clinical peak bodies including the:

- Pharmacy Guild of Australia,
- Pharmaceutical Society of Australia,
- Royal Australian College of General Practitioners,
- Australian Medical Association, and
- Society of Hospital Pharmacists of Australia

Some of those groups acknowledged the benefits of prescribers and pharmacists adopting electronic prescribing as the preferred option for remote medicines supply. However, due to the disruptions caused from the holiday period and COVID vaccination program, they are also supportive of the continued arrangements.

The Australian Digital Health Agency, the Department of Veterans' Affairs and Services Australia have been informed of this extension. The Department is communicating the extension of the Special Arrangement on its website and through direct communications to:

- Australian Medical Association,
- Pharmaceutical Society of Australia,
- Australian College of Rural and Remote Medicine,
- Royal Australian College of General Practitioners,
- Rural Doctors of Australia,
- Society of Hospital Pharmacists of Australia,
- Medicines Australia,
- Australian Dental Association,
- Australian Indigenous Doctor's Association,
- Medical Software Industry Association, and
- State and Territory governments through the Electronic Prescribing Working Group (EPWG).

All State and Territory representatives have advised they will amend any state or territory legislation as required.

This instrument commences on the day after registration.

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of this instrument are set out in the Attachment.

Details of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021*

**Section 1 Name**

This section provides that the name of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021*.

The instrument can also be cited as PB 137 of 2021.

**Section 2 Commencement**

This section provides that the instrument commences on the day after registration.

**Section 3 Authority**

This section provides that the instrument is made under subsection 100(2) of the *National Health Act 1953*.

**Section 4 Schedules**

This section provides that 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 (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*

Item 1 – Section 4

This item extends the repeal date of the instrument by three months to the start of 1 April 2022.

Items 2, 3 and 4 - Section 6

These items update references to refer to the 2021 3C Determination instead of the 2020 3C Determination. Items 2 and 3 amend the references in subsection 6(1) of the definitions of *phone attendance* and *telehealth attendance*, which remain the same, and item 4 amends the reference in subsection 6(2) to refer to the 2021 3C Determination for the purpose of any references to that legislation as in force from time to time.

Item 5 – Paragraph Subsection 9(1)(c)

This item updates the reference to refer to items in the 2021 3C Determination. Paragraph 9(1)(c) provides that the Special Arrangement applies to all items in the 2021 3C Determination.

Item 6 – after Section 17

This item adds section 17A which is a transitional provision that provides the provisions in the Special Arrangement in force immediately prior to commencement of amendments in the Amendment Instrument continue to apply for the supply of a pharmaceutical benefit that was made before the commencement of the amendment.

Item 7 - Subsection 18(1)

This item updates the definition of *repeal date* to 1 April 2022, in line with the amended repeal date in section 4 of the Special Arrangement.

## **Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### ***National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021***

**PB 137 of 2021**

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### **Overview of the Disallowable Legislative Instrument**

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Additional Extension) Special Arrangement 2021* (the Amendment Instrument) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement).

Given the current COVID-19 situation and continuation of the COVID-19 restrictions, as well as the vast majority of community pharmacies still fulfilling commitments under the COVID-19 vaccination program, the Special Arrangement will be extended from being repealed on 31 December 2021 to the start of 1 April 2022.

The Amendment Instrument also updates references to refer to the *Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021* (the 2021 3C Determination), which replaces the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020* (the 2020 3C Determination).

The amendment continues support for the supply of pharmaceutical benefits to patients who find a telehealth or telephone attendance more convenient and effective. It clarifies arrangements for the supply of a pharmaceutical benefit through image-based prescribing by including a transitional provision which allows for supply in accordance with the Special Arrangement for prescriptions that are dated before the Special Arrangement is repealed.

### **Human rights implications**

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it assists in the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Disallowable Legislative Instrument is compatible with Articles 2 and 12 of the ICESCR as it contributes to the efficient operation and effective administration of the scheme.

### **Conclusion**

The Disallowable Legislative Instrument is compatible with human rights because it promotes the protection of human rights, including the right to access to healthcare.