

EXPLANATORY STATEMENT

National Health Act 1953

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

PB 37 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 the 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 (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 The Amendment Instrument extends the date of repeal of the Special Arrangement by six months so it is repealed on 30 September 2021.

Background

As part of the COVID-19 National Health Plan, temporary Medicare Benefits Schedule (MBS) items allow doctors, nurses, midwives and mental health professionals to deliver services via telehealth or telephone services. These arrangements are described in the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020* (the 2020 3C Determination).

In support of the telehealth measure the Australian Government also enabled the supply of PBS medicines through image based prescriptions. This assists in protecting people most at-risk in the community from exposure to COVID-19. Given the continuing risk of COVID-19 and associated restrictions, the Special Arrangement will be extended from being repealed on 31 March 2021 to 30 September 2021, to ensure that people who are confined to their home can still access necessary medicines.

The Special Arrangement provides an interim measure to provide a patient who is confined to home access to necessary medicine through “Image Based Prescription for Medicine Supply”.

The Special Arrangement allows prescribers to provide a pharmacy with a digital image or copy of a patient’s prescription via fax, email or text message, enabling the pharmacy to dispense the required medicines, and deliver or post them to the patient.

The Special Arrangement is available to all patients who have had a telehealth or telephone attendance with their prescriber, as described in the 2020 3C Determination. It provides an option for a patient to easily access their medicines while self-isolating. However, if a patient instead prefers to receive their paper-based prescription following a telehealth or telephone attendance, they may still collect their prescription in person or receive it by post and arrange supply of medicines separately in line with existing processes.

The Special Arrangement applies to all pharmaceutical benefits available for supply under Part VII of the Act, other than Schedule 8 and 4(D) medicines such as opioids and Fentanyl 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*.

Community pharmacies have also raised concerns surrounding the Pharmaceutical Benefits Scheme (PBS) requirement for patients (or a nominated agent) to sign the prescription to acknowledge receipt of supply of a pharmaceutical benefit. 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.

The Special Arrangement temporarily 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). 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 to 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.

The Special Arrangement will now be repealed on 30 September 2021.

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.

Consultation

The Department has been contacted by the Pharmacy Guild of Australia and various jurisdictions requesting an extension to the Special Arrangement. The Australian Digital Health Agency, the Department of Veterans' Affairs and Services Australia have been informed of the extension. The Department is communicating the extension 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, the Australian Dental Association and the Australian Indigenous Doctor's Association. Consultation has occurred with state and territory governments through the Electronic Prescribing Working Group about the Special Arrangement including its amendment and extension. All state and territory representatives have advised they will amend any state or territory legislation as required.

Commencement

This instrument commences the day after registration.

Details of the instrument are set out in the **Attachment**.

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

ATTACHMENT

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

1 Name

This section provides that the name of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Extension) Special Arrangement 2021*. The instrument can also be cited as PB 37 of 2021.

2 Commencement

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

3 Authority

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

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 date of repeal of the Special Arrangement by six months so it is repealed on 30 September 2021.

Statement of Compatibility with Human Rights

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

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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 (Extension) Special Arrangement 2021* (the amendment) amends the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*. The Amendment Instrument extends the date of repeal of the Special Arrangement by six months so it is repealed on 30 September 2021. Given the current COVID-19 situation and continuation of the COVID-19 restrictions, the Special Arrangement will be extended from being repealed on 31 March 2021 to 30 September 2021, to ensure that people who are confined to their home can still access necessary medicines.

The amendment enables the supply of pharmaceutical benefits to patients who have had a telehealth or telephone attendance more convenient and effective. The amendment modifies arrangements for the supply of a pharmaceutical benefit on a paper prescription by temporarily allowing the option for an approved supplier to supply from a digital image or copy of the prescription received from the PBS prescriber before the presentation of the prescription. If a patient instead prefers to receive their paper-based prescription and arrange supply of medicines themselves following a telehealth or telephone attendance, they may still collect their prescription in person or receive it by post and arrange supply of medicines separately, in line with existing processes.

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 as it promotes the protection of human rights.